SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

_____

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the quarterly period ended September 30, 2002.

OR

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934.

For the transition period from _____ to _____.

Commission File Number 1-10492

ORASURE TECHNOLOGIES, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware	36-4370966
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)

150 Webster Street, Bethlehem, Pennsylvania	18015
(Address of Principal Executive Offices)	(Zip code)

(610) 882-1820
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No [ ]

Number of shares of Common Stock, par value $.000001 per share, outstanding as of November 6, 2002: 37,546,308

PART I. FINANCIAL INFORMATION

Item 1. FINANCIAL STATEMENTS

ORASURE TECHNOLOGIES, INC.
BALANCE SHEETS
(Unaudited)

	September 30, 2002	December 31, 2001
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 5,231,118	$ 2,426,346
Short-term investments	8,136,638	12,764,903
Accounts receivable, net of allowance for doubtful accounts of $187,271 and $209,492	4,805,664	6,057,927
Note receivable from officer	-	75,000
Inventories	4,583,159	4,444,772
Prepaid expenses and other	577,443	1,038,511
Total current assets	23,334,022	26,807,459
PROPERTY AND EQUIPMENT, net	7,449,252	7,800,137
PATENTS AND PRODUCT RIGHTS, net	1,967,719	2,042,533
OTHER ASSETS	615,253	634,546
	$ 33,366,246	$ 37,284,675
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current portion of long-term debt	$ 1,004,192	$ 1,057,572
Accounts payable	2,031,604	2,874,061
Accrued expenses	3,082,675	3,111,886
Total current liabilities	6,118,471	7,043,519
LONG-TERM DEBT	3,479,239	3,586,458
OTHER LIABILITIES	114,025	114,025
STOCKHOLDERS' EQUITY:		
Preferred stock, par value $.000001, 25,000,000 shares authorized, none issued	-	-
Common stock, par value $.000001, 120,000,000 shares authorized, 37,545,287 and 37,403,269 shares issued and outstanding	38	37
Additional paid-in capital	153,210,127	152,758,591
Accumulated other comprehensive loss	(202,686)	(125,664)
Accumulated deficit	(129,352,968)	(126,092,291)
Total stockholders' equity	23,654,511	26,540,673
	$ 33,366,246	$ 37,284,675

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
REVENUES:				
Product	$ 8,103,274	$ 8,236,352	$ 23,445,971	$ 23,207,345
Licensing and product development	3,259	362,302	316,068	1,303,129
	8,106,533	8,598,654	23,762,039	24,510,474
COSTS OF PRODUCTS SOLD	3,349,522	2,872,753	9,444,203	8,579,752
Gross profit	4,757,011	5,725,901	14,317,836	15,930,722
COSTS AND EXPENSES:				
Research and development	1,890,266	2,247,975	6,520,753	6,838,056
Sales and marketing	1,947,388	2,061,817	6,327,894	5,988,432
General and administrative	1,320,649	1,427,081	4,886,530	4,494,217
Restructuring-related	-	-	-	450,000
	5,158,303	5,736,873	17,735,177	17,770,705
Operating loss	(401,292)	(10,972)	(3,417,341)	(1,839,983)
INTEREST EXPENSE	(70,108)	(101,555)	(233,453)	(310,279)
INTEREST INCOME	86,827	241,805	390,811	742,818
FOREIGN CURRENCY GAIN (LOSS)	(2,271)	(114,819)	(694)	2,911
Income (loss) before income taxes	(386,844)	14,459	(3,260,677)	(1,404,533)
INCOME TAXES	-	1,199	-	(20,745)
NET INCOME (LOSS)	$ (386,844)	$ 15,658	$ (3,260,677)	$ (1,425,278)
EARNINGS (LOSS) PER SHARE:				
BASIC	$ (0.01)	$ 0.00	$ (0.09)	$ (0.04)
DILUTED	$ (0.01)	$ 0.00	$ (0.09)	$ (0.04)
WEIGHTED AVERAGE NUMBER OF SHARES OUTSTANDING:				
BASIC	37,536,302	37,057,079	37,488,419	36,740,600
DILUTED	37,536,302	39,009,095	37,488,419	36,740,600

The accompanying notes are an integral part of these statements.

ORASURE TECHNOLOGIES, INC.
STATEMENTS OF CASH FLOWS
(Unaudited)

	Nine Months Ended September 30,	
	2002	2001
OPERATING ACTIVITIES:		
Net loss	$ (3,260,677)	$ (1,425,278)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	50,939	70,580
Amortization of deferred revenue	(107,500)	(107,500)
Depreciation and amortization	1,639,857	1,537,873
Loss on disposition of property and equipment	2,053	11,353
Gain on disposition of investment in affiliated company	-	(16,853)
Write-off of inventory	949,752	-
Changes in assets and liabilities:		
Accounts receivable	1,252,263	(2,367,200)
Notes receivable from officer	75,000	100,649
Inventories	(1,088,139)	(1,924,498)
Prepaid expenses and other assets	461,068	118,442
Accounts payable and accrued expenses	(764,168)	(253,457)
Net cash used in operating activities	(789,552)	(4,255,889)
INVESTING ACTIVITIES:		
Purchases of short-term investments	(3,761,117)	(23,250,109)
Proceeds from the sale of short-term investments	8,316,007	24,810,795
Purchases of property and equipment	(987,419)	(2,094,220)
Proceeds from the sale of property and equipment	2,393	29,067
Purchase of patent sublicense	(200,000)	-
Proceeds from disposition of investment in affiliated company	-	106,102
Increase in other assets	(11,892)	(224,888)
Net cash provided by (used in) investing activities	3,357,972	(623,253)
FINANCING ACTIVITIES:		
Borrowings of long-term debt	4,078,982	-
Repayments of term debt	(4,239,581)	(840,630)
Proceeds from issuance of common stock	400,598	2,980,233
Net cash provided by financing activities	239,999	2,139,603
EFFECT OF FOREIGN EXCHANGE RATE CHANGES ON CASH	(3,647)	(60,381)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	2,804,772	(2,799,920)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	2,426,346	5,095,639
CASH AND CASH EQUIVALENTS, END OF PERIOD	$ 5,231,118	$ 2,295,719

The accompanying notes are an integral part of these statements.

Notes to Financial Statements
(Unaudited)

1. The Company

OraSure Technologies, Inc. (the "Company") develops, manufactures and markets oral specimen collection devices using its proprietary oral fluid technologies, proprietary diagnostic products including in vitro diagnostic tests, and other medical devices. These products are sold in the United States and certain foreign countries to clinical laboratories, physician offices, hospitals, commercial and industrial entities, government agencies, and various distributors.

2. Summary of Significant Accounting Policies

Basis of Presentation. The accompanying financial statements are unaudited and, in the opinion of management, include all adjustments (consisting only of normal and recurring adjustments) necessary for a fair presentation of the results for these interim periods. These financial statements should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2001. Results of operations for the three-month and nine-month periods ended September 30, 2002 are not necessarily indicative of the results of operations expected for the full year. Certain reclassifications have been made to the prior year financial statements to conform to the current year presentation.

Use of Estimates. The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make certain estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Inventories. Inventories are stated at the lower of cost or market determined on a first-in, first-out basis and are comprised of the following:

	September 30, 2002	December 31, 2001
Raw materials	$3,425,060	$2,918,825
Work-in-process	578,092	644,397
Finished goods	580,007	881,550
	$4,583,159	$4,444,772

Revenue Recognition. The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred.

The Company follows U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101 "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 draws on existing accounting rules and provides specific guidance on revenue recognition of up-front non-refundable licensing and development fees. In accordance with SAB 101, up-front licensing fees are deferred and recognized ratably over the related license period. Product development revenues are recognized over the period in which the related product development efforts are performed. Amounts received prior to the performance of product development efforts are recorded as deferred revenues and are included in the accrued expenses caption on the accompanying balance sheet. Grant revenue is recognized as the related work is performed and costs are incurred.

In accordance with Emerging Issues Task Force ("EITF") Issue No. 00-10, "Accounting for Shipping and Handling Fees and Costs," the Company records shipping and handling charges billed to customers as revenue, and the related expense as cost of products sold.

Significant Customer Concentration. For the three-month and nine-month periods ended September 30, 2002, one customer accounted for 28 and 26 percent of total revenues, respectively, as compared to 25 and 28 percent for each of the same periods of 2001.

Research and Development. Research and development costs are charged to expense as incurred.

Foreign Currency Translation. Pursuant to Statement of Financial Accounting Standards ("SFAS") No. 52, "Foreign Currency Translation," the assets and liabilities of the Company's foreign operations are translated from Euros into U.S. dollars at current exchange rates as of the balance sheet date, and revenues and expenses are translated at average exchange rates for the period. Resulting translation adjustments are reflected as a separate component of stockholders' equity.

Net Loss Per Common Share. The Company has presented basic and diluted earnings (loss) per common share pursuant to SFAS No. 128, "Earnings per Share" ("SFAS 128"), and the Securities and Exchange Commission Staff Accounting Bulletin No. 98. In accordance with SFAS 128, basic earnings (loss) per share is computed by dividing net income (loss) by the weighted average number of shares outstanding during the reported period. Diluted earnings per share is computed in a manner similar to basic earnings per share except that the weighted average number of shares outstanding is increased to include incremental shares from the assumed exercise of stock options and warrants, if dilutive. The number of incremental shares is calculated by assuming that outstanding stock options and warrants were exercised and the proceeds from such exercises were used to acquire shares of common stock at the average market price during the reporting period.

The computations of basic and diluted earnings (loss) per share are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2002	2001	2002	2001
Net income (loss)	$ (386,844)	$ 15,658	$ (3,260,677)	$ (1,425,278)
Weighted average shares of common stock outstanding:				
Basic	37,536,302	37,057,079	37,488,419	36,740,600
Dilutive effect of stock options and warrants	-	1,952,016	-	-
Diluted	37,536,302	39,009,095	37,488,419	36,740,600
Earnings (loss) per share:				
Basic	$ (0.01)	$ 0.00	$ (0.09)	$ (0.04)
Diluted	$ (0.01)	$ 0.00	$ (0.09)	$ (0.04)

The computations of diluted earnings (loss) per share for the three-month period ended September 30, 2002 and for the nine-month periods ended September 30, 2002 and 2001 exclude the effect of outstanding common stock options and warrants to purchase 984,983, 2,974,620 and 4,207,396 shares, respectively, because the effect of including such shares is anti-dilutive.

Other Comprehensive Income (Loss). The Company follows SFAS No. 130, "Reporting Comprehensive Income." This statement requires the classification of items of other comprehensive income (loss) by their nature, and disclosure of the accumulated balance of other comprehensive income (loss) separately from retained earnings and additional paid-in capital in the equity section of the balance sheet.

Restructuring-related Expenses. In February 2001, the Company announced plans to restructure certain of its manufacturing operations. As a result of this restructuring, the Company incurred an infrequent charge of $450,000

for restructuring costs, primarily comprised of expenses for employee severance, travel and transport resulting from relocating and consolidating manufacturing operations. All restructuring-related expenses were paid by June 30, 2001.

Recent Accounting Pronouncements. In June 2002, the Financial Accounting Standards Board ("FASB") issued SFAS No. 146, "Accounting for Costs Associated with Exit or Disposal Activities" ("SFAS No. 146"). SFAS No. 146 addresses significant issues regarding the recognition, measurement, and reporting of costs associated with exit and disposal activities, including restructuring activities. SFAS No. 146 also addresses recognition of certain costs related to terminating a contract that is not a capital lease, costs to consolidate facilities or relocate employees, and termination benefits provided to employees that are involuntarily terminated under the terms of a one-time benefit arrangement that is not an ongoing benefit arrangement or an individual deferred-compensation contract. SFAS No. 146 is effective for exit or disposal activities that are initiated after December 31, 2002. The adoption of SFAS No. 146 is not expected to have any impact on the Company's financial position or results of operations.

3. Long-Term Debt

In September 2002, the Company entered into a new $10.9 million credit facility ("New Credit Facility") with a new bank, pursuant to which the Company refinanced substantially all of its previously outstanding mortgage and term debt and increased its equipment and working capital lines of credit. The New Credit Facility is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to the bank's prime rate, and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest.

Under the non-revolving equipment line of credit, the Company can borrow up to $3.0 million to finance eligible equipment purchases through September 11, 2003. Interest on outstanding borrowings shall accrue at a rate, selected at the Company's option, equal to the bank's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of September 30, 2002, the Company had an outstanding balance of approximately $192,000 under this facility with a fixed annual interest rate of 5.07%.

Under the revolving working capital line of credit, the Company can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings shall accrue at a rate, selected at the Company's option, equal to the bank's prime rate less 0.25% or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 9, 2003, with interest payable monthly. The Company had no outstanding borrowings under this facility at September 30, 2002.

All borrowings under the New Credit Facility are collateralized by a first priority security interest in all of the assets of the Company, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventory, and a mortgage on the Company's manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working-capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The New Credit Facility contains certain covenants containing minimum requirements for the Company's quick ratio, liquidity, and tangible net worth and requires the Company to achieve positive consolidated net income for the year ending December 31, 2003 and for each year thereafter. The New Credit Facility also restricts the Company's ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of the bank.

4. Related Party Transactions

Officer Note and Employment Agreement. In March 2000, the Company issued a note receivable to an executive officer of the Company ("Officer Note") for $75,000, for relocation purposes. The Officer Note did not bear interest if it was repaid on or before the earlier of the tenth day following the close of sale on the officer's previous residence or the due date of the Officer Note, as extended. On January 31, 2002, the Company terminated an employment agreement with this executive officer and he agreed to repay the Officer Note in bi-weekly principal installments of approximately $7,000, commencing in April 2002. As of September 30, 2002, this Officer Note had been repaid.

Facility Lease and Amendment.

Effective March 1, 2002, the Company signed a 10-year operating lease with Tech III Partners, LLC, an entity owned and controlled by two of the Company's executive officers. Under the terms of the original agreement, the Company will lease a 48,000 square foot facility adjacent to the Company's headquarters, at a base rent of $480,000 per year, increasing to $528,000 per year, during the initial 10-year term. The lease also provides for certain renewal and purchase options. As a result of Tech rII Partners, LLC investing an additional $2.5 million in tenant fit-out costs for the leased facility, the original operating lease was amended in October 2002, pursuant to which the base rent was increased to $780,000 per year, increasing to $858,000 per year, during the initial 10-year term. The Company's purchase option was also amended to reflect the cost of the tenant fit-out expenditures.

5. Segment and Geographic Area Information

Under the disclosure requirements of SFAS No. 131, "Segment Disclosures and Related Information," the Company operates within one segment, medical devices and products. The Company's products are sold principally in the United States and Europe. Segmentation of operating income and identifiable assets is not applicable since all of the Company's revenues outside the United States are export sales.

The following table represents total revenues by geographic area (in thousands, except %):

	Three months ended September 30,				Nine months ended September 30,			
	2002	%	2001	%	2002	%	2001	%
United States	$7,158	88%	$7,355	86%	$20,819	88%	$20,650	84%
Europe	538	7%	814	9%	2,018	8%	2,586	11%
Other regions	411	5%	430	5%	925	4%	1,275	5%
	$8,107	100%	$8,599	100%	$23,762	100%	$24,511	100%

6. Distribution and Supply Agreements

In October 2002, the Company entered into new agreements with bioMerieux, Inc. ("BMX"), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture the Company's oral fluid Western Blot HIV-1 confirmatory test, and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, the Company will pay BMX three installments of $250,000 each, the last of which will occur on March 31, 2003. The Company will record the $750,000 in aggregate payments as Patent and Product

Rights on the Balance Sheet and will amortize this amount through December 2005, the initial term of the agreements. In addition, the Company paid BMX an additional $250,000 to settle certain pending contract disputes which has been accrued as of September 30, 2002 in the accompanying Balance Sheet.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Statements below regarding future events or performance are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These include statements about expected revenues, earnings, expenses, cash flow or other financial performance, products, markets, and regulatory filings and approvals. Forward-looking statements are not guarantees of future performance or results. Factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include: ability to market products; impact of competitors, competing products and technology changes; ability to develop, commercialize and market new products; market acceptance of oral fluid testing products and up-converting phosphor technology products; ability to fund research and development and other projects and operations; ability to obtain and timing of obtaining necessary regulatory approvals; ability to develop product distribution channels; uncertainty relating to patent protection and potential patent infringement claims; availability of licenses to patents or other technology; ability to enter into international manufacturing agreements; obstacles to international marketing and manufacturing of products; loss or impairment of sources of capital; ability to meet financial covenants in agreements with financial institutions; exposure to product liability and other types of litigation; changes in international, federal or state laws and regulations; changes in relationships with strategic partners and reliance on strategic partners for the performance of critical activities under collaborative arrangements; changes in accounting practices and interpretation of accounting requirements; customer inventory practices and consolidations; equipment failures and ability to obtain needed raw materials and components; the impact of terrorist attacks and civil unrest; and general business, political and economic conditions. These and other factors that could cause the forward-looking statements to be materially different are described in greater detail in the Company's filings with the Securities and Exchange Commission, including its registration statements, its Annual Report on Form 10-K for the year ended December 31, 2001, and its Quarterly Reports on Form 10-Q. Although forward-looking statements help to provide information about future prospects, they may not be reliable. The forward-looking statements are made as of the date of this Report and the Company undertakes no duty to update these statements.

Results of Operations

Three months ended September 30, 2002 compared to September 30, 2001

Total revenues decreased 6% to approximately $8.1 million in the third quarter of 2002 from approximately $8.6 million in the comparable quarter in 2001, primarily as a result of lower licensing and product development revenue together with lower international sales of the OraQuick(R) rapid HIV antibody test, partially offset by increased sales of OraSure(R) oral fluid collection devices and test kits. Product revenues for the third quarter of 2002 decreased approximately 2% to $8.1 million compared to $8.2 million for the third quarter of 2001.

The table below shows the amount of the Company's total revenues (in thousands, except %) generated in each of its principal markets and by licensing and product development activities.

	Three months ended September 30,				
	Dollars		%	Percentage of Total Revenues	
Market Revenues	2002	2001	Change	2002	2001
Insurance risk assessment	$ 2,987	$ 2,986	0%	37%	35%
Infectious disease testing	1,472	1,604	-8%	18%	18%
Substance abuse testing	1,805	1,692	7%	22%	20%
Physicians' offices therapies	1,840	1,955	-6%	23%	23%
Product revenues	8,104	8,237	-2%	100%	96%
Licensing and product development	3	362	-99%	0%	4%
Total revenues	$ 8,107	$ 8,599	-6%	100%	100%

Sales to the insurance risk assessment market remained flat at approximately $3.0 million in the third quarter of 2002. Increased sales of OraSure(R) oral fluid collection devices internationally were offset by lower assay revenues resulting from continuing efficiency in processing urine tests at LabOne, Inc., the Company's largest customer. This efficiency is expected to have a continuing effect on the Company, resulting in an annualized revenue reduction of up to $1.0 million during 2002, based on the Company's 2001 urine test sales volumes.

Sales to the infectious disease testing market decreased 8% to approximately $1.5 million in the third quarter of 2002, primarily as a result of reduced sales of the Company's OraQuick(R) rapid HIV antibody test in the international marketplace, partially offset by an approximate 20% increase in the sale of OraSure(R) oral fluid collection devices and test kits.

Sales to the infectious disease testing market are expected to increase as a result of the Company's agreement with Abbott Laboratories ("Abbott") for the distribution of the Company's OraQuick(R) rapid HIV-1 antibody test, which was signed in June 2002. Under the terms of the agreement, Abbott was appointed as co-exclusive distributor of the OraQuick(R) HIV-1 device in the United States and is required to meet certain minimum purchase commitments. Pursuant to these commitments, the Company expects to receive product revenues of approximately $4.0 million through the end of 2003. On November 7, 2002, the Company received U.S. Food and Drug Administration ("FDA") approval of the OraQuick(R) test for detecting HIV-1 antibodies in finger-stick whole blood samples. Pursuant to this approval, the Company is authorized to manufacture and sell the OraQuick(R) test in the United States.

Sales to the substance abuse testing market increased 7% to approximately $1.8 million as a result of increased sales of Intercept(R) collection devices and oral fluid drug assays for workplace and criminal justice testing, partially offset by lower analytical equipment sales and lower sales of the Company's Q.E.D.(R) saliva alcohol test.

During the third quarter of 2002, the Company's three newest Intercept(R) laboratory distributors, Quest Diagnostics, Clinical Reference Laboratory and NWT, Inc., began selling the Intercept(R) drug testing system into the workplace testing market. If the sales efforts by these distributors are successful, the Company would expect Intercept(R) revenues to increase above current levels.

Sales of the Company's Histofreezer(R) portable cryosurgical system in the physicians' office therapies market decreased 6% to approximately $1.8 million in the third quarter of 2002. This decrease was primarily the result of significantly lower international distributor sales, partially offset by an increase in distributor sales in the United States.

Licensing and product development revenue decreased to $3,000 in the third quarter of 2002 from $362,000 in 2001. During the third quarter of 2001, the Company received certain development milestone payments from Meridian Bioscience, a one-time payment from a potential corporate partner and certain funded research and development payments from the National Institutes of Health pursuant to a Phase II Small Business Innovation Research ("SBIR") grant. There were no such payments during the third quarter of 2002.

The Company's gross margin decreased to 59% in the third quarter of 2002 from 67% in 2001. This decrease was primarily attributable to the lower amount of licensing and product development revenues, higher costs associated with the advanced preparation for OraQuick(R) manufacturing, and higher scrap rates in the third quarter of 2002. The higher scrap rates were caused by several factors, including product expiration and obsolescence and unexpected changes in product demand. The Company is implementing remedial measures, which are intended to reduce scrap rates in the future.

Research and development expenses decreased 16% to approximately $1.9 million in the third quarter of 2002 from approximately $2.2 million in 2001, primarily as a result of lower staffing costs and lower consulting fees.

Sales and marketing expenses decreased 6% to approximately $1.9 million in the third quarter of 2002 from approximately $2.1 million in 2001. This decrease was primarily the result of lower staffing and related expenses. Sales and marketing expenses are expected to increase in the future as the Company launches new products and attempts to maximize sales of its existing product lines.

General and administrative expenses decreased 7% to approximately $1.3 million in the third quarter of 2002 from approximately $1.4 million in 2001. This decrease was primarily attributable to lower executive recruiting fees.

Interest expense decreased to $70,000 in the third quarter of 2002 from $102,000 in 2001 as a result of lower outstanding loan balances. Interest income decreased to $87,000 in the third quarter of 2002 from $242,000 in 2001, as a result of lower cash and cash equivalents available for investment and lower interest rates on the Company's investments.

In September 2002, the Company refinanced certain existing term and mortgage debt, and entered into a new credit facility, with Comerica Bank. As a result of the refinancing of term and mortgage debt, the Company lowered the effective interest rate on its outstanding indebtedness by approximately 300 basis points, which is expected to result in a reduction in interest expense of over $100,000 per year, based on the Company's current level of outstanding indebtedness.

The Company recorded a foreign currency loss of $2,000 in the third quarter of 2002 compared to a foreign currency loss of $115,000 in the third quarter of 2001.

Results of Operations

Nine months ended September 30, 2002 compared to September 30, 2001

Total revenues decreased 3% to approximately $23.8 million for the nine months ended September 30, 2002 from approximately $24.5 million in the comparable nine month period in 2001, primarily as a result of lower licensing and product development revenue and lower assay sales in the insurance risk assessment market, partially offset by increased sales of OraSure(R) oral fluid collection devices and test kits in the infectious disease testing market and increased sales of the Histofreezer(R) portable cryosurgical product in the physicians' office therapies market. Product revenues for the first nine months of 2002 increased approximately 1% to $23.4 million compared to $23.2 million for the first nine months of 2001.

The table below shows the amount of the Company's total revenues (in thousands, except %) generated in each of its principal markets and by licensing and product development activities.

	Nine months ended September 30,				
	Dollars		%	Percentage of Total Revenues	
Market Revenues	2002	2001	Change	2002	2001
Insurance risk assessment	$ 8,900	$ 9,376	-5%	38%	38%
Infectious disease testing	4,505	4,257	6%	19%	18%
Substance abuse testing	4,808	4,841	-1%	20%	20%
Physicians' offices therapies	5,233	4,733	11%	22%	19%
Product revenues	23,446	23,207	1%	99%	95%
Licensing and product development	316	1,303	-76%	1%	5%
Total revenues	$ 23,762	$ 24,510	-3%	100%	100%

Sales to the insurance risk assessment market declined by 5% to approximately $8.9 million for the nine months ended September 30, 2002 from approximately $9.4 million in the comparable period in 2001, primarily as a result of lower assay sales due to continuing efficiency in processing urine tests at LabOne, Inc., the Company's largest customer. This efficiency is expected to have a continuing effect on the Company, resulting in an annualized revenue reduction of up to $1.0 million during 2002, based on the Company's 2001 urine test sales volumes.

Sales to the infectious disease testing market increased 6% to approximately $4.5 million for the nine months ended September 30, 2002 from approximately $4.3 million in the comparable period in 2001, primarily as a result of an approximate 23% increase in the sale of OraSure(R) oral fluid collection devices and test kits. Offsetting this increase were reduced international sales of the Company's OraQuick(R) rapid HIV antibody test, which accounted for approximately $650,000 in revenues for the first nine months of 2001.

Sales to the substance abuse testing market were flat at approximately $4.8 million for the nine months ended September 30, 2002, as a result of a increased sales of Intercept(R) collection devices and oral fluid drug assays, offset by approximately $600,000 of lower analytical equipment sales and lower sales of the Company's Q.E.D.(R) saliva alcohol test.

Sales of the Company's Histofreezer(R) products in the physicians' office therapies market increased 11% to approximately $5.2 million for the nine months ended September 30, 2002 from approximately $4.7 million in the comparable period in 2001. This increase was the result of an increase in distributor sales in the United States, partially offset by significantly lower international distributor sales.

Licensing and product development revenue decreased 76% to $316,000 for the nine months ended September 30, 2002 from approximately $1.3 million in the comparable period in 2001. During the nine months ended September 30, 2001, the Company received certain development milestone payments from Meridian Bioscience and Drager Safety and certain funded research and development payments from the National Institutes of Health pursuant to a Phase II SBIR grant. There were no such payments during the nine months ended September 30, 2002.

The Company's gross margin decreased to approximately 60% for the nine months ended September 30, 2002 from 65% for the comparable period in 2001. The decrease was primarily attributable to the lower amount of licensing and product development revenues and higher scrap rates in the first nine months of 2002. The higher scrap rates were caused by several factors, including product expiration and obsolescence and unexpected changes in product demand. The Company is implementing remedial measures, which are intended to reduce scrap rates in the future.

Research and development expenses decreased 5% to approximately $6.5 million from approximately $6.8 million in the comparable period in 2001. Decreased expenditures for staffing, consulting and travel were partially offset by increased costs associated with clinical trials related to the Company's efforts to obtain FDA approval of the OraQuick(R) rapid HIV-1 antibody test.

Sales and marketing expenses increased 6% to approximately $6.3 million for the nine months ended September 30, 2002 from approximately $6.0 million in the comparable period in 2001. This increase was primarily the result of higher consulting fees for the development of strategic marketing plans. Sales and marketing expenses are expected to increase in the future as the Company launches new products and attempts to maximize sales of its existing product lines.

General and administrative expenses increased 9% to approximately $4.9 million for the nine months ended September 30, 2002 from approximately $4.5 million for the comparable period in 2001. This increase was primarily attributable to an approximate $0.5 million severance charge related to the departure of the Company's former Chief Executive Officer.

Restructuring-related expenses were $450,000 in the nine months ended September 30, 2001 as a result of a manufacturing restructuring. There was no such charge in the first nine months of 2002.

Interest expense decreased to $233,000 for the nine months ended September 30, 2002 from $310,000 for the comparable period in 2001, as a result of lower outstanding loan balances. Interest income decreased to $391,000 for the nine months ended September 30, 2002 from $743,000 for the comparable period in 2001, as a result of lower cash and cash equivalents available for investment and lower interest rates on the Company's investments.

In September 2002, the Company refinanced certain existing term and mortgage debt, and entered into a new credit facility, with Comerica Bank. As a result of the refinancing of term and mortgage debt, the Company lowered the effective interest rate on its outstanding indebtedness by approximately 300 basis points, which is expected to result in a reduction in interest expense of over $100,000 per year, based on the Company's current level of outstanding indebtedness.

Liquidity and Capital Resources

	September 30, 2002	December 31, 2001
	(In thousands)	
Cash and cash equivalents	$ 5,231	$ 2,426
Short-term investments	8,137	12,765
Working capital	17,216	19,764

The Company's cash, cash equivalents and short-term investments decreased approximately $1.8 million during the first nine months of 2002 to approximately $13.4 million at September 30, 2002, primarily as a result of the Company's net loss for the first nine months of 2002, a reduction of accounts payable and accrued expenses, and certain capital expenditures. Offsetting these uses of cash were an increase in accounts receivable collections and proceeds from stock option exercises. At September 30, 2002, the Company's working capital was approximately $17.2 million.

In September 2002, the Company entered into a new $10.9 million credit facility ("New Credit Facility") with Comerica Bank, pursuant to which the Company refinanced substantially all of its previously outstanding mortgage and term debt and increased its equipment and working capital lines of credit. The New Credit Facility is comprised of an $887,000 mortgage loan, a $3.0 million term loan, a $3.0 million non-revolving equipment line of credit, and a $4.0 million revolving working capital line of credit.

The $887,000 mortgage loan matures in September 2012, bears interest at an annual floating rate equal to Comerica's prime rate, and is repayable in fixed monthly principal and interest installments of $7,426 through September 2007, at which time the interest rate and fixed monthly repayment amount will be reset for the remaining 60 monthly installments.

The $3.0 million term loan matures in March 2006, bears interest at a fixed rate of 4.99% and is repayable in forty-two consecutive equal monthly principal payments of $71,429, plus interest.

Under the non-revolving equipment line of credit, the Company can borrow up to $3.0 million to finance eligible equipment purchases through September 11, 2003. Interest on outstanding borrowings shall accrue at a rate, selected at the Company's option, equal to Comerica's prime rate, 180-day or 360-day LIBOR plus 2.625%, or the 4-year Treasury Note Rate plus 2.30%, determined at the time of each borrowing. Borrowings are repayable in 48 consecutive, equal monthly principal installments, plus interest. As of September 30, 2002, the Company had an outstanding balance of approximately $192,000 under this facility with a fixed annual interest rate of 5.07%.

Under the revolving working capital line of credit, the Company can borrow up to $4.0 million to finance working capital and other needs. Interest on outstanding borrowings shall accrue at a rate, selected at the Company's option, equal to Comerica's prime rate less 0.25%, or 30-day LIBOR plus 2.55%, determined at the time of the initial borrowing. Borrowings are repayable by September 9, 2003, with interest payable monthly. The Company had no outstanding borrowings under this facility at September 30, 2002.

All borrowings under the New Credit Facility are collateralized by a first priority security interest in all of the assets of the Company, including present and future accounts receivable, chattel paper, contracts and contract rights, equipment and accessories, general intangibles, investments, instruments, inventory, and a mortgage on the Company's manufacturing facility in Bethlehem, Pennsylvania. Borrowings under the equipment and working capital lines of credit are limited to commercially standard percentages of equipment purchases and accounts receivable, respectively. The New Credit Facility contains certain covenants containing minimum requirements for the Company's quick ratio, liquidity, and tangible net worth and requires the Company to achieve positive consolidated net income for the year ending December 31, 2003 and for each year thereafter. The New Credit Facility also restricts the Company's ability to pay dividends, to make certain investments, to incur additional indebtedness, to sell or otherwise dispose of a substantial portion of assets, and to merge or consolidate operations with an unaffiliated entity, without the consent of Comerica.

The combination of the Company's current cash position and available borrowings under the Company's credit facilities is expected to be sufficient to fund the Company's foreseeable operating and capital needs. However, the Company's cash requirements may vary materially from those now planned due to many factors, including, but not limited to, the progress of the Company's research and development programs, the scope and results of clinical testing, the magnitude of capital expenditures, changes in existing and potential relationships with business partners, the time and cost of obtaining regulatory approvals, the costs involved in obtaining and enforcing patents, proprietary rights and any necessary licenses, the ability of the Company to establish development and commercialization capacities or relationships, the costs of manufacturing, the success of the Company's sales and marketing efforts, market acceptance of new products and other factors.

In October 2002, the Company entered into new agreements with bioMerieux, Inc. ("BMX"), which replaced existing agreements between the parties, for the supply by BMX of HIV-1 antigen required to manufacture the Company's oral fluid Western Blot HIV-1 confirmatory test, and for the distribution by BMX of the oral fluid Western Blot product on an exclusive worldwide basis. These agreements have an initial term ending December 31, 2005, which may be extended until December 31, 2007 under certain circumstances. As consideration for BMX entering into the new agreements, the Company will pay BMX three installments of $250,000 each, the last of which will occur on March 31, 2003. In addition, the Company paid BMX an additional $250,000 to settle certain pending contract disputes.

Net cash used in operating activities was approximately $800,000 for the nine months ended September 30, 2002, primarily as a result of the loss for the period, net of depreciation, increased inventory levels, and the reduction of accounts payable and accrued expenses, offset by increased accounts receivable collections.

Net cash provided by investing activities for the nine months ended September 30, 2002 was approximately $3.4 million, primarily as a result of $4.6 million in net proceeds received from the sale of short-term investments, offset by the purchase of approximately $1.0 million of capital equipment and a $200,000 payment to secure a sublicense to certain lateral flow technology patents.

Net cash provided by financing activities was approximately $240,000 for the nine months ended September 30, 2002 as a result of approximately $160,000 of term debt repayments, offset by approximately $400,000 in proceeds from the exercise of stock options.

Certain Relationships and Related Transactions

The Company has entered into a Commercial Lease (the "Lease") with Tech III Partners, LLC ("Tech Partners"), which provides for the construction of a 48,000 square foot facility on land adjacent to the Company's Bethlehem, Pennsylvania headquarters, and the lease of that facility to the Company. Tech Partners is owned and controlled by Michael J. Gausling, the Company's President and Chief Executive Officer, and Dr. R. Sam Niedbala, the Company's Executive Vice President and Chief Science Officer. The facility will house manufacturing, warehousing, and administrative operations required to support the expected growth of the Company's business. Construction of the facility is now complete. In October 2002, the Company entered into an amendment of the Lease with Tech Partners in order to reflect an increase in the base rental rate required to reflect certain additional tenant fit-out costs.

The Lease, as amended, has an initial ten-year term ending in October 2012 and a base rent starting at $780,000 and increasing to $858,240 per year over that term. The base rental rate may be increased after the fifth year of the initial term in order to reflect changes in the interest rate on debt incurred by Tech Partners to finance construction of the leased facilities. The Company has not guaranteed any debt incurred by Tech Partners. The Lease also provides the Company with options to renew the Lease for an additional five years at a rental rate of $975,360 per year, and to purchase the facility at any time during the initial ten-year term based on a formula set forth in the Lease. Prior to deciding to enter into the Lease and the Amendment, the Company's Board of Directors retained Imperial Realty Appraisal LLC, an independent commercial real estate appraisal firm, to evaluate the proposed base rental rate. Imperial Realty issued opinions indicating that the annual base rent set forth in the Lease, as amended, is below the market rental rate the Company could otherwise expect to pay to lease a comparable commercial property in the same general geographic market. The terms of the Lease are otherwise substantially similar to the commercial lease entered into by the Company with a third party for its existing Bethlehem, Pennsylvania headquarters.

Critical Accounting Policies and Estimates

Management's Discussion and Analysis of Financial Condition and Results of Operations discusses the Company's financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. On an on-going basis, management evaluates its judgments and estimates, including those related to bad debts, inventories, investments, intangible assets, income taxes, revenue recognition, contingencies, and litigation. Management bases its judgments and estimates on historical experience and on various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

Management considers the following policies to be most critical in understanding the more complex judgments that are involved in preparing the Company's financial statements and the uncertainties that could impact its results of operations, financial condition, and cash flows.

Revenue Recognition. The Company follows U.S. Securities and Exchange Commission Staff Accounting Bulletin No. 101, "Revenue Recognition in Financial Statements" ("SAB 101"). SAB 101 draws on existing accounting rules and provides specific guidance on revenue recognition of up-front, non-refundable licensing and development fees. The Company licenses certain products or technology to outside third parties, in return for which the Company receives up-front licensing fees, some of which can be significant. In accordance with SAB 101, the Company is required to defer immediate recognition of these fees as revenue, and instead ratably recognize this revenue over the related license period.

The Company also enters into research and development contracts with corporate, government or private entities. These contracts generally provide for payments to the Company upon achievement of certain research or development milestones. Product development revenues from these contracts are recognized only if the specified milestone is achieved and accepted by the customer and payment from the customer is probable. Any amounts received prior to the performance of product development efforts are recorded as deferred revenues. Recognition of revenue under these contracts can be sporadic, as it is the result of achieving specific research and development milestones. Furthermore, revenue from future milestone payments will not be recognized if the underlying research and development milestone is not achieved.

The Company recognizes product revenues when products are shipped. The Company does not grant price protection or product return rights to its customers, except for warranty returns. Where a product fails to comply with its limited warranty, the Company can either replace the product or provide the customer with a refund of the purchase price or credit against future purchases. Historically, returns arising from warranty issues have been infrequent and immaterial. Accordingly, the Company expenses warranty returns as incurred. While such returns have been immaterial in the past, management cannot guarantee that the Company will continue to experience the same low rate of warranty claims as it has in the past. Any significant increase in product warranty claims could have a material adverse impact on the Company's operating results for the period in which such claims occur.

Allowance for Uncollectible Accounts Receivable. Accounts receivable are reduced by an estimated allowance for amounts that may become uncollectible in the future. On an ongoing basis, management performs credit evaluations of the Company's customers and adjusts credit limits based upon the customer's payment history and creditworthiness, as determined by a review of their current credit information. The Company continuously monitors collections and payments from its customers. Based upon the Company's historical experience and any specific customer collection issues that are identified, management uses its judgment to establish and evaluate the adequacy of the Company's allowance for estimated credit losses. While such credit losses have been within the Company's expectations and the allowance provided, the Company cannot guarantee that it will continue to experience the same credit loss rates as it has in the past. Furthermore, some of the Company's accounts receivable have resulted from sales to distributors located in foreign countries. Any significant changes in the liquidity or financial position of its customers, or the economies or political climate of certain foreign nations, could have a material adverse impact on the collectibility of the Company's accounts receivable and its future operating results.

Inventories. The Company's inventories are valued at the lower of cost or market, determined on a first-in, first-out basis, and include the cost of raw materials, labor and overhead. The majority of the Company's inventories are subject to expiration dating. The Company continually evaluates the carrying value of its inventories and when, in the opinion of management, factors indicate that impairment has occurred, either a reserve is established against the inventories' carrying value or the inventories are completely written off. Management bases these decisions on the level of inventories on hand in relation to the Company's estimated forecast of product demand, production requirements over the next twelve months and the expiration dates of raw materials and finished goods. Although the Company makes every effort to ensure the accuracy of its forecasts of future product demand, any significant unanticipated changes in demand could have a significant impact on the carrying value of the Company's inventories and its reported operating results.

Contingencies. In the ordinary course of business, the Company has entered into various contractual relationships with strategic corporate partners, customers, distributors, research laboratories and universities, licensors, licensees, suppliers, vendors and other parties. As such, the Company could be subject to litigation, claims or assessments arising from any or all of these relationships. The Company accounts for contingencies such as these in accordance with Statement of Financial Accounting Standards ("SFAS") No. 5, "Accounting for Contingencies." SFAS No. 5

requires the Company to record an estimated loss contingency when information available prior to issuance of the Company's financial statements indicates that it is probable that an asset has been impaired or a liability has been incurred at the date of the financial statements and the amount of the loss can be reasonably estimated. Accounting for contingencies arising from contractual or legal proceedings requires Company management to use its best judgment when estimating an accrual related to such contingencies. As additional information becomes known, the Company's accrual for a loss contingency could fluctuate, thereby creating variability in the Company's results of operations from period to period. Likewise, an actual loss arising from a loss contingency which significantly exceeds the amount accrued for in the Company's financial statements could have a material adverse impact on the Company's operating results for the period in which such actual loss becomes known.

Income Taxes. The Company has a history of losses, which has generated a sizeable federal tax net operating loss ("NOL") carryforward of approximately $69.1 million as of December 31, 2001. Generally accepted accounting principles require the Company to record a valuation allowance against the deferred tax asset associated with this NOL carryforward if it is more likely than not that the Company will not be able to utilize the NOL carryforward to offset future taxes. Due to the size of the NOL carryforward in relation to the Company's history of unprofitable operations, the Company has not recognized any of this net deferred tax asset.

It is possible that the Company could be profitable in the future at levels which would cause management to conclude that it is more likely than not that the Company will be able to realize all or a portion of the NOL carryforward. Upon reaching such a conclusion, the Company would immediately record the estimated net realizable value of the deferred tax asset at that time and would then begin to provide for income taxes at a rate equal to the Company's combined federal and state effective rates, which management believes would approximate 40%. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause the Company's provision for income taxes to vary significantly from period to period.

Item 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

The Company does not hold any amounts of derivative financial instruments or derivative commodity instruments, and accordingly, has no material derivative risk to report under this Item.

The Company's holdings of financial instruments are comprised of U.S. corporate debt, certificates of deposit, government securities and commercial paper. All such instruments are classified as securities available for sale. The Company's debt security portfolio represents funds held temporarily pending use in its business and operations. The Company seeks reasonable assuredness of the safety of principal and market liquidity by investing in rated fixed income securities while at the same time seeking to achieve a favorable rate of return. Market risk exposure consists principally of exposure to changes in interest rates. If changes in interest rates would affect the investments adversely, the Company could decide to hold the security to maturity or sell the security. The Company's holdings are also exposed to the risk of change in the credit quality of issuers. The Company typically invests in the shorter end of the maturity spectrum.

The Company does not currently have any foreign currency exchange contracts or purchase currency options to hedge local currency cash flows. The Company has operations in The Netherlands that are subject to foreign currency fluctuations. As currency rates change, translation of revenues and expenses for these operations from Euros to U.S. dollars affects year-to-year comparability of operating results. Revenues generated in The Netherlands represented approximately $400,000 and $1.3 million or 4.9% and 5.5% of the Company's total revenues for the three months and nine months ended September 30, 2002, respectively. Management does not expect the risk of foreign currency fluctuations to be material.

Item 4. CONTROLS AND PROCEDURES.

(a) Evaluation of Disclosure Controls and Procedures. Within the 90 days preceding the filing of this Report, an evaluation was performed under the supervision and with the participation of the Company's management, including the Company's Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation

of the Company's disclosure controls and procedures. Based on that evaluation, the Company's management, including such officers, concluded that the Company's disclosure controls and procedures were effective in timely alerting them to material information relating to the Company, which is required to be included in its periodic filings with the Securities and Exchange Commission.

(b) Changes in Internal Controls. There have been no significant changes in the Company's internal controls or in other factors that could significantly affect internal controls (including any corrective actions with regard to significant deficiencies or material weaknesses) subsequent to the date of the evaluation referred to in paragraph (a) of this Item.

PART II. OTHER INFORMATION

Item 6. EXHIBITS AND REPORTS ON FORM 8-K.

(a) Exhibits.

Exhibits are listed on the attached exhibit index following the signature page of this report.

(b) Reports on Form 8-K.

None.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ORASURE TECHNOLOGIES, INC.

/s/ Ronald H. Spair

Date: November 13, 2002
Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

/s/ Mark L. Kuna

Date: November 13, 2002
Mark L. Kuna
Controller
(Principal Accounting Officer)

Certification

I, Michael J. Gausling, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OraSure Technologies, Inc;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d -14) for the registrant and we have:

    a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

    b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

    c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date.

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: November 13, 2002

/s/ Michael J. Gausling

Michael J. Gausling
President and Chief Executive Officer
(Principal Executive Officer)

Certification

I, Ronald H. Spair, certify that:

1. I have reviewed this quarterly report on Form 10-Q of OraSure Technologies, Inc;

2. Based on my knowledge, this quarterly report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this quarterly report;

3. Based on my knowledge, the financial statements, and other financial information included in this quarterly report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this quarterly report;

4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d -14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and

c) Presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officers and I have indicated in this quarterly report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses

Date: November 13, 2002

/s/ Ronald H. Spair

Ronald H. Spair
Executive Vice President and
Chief Financial Officer
(Principal Financial Officer)

EXHIBIT INDEX

Exhibit	
10.1	Loan and Security Agreement, dated as of September 10, 2002, between Comerica Bank - California and OraSure Technologies, Inc.
10.2	Amendment No. 1 to Commercial Lease, dated as of October 21, 2002, between Tech III Partners, LLC and OraSure Technologies, Inc.
10.3	Distribution Agreement, dated as of October 11, 2002, between OraSure Technologies, Inc. and bioMerieux, Inc.*
10.4	Supply Agreement, dated as of October 11, 2002, between OraSure Technologies, Inc. and bioMerieux, Inc.*
99.1	Certification pursuant to 18 U.S.C.(S) 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
99.2	Certification pursuant to 18 U.S.C.(S) 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

*Portions of this Exhibit were omitted and filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.

EXHIBIT 10.1

ORASURE TECHNOLOGIES, INC.

LOAN AND SECURITY AGREEMENT

September 10, 2002

This LOAN AND SECURITY AGREEMENT is entered into as of September 10, 2002, by and between COMERICA BANK--CALIFORNIA ("Bank") and ORASURE TECHNOLOGIES, INC., a Delaware corporation ("Borrower").

RECITALS

Borrower wishes to obtain credit from time to time from Bank, and Bank desires to extend credit to Borrower. This Agreement sets forth the terms on which Bank will advance credit to Borrower, and Borrower will repay the amounts owing to Bank.

AGREEMENT

The parties agree as follows:

1. DEFINITIONS AND CONSTRUCTION.

1.1 Definitions. As used in this Agreement, all capitalized terms shall have the definitions set forth on Exhibit A. Any term used in the Code and not defined herein shall have the meaning given to the term in the Code.

1.2 Accounting Terms. Any accounting term not specifically defined on Exhibit A shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the notes and schedules accompanying such financial statements to the extent such statements are for an annual or quarterly period.

2. LOAN AND TERMS OF PAYMENT.

2.1 Credit Extensions.

(a) Loans; Promise to Pay. Bank agrees to advance Borrower Credit Extensions, in lawful money of the United States of America, pursuant to the terms hereof. Borrower promises to pay to Bank, in lawful money of the United States of America, the aggregate unpaid principal amount of all Credit Extensions made by Bank to Borrower, together with interest accrued on the unpaid principal amount of such Credit Extensions, at rates determined in accordance with the terms hereof.

(b) Revolving Advances.

(i) Amount. Subject to and upon the terms and conditions of this Agreement, Borrower may from time to time request, and Bank will provide, Revolving Advances in an aggregate outstanding amount not to exceed the lesser of (A) the Committed Revolving Line Amount or (B) the Borrowing Base. The Borrowing Base for a Revolving Advance shall be determined from the most recent Borrowing Base Certificate delivered by Borrower, in accordance with Section 6.2(f), prior to such Revolving Advance.

(ii) Interest; Repayment. Interest shall accrue on each Revolving Advance at a rate determined in accordance with Section 2.3(a)(i), and shall be payable in accordance with Section 2.3(c). Each such Revolving Advance may be repaid and reborrowed at any time prior to the Revolving Maturity Date, at which time all Revolving Advances under this Section 2.1(b) shall be immediately due and payable. Borrower may prepay any Revolving Advance, without penalty or premium, prior to the Revolving Maturity Date in the event the Revolving Advance is a Variable Rate Advance, but, except as provide in Section 2.2, Borrower shall be subject to, and shall pay, a LIBOR Prepayment Penalty in the event that the Revolving Advance is a LIBOR Advance and the Borrower repays such LIBOR Advance prior to the last scheduled day of the applicable LIBOR Interest Period.

(iii) Form of Request. Whenever Borrower desires a Revolving Advance, Borrower will notify Bank by facsimile transmission or telephone no later than 12:00 noon Pacific time, on the Business Day that the Revolving Advance is to be made. Each such notification shall be promptly confirmed by a

Payment/Advance Form in substantially the form of Exhibit C. Bank is authorized to make Revolving Advances under this Agreement, based upon instructions received from a Responsible Officer or a designee of a Responsible Officer, or without instructions if in Bank's reasonable discretion such Revolving Advances are necessary to meet Obligations which have become due and remain unpaid. Bank shall be entitled to rely on any telephonic notice given by a person who Bank reasonably and in good faith believes to be a Responsible Officer or a designee thereof, and Borrower shall indemnify and hold Bank harmless for any damages or loss suffered by Bank as a result of such reliance. Bank will credit the amount of Revolving Advances made under this Section 2.1(b) to Borrower's deposit account at Bank.

(c) Term Advance.

(i) Amount. Subject to and upon the terms and conditions of this Agreement, Bank agrees to make a Term Advance to Borrower on the Closing Date in an amount equal to the Committed Term Loan Amount. Proceeds from the Term Advance will be used to repay the outstanding principal amount of and accrued interest on Borrower's term indebtedness with Lafayette Ambassador Bank as of the Closing Date. Any proceeds from the Term Advance remaining after such repayment will be credited to Borrower's deposit account at Bank.

(ii) Interest; Repayment. Interest shall accrue on the Term Advance at a rate determined in accordance with Section 2.3(a)(ii), and shall be payable in accordance with Section 2.3(c). The Term Advance shall be repaid in forty-two (42) consecutive, equal monthly payments of principal, plus all accrued interest, beginning on October 1, 2002 and continuing on the first day of each month thereafter through the Term Maturity Date, at which time all amounts due in connection with the Term Advance made under this Section 2.1(c) shall be immediately due and payable. The Term Advance, once repaid, may not be reborrowed. Borrower may prepay the Term Advance prior to the Term Maturity Date, without penalty or premium, in the event the Term Advance is a Variable Rate Advance, but Borrower shall be subject to, and shall pay, (A) a LIBOR Prepayment Penalty in the event the Term Advance is a LIBOR Advance and the Borrower repays such LIBOR Advance prior to the last scheduled day of the applicable LIBOR Interest Period, or (B) a Prepayment Penalty in the event the Term Advance is a Fixed Rate Advance and the Borrower repays such Fixed Rate Advance prior to the last day of the applicable Fixed Rate Interest Period.

(d) Non-Revolving Advances

(i) Amount. Subject to and upon the terms and conditions of this Agreement, Borrower may on any Non-Revolving Advance Date request, and Bank shall provide, Non-Revolving Advances in an aggregate outstanding amount not to exceed the Committed Non-Revolving Line Amount. Non-Revolving Advances shall be used to reimburse Borrower for 90% of the invoice amount of CAPEX Equipment which Borrower shall have purchased or, in the case of an installment purchase, made the final installment payment for, within ninety (90) days of the applicable Non-Revolving Advance Date. Invoice amounts subject to reimbursement under this Section 2.1(d)(i) shall exclude taxes, shipping, warranty charges, freight discounts and installation expense to the extent such items are itemized separately from the purchase price for the affected CAPEX Equipment.

(ii) Interest; Repayment. Interest shall accrue on each Non-Revolving Advance at a rate determined in accordance with Section 2.3(a)(iii), and shall be payable in accordance with Section 2.3(c). Each Non-Revolving Advance made to Borrower shall be repaid in forty-eight (48) consecutive, equal monthly payments of principal, plus accrued interest thereon, beginning on the first day of the first month following the date of such Non-Revolving Advance and on the first day of each month thereafter and, in all events, all Non-Revolving Advances shall be due and payable no later than the Non-Revolving Maturity Date. Each Non-Revolving Advance, once repaid, may not be reborrowed. Borrower may prepay any Non-Revolving Advance, without penalty or premium, prior to the final maturity date for such Non-Revolving Advance in the event that the Non-Revolving Advance is a Variable Rate Advance, but Borrower shall be subject to, and shall pay, (A) a LIBOR Prepayment Penalty in the event the Non-Revolving Advance is a LIBOR Advance and Borrower repays such LIBOR Advance prior to the last scheduled day of the applicable LIBOR Interest Period, or (B) a Prepayment Penalty in the event that the Non-Revolving Advance is a Fixed Rate Advance and the Borrower repays such Fixed Rate Advance prior to the last day of the applicable Fixed Rate Interest Period.

(iii) Form of Request. Whenever Borrower desires a Non-Revolving Advance, Borrower will notify Bank (which notice shall be irrevocable) by facsimile transmission to be received no later than 12:00 noon Pacific time, on the Business Day that is three (3) Business Days prior to the date the Non-Revolving Advance is to be made. Such notice shall be substantially in the form of Exhibit C. The notice shall be signed by a Responsible Officer or its designee and include a copy of the invoices for any CAPEX Equipment to be financed. Bank will credit the amount of Non-Revolving Advances made under this Section 2.1(d) to Borrower's deposit account at Bank.

(e) Mortgage Advance.

(i) Amount. Subject to and upon the terms and conditions of this Agreement, Bank agrees to make the Mortgage Advance to Borrower on the Closing Date in the amount of the Committed Mortgage Loan Amount. The Mortgage Advance made under this Section 2.1(e) will be used to repay the outstanding principal amount of Borrower's mortgage indebtedness with Lafayette Ambassador Bank as of the Closing Date.

(ii) Interest; Repayment. Interest shall accrue on the Mortgage Advance at a rate determined in accordance with Section 2.3(a)(iv), and shall be payable in accordance with Section 2.3(c). The Mortgage Advance shall be payable in sixty (60) equal monthly installments of $7,426.02 (which reflects a 15-year amortization and an assumed interest rate of 5.95% for the initial five (5) years following the date hereof), beginning on October 1, 2002 and continuing on the first day of each month thereafter through September 1, 2007 and, thereafter, the interest rate shall be reset as provided in Sections 2.3(a)(iv) and (d) hereof, and the Mortgage Advance shall then be payable in sixty (60) equal monthly installments beginning October 1, 2007 and continuing on the first day of each month thereafter through the Mortgage Maturity Date, at which time all amounts of principal and accrued interest remaining unpaid in connection with the Mortgage Advance shall be immediately due and payable. The Mortgage Advance, once repaid, may not be reborrowed. Borrower may prepay the Mortgage Advance, without penalty or premium, prior to the Mortgage Maturity Date in the event the Mortgage Advance is a Variable Rate Advance, but Borrower shall be subject to, and shall pay, a Prepayment Penalty in the event the Mortgage Advance is a Fixed Rate Advance and Borrower repays such Fixed Rate Advance prior to last day of the applicable Fixed Rate Interest Period.

2.2 Overadvances. If the aggregate amount of the outstanding Revolving Advances exceeds the lesser of the Committed Revolving Line Amount or the Borrowing Base at any time, Borrower shall pay to Bank, in cash, the amount of such excess promptly after becoming aware of such circumstance. If Borrower is required to prepay any Revolving Advance because of a change by Bank in the standards of eligibility for Eligible Accounts (as permitted by the definition thereof), Borrower may do so without penalty or premium.

2.3 Interest Rates; Late Fee; Default Rate; Payments; Computation; Interest Rate Conversion.

(a) Interest Rates. Except as set forth in Section 2.3(b) and subject to Sections 2.3(d) and (e), the interest rate on each Credit Extension made hereunder shall be determined as follows:

(i) Revolving Advances. The Revolving Advances shall bear interest, on the outstanding daily balance thereof, at Borrower's option, at a rate per annum equal to (A) the Prime Rate less 0.25%, or (B) 30-day LIBOR plus 2.55%, in each case initially determined at the time of funding.

(ii) Term Advance. The Term Advance shall bear interest, on the outstanding daily balance thereof, at Borrower's option, at a rate per annum equal to (A) the Prime Rate, (B) 180-day or 360-day LIBOR plus 2.625%, or (C) the 3.5 year Treasury Note Rate plus 2.30%, in each case initially determined at the time of funding.

(iii) Non-Revolving Advances. The Non-Revolving Advances shall bear interest, on the outstanding daily balance thereof, at Borrower's option, at a rate per annum equal to (A) the Prime Rate, (B) 180-day or 360-day LIBOR plus 2.625%, or (C) the 4-year Treasury Note Rate plus 2.30%, in each case initially determined at the time of funding.

(iv) Mortgage Advance. The Mortgage Advance shall bear interest, on the outstanding daily balance thereof, at Borrower's option, at a rate per annum equal to (A) the Prime Rate, or (B) the 5-year Treasury Note Rate plus 2.85%, in each case initially determined at the time of funding.

(b) Late Fee; Default Rate. If any payment is not made within ten days after the date such payment is due, Borrower shall pay Bank a late fee equal to the lesser of (i) 5% of the amount of such unpaid amount or (ii) the maximum amount permitted to be charged under applicable law. All Obligations shall bear interest, from and after the occurrence and during the continuance of an Event of Default, at a rate equal to five percentage points above the interest rate applicable immediately prior to the occurrence of the Event of Default.

(c) Payments. Unless otherwise provided, interest on the Credit Extensions hereunder shall be due and payable on the first calendar day of each month during the term hereof. Bank shall, at its option and upon notice to Borrower, charge such interest, all Bank Expenses, and all Periodic Payments against any of Borrower's deposit accounts or against the Revolving Facility with respect to interest on the Revolving Advances, in which case those amounts shall thereafter accrue interest at the rate then applicable hereunder. Any interest not paid when due shall be compounded by becoming a part of the Obligations, and such interest shall thereafter accrue interest at the rate then applicable hereunder.

(d) Computation; Interest Rate Adjustment. Interest on each Credit Extension shall accrue from and including the date of such Credit Extension, to but excluding the date of repayment, provided such payment is received by Bank prior to 2:00 p.m. Pacific time on the date of repayment. In the event a Credit Extension is a Variable Rate Advance and the Prime Rate is changed from time to time after the date thereof, the rate of interest on such Variable Rate Advance shall be increased or decreased, effective as of the day the Prime Rate is changed, by an amount equal to such change in the Prime Rate. In the event a Credit Extension is a LIBOR Advance, the rate of interest on such Credit Extension shall be initially fixed on the date of such Credit Extension based on the LIBOR Interest Period selected by Borrower and increased or decreased, as applicable, on the first day of each subsequent LIBOR Interest Period. In the event the Mortgage Advance is a Fixed Rate Advance, the applicable interest rate on the Mortgage Advance shall be initially fixed at the date of funding and shall remain in effect until the end of the first Fixed Rate Interest Period. Thereafter, the interest rate shall be reset in accordance with Section 2.3(a)(iv) effective as of the first day of the second Fixed Rate Interest Period, unless Borrower elects to convert the Mortgage Advance to a Variable Rate Advance pursuant to Section 2.3(e) hereof. All interest chargeable under the Loan Documents shall be computed on the basis of a 360 day year and the actual number of days elapsed

(e) Interest Rate Conversion. Notwithstanding Section 2.3(d), (i) with respect to any Credit Extension other than the Mortgage Advance, Borrower shall have the right at any time to convert such Credit Extension from a Variable Rate Advance to a LIBOR Advance and, on the first day of any LIBOR Interest Period, to convert such Credit Extension from a LIBOR Advance to a Variable Rate Advance or to select a different LIBOR Interest Period with respect to such Credit Extension (to the extent a different LIBOR Interest Period is permitted under Section 2.3(a)), and (ii) with respect to the Mortgage Advance, Borrower shall have the right, effective as of the first day of the second Fixed Rate Interest Period, to convert the Mortgage Advance from a Fixed Rate Advance to a Variable Rate Advance or from a Variable Rate Advance to a Fixed Rate Advance, as the case may be. Any conversion of a Credit Extension or change in the LIBOR Interest Period hereunder shall be at Borrower's option and without penalty or premium. The new interest rate resulting from a converted Credit Extension or a changed LIBOR Interest Period shall be determined in accordance with Section 2.3(a). If Borrower decides to convert a Credit Extension or change a LIBOR Interest Period hereunder, Borrower will notify Bank by facsimile or telephone no later than 3:00 p.m. Pacific time, on the day the conversion or change is to occur which must be a Business Day. Each notice shall specify the date of the conversion or change, the Credit Extension to be converted or changed, and the new interest rate or new LIBOR Interest Period selected by Borrower.

2.4 Crediting Payments. Prior to the occurrence of an Event of Default, Bank shall credit a wire transfer of funds, check or other item of payment from Borrower to such deposit account or Obligation as Borrower specifies. After the occurrence of an Event of Default, the receipt by Bank of any wire transfer of funds, check, or other item of payment shall be immediately applied to conditionally reduce Obligations, but shall not be considered a payment on account unless such payment is of immediately available federal funds or unless and until such check or other item of payment is honored when presented for payment. Notwithstanding anything to the

contrary contained herein, any wire transfer or payment received by Bank after 12:00 noon Pacific Time shall be deemed to have been received by Bank as of the opening of business on the immediately following Business Day. Whenever any payment to Bank under the Loan Documents would otherwise be due (except by reason of acceleration) on a date that is not a Business Day, such payment shall instead be due on the next Business Day, and additional fees or interest, as the case may be, shall accrue and be payable for the period of such extension.

2.5 Fees. Borrower shall pay to Bank the following:

(a) Facility Fee. A Facility Fee of $30,000 in the aggregate, $15,000 of which has been paid to Bank and receipt of which is hereby acknowledged by Bank, and $15,000 of which shall be paid on the Closing Date hereof, all of which shall be earned and nonrefundable;

(b) Bank Expenses. On the Closing Date, all Bank Expenses incurred through the Closing Date, and, after the Closing Date, all subsequently incurred Bank Expenses within fifteen (15) days of Borrower's receipt of an invoice therefor, provided that any such invoice must include a written statement describing in reasonable detail the Bank Expenses set forth therein.

2.6 Term. This Agreement shall become effective on the Closing Date and, subject to Section 12.8 and 12.9(d), shall continue in full force and effect for so long as any Obligations remain outstanding or Bank has any obligation to make Credit Extensions under this Agreement. Notwithstanding the foregoing, Bank shall have the right to terminate its obligation to make Credit Extensions under this Agreement immediately and without notice upon the occurrence and during the continuance of an Event of Default.

3. CONDITIONS OF LOANS.

3.1 Conditions Precedent to Initial Credit Extension. The obligation of Bank to make the initial Credit Extension is subject to the condition precedent that Bank shall have received payment by Borrower of all Bank Expenses then due as specified in Section 2.5, and the following documents in form and substance reasonably satisfactory to Bank (except for the landlord's waivers specified in Section 3.1(o), the provision of which shall not be a condition precedent so long as Borrower uses commercially reasonable efforts to obtain such waivers):

(a) this Agreement duly executed by Borrower;

(b) an officer's certificate of Borrower with respect to incumbency and resolutions authorizing the execution and delivery of this Agreement;

(c) a financing statement(s) (Form UCC-1) regarding Bank's security interest in the Collateral;

(d) a mortgage granting Bank a first lien mortgage on the Property duly executed by Borrower;

(e) a mortgage granting Bank a third lien mortgage on the Property duly executed by Borrower;

(f) a subordination agreement with PIDA;

(g) three (3) separate securities account control agreements duly executed by Borrower;

(h) agreement to provide insurance;

(i) current SOS Reports indicating that except for Permitted Liens, there are no other security interests or Liens of record in the Collateral;

(j) an audit of the Collateral, the results of which shall be satisfactory to Bank;

(k) interim financial statements of Borrower for the quarter ended June 30, 2002;

(l) an appraisal of the Property;

(m) Phase I and Phase II Environmental Studies for the Property;

(n) a flood recertification;

(o) a landlord's waiver for the property leased by Borrower at 150 Webster Street, Bethlehem, Pennsylvania 18015, 8505 SW Creekside Place, Beaverton, Oregon 97008 and 220 East First Street, Bethlehem, Pennsylvania 18015;

(p) a marked-up title commitment insuring Bank's first and third lien mortgages on the Property; and

(q) such other documents or certificates, and completion of such other matters, as Bank may reasonably deem necessary or appropriate.

3.2 Conditions Precedent to all Credit Extensions. The obligation of Bank to make each Credit Extension, including the initial Credit Extension, is further subject to the following conditions:

(a) timely receipt by Bank of a Payment/Advance Form for such Credit Extension, to the extent required under Section 2.1; and

(b) the representations and warranties contained in Section 5 shall be true and correct in all material respects on and as of the date of such Payment/Advance Form and on the effective date of each Credit Extension as though made at and as of each such date, and no Event of Default shall have occurred and be continuing, or would exist after giving effect to such Credit Extension (provided, however, that those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date). The making of each Credit Extension shall be deemed to be a representation and warranty by Borrower on the date of such Credit Extension as to the accuracy of the facts referred to in this Section 3.2(b).

4. CREATION OF SECURITY INTEREST.

4.1 Grant of Security Interest. Borrower grants and pledges to Bank a continuing security interest in the Collateral to secure prompt repayment of any and all Obligations and to secure prompt performance by Borrower of each of its covenants and duties under the Loan Documents. Except as set forth in the Schedule, such security interest, when perfected by filing in accordance with applicable law, will constitute a valid, first priority security interest in the Collateral. Notwithstanding any termination, Bank's Lien on the Collateral shall remain in effect for so long as any Obligations are outstanding.

4.2 Perfection of Security Interest. Borrower authorizes Bank to file at any time financing statements, continuation statements, and amendments thereto that describe the Collateral and which contain any other information required by the Code for the sufficiency of filing office acceptance of any financing statement, continuation statement, or amendment, including whether Borrower is an organization, the type of organization and any organizational identification number issued to Borrower, if applicable. Any such financing statements may be signed by Bank on behalf of Borrower, as provided in the Code, and may be filed at any time in any jurisdiction whether or not Revised Article 9 of the Code is then in effect in that jurisdiction. Bank shall provide Borrower with a copy of all filings made hereunder. Borrower shall from time to time execute and deliver to Bank, at the request of Bank, all other documents that Bank may reasonably request, in form satisfactory to Bank, to perfect and continue perfected Bank's security interests in the Collateral and in order to fully consummate all of the transactions contemplated under the Loan Documents. Borrower shall have possession of the Collateral, except where expressly otherwise provided in this Agreement. Where Collateral is in possession of a third party bailee, Borrower shall take such steps as Bank reasonably requests for Bank to (i) obtain an acknowledgment, in form and substance satisfactory to Bank, of the bailee that the bailee holds such Collateral for the benefit of Bank, (ii) obtain "control"

of any Collateral consisting of investment property, deposit accounts, letter-of-credit rights or electronic chattel paper (as such items and the term "control" are defined in Revised Article 9 of the Code), with any agreements establishing control to be in form and substance satisfactory to Bank. Borrower will not create any chattel paper without placing a legend on the chattel paper acceptable to Bank indicating that Bank has a security interest in the chattel paper.

4.3 Right to Inspect. Bank (through any of its officers, employees, or agents) shall have the right, upon not less than five (5) days prior notice, from time to time during Borrower's usual business hours but no more than once a year (unless an Event of Default has occurred and is continuing), and at Borrower's expense, to inspect Borrower's Books and to make copies thereof and to check, test, and appraise the Collateral in order to verify Borrower's financial condition or the amount, condition of, or any other matter relating to, the Collateral, in accordance with this Agreement.

5. REPRESENTATIONS AND WARRANTIES.

Borrower represents and warrants as follows:

5.1 Due Organization and Qualification. Borrower and each Subsidiary is a corporation duly existing under the laws of the state of its organization, and is qualified and licensed to do business in any state in which the conduct of its business or its ownership of property requires that it be so qualified, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect.

5.2 Due Authorization; No Conflict. The execution, delivery, and performance of the Loan Documents are within Borrower's corporate powers, have been duly authorized by Borrower, and are not in conflict with nor constitute a breach of any provision contained in Borrower's Certificate of Incorporation or Bylaws, nor will they constitute an event of default under any material agreement by which Borrower is bound. Borrower is not in default under any agreement by which it is bound, except to the extent such default would not reasonably be expected to cause a Material Adverse Effect.

5.3 Collateral. Borrower's title to the Collateral is free and clear of Liens, except for Permitted Liens. Except as set forth in the Schedule or as permitted under Sections 7.7 or 7.10, all Collateral is located solely in the Collateral States. The Eligible Accounts are bona fide existing obligations. The property or services giving rise to such Eligible Accounts has been delivered or rendered to the account debtor or its agent for immediate shipment to and unconditional acceptance by the account debtor. Borrower has not received notice of actual or imminent Insolvency Proceeding of any account debtor whose accounts are included in any Borrowing Base Certificate as an Eligible Account. All Inventory is in all material respects of good and merchantable quality, free from all material defects, except for Inventory for which adequate reserves have been made. Except as set forth in the Schedule or as permitted under Section 7.7, none of Borrower's Investments is maintained or invested with a Person other than Bank or Bank's Affiliates.

5.4 Intellectual Property. Borrower is the sole owner of the Intellectual Property, except for (i) Intellectual Property where Borrower has granted a license to its customers, research partners or other Persons for the distribution or development of products or otherwise in the ordinary course of business, (ii) Intellectual Property in which Borrower has received a license or other rights from another Person or (iii) as otherwise disclosed in the Schedule. To the best of Borrower's knowledge, each of the Copyrights, Trademarks and Patents is valid and enforceable, and no part of the Intellectual Property has been judged invalid or unenforceable, in whole or in part, and no claim has been made to Borrower that any part of the Intellectual Property violates the rights of any third party except to the extent such claim would not reasonably be expected to cause a Material Adverse Effect.

5.5 Name; Location of Chief Executive Office. Except as disclosed in the Schedule, during the past five (5) years Borrower has not done business under any name other than that specified on the signature page hereof, and its exact legal name is as set forth in the first paragraph of this Agreement. The chief executive office of Borrower is located in the Chief Executive Office State at the address indicated in Section 10 hereof.

5.6 Litigation. Except as set forth in the Schedule, there are no actions or proceedings pending by or against Borrower or any Subsidiary before any court or administrative agency in which an adverse decision is likely and would reasonably be expected to have a Material Adverse Effect, or a material adverse effect on Borrower's interest or Bank's security interest in the Collateral.

5.7 No Material Adverse Change in Financial Statements. All consolidated financial statements related to Borrower and its Subsidiaries, taken as a whole, that are delivered by Borrower to Bank fairly present in all material respects Borrower's consolidated financial condition as of the date thereof and Borrower's consolidated results of operations for the period covered by such statements. There has not been a material adverse change in the consolidated financial condition of Borrower since the date of the most recent of such financial statements submitted to Bank.

5.8 Payment of Debts; Solvency. Borrower is able to pay its debts (including trade debts) as they mature; and Borrower is Solvent.

5.9 Compliance with Laws and Regulations. Borrower and each Subsidiary have met the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA. No event has occurred resulting from Borrower's failure to comply with ERISA that is reasonably likely to result in Borrower's incurring any liability that could have a Material Adverse Effect. Borrower is not an "investment company" or a company "controlled" by an "investment company" within the meaning of the Investment Company Act of 1940. Borrower is not engaged principally, or as one of its primary activities, in the business of extending credit for the purpose of purchasing or carrying margin stock (within the meaning of Regulations T and U of the Board of Governors of the Federal Reserve System). Borrower has not violated any statutes, laws, ordinances or rules applicable to it, including, without limitation, the Federal Fair Labor Standards Act, all Environmental Laws, all federal and state securities laws and regulations, the rules of the NASDAQ Stock Market and all rules and regulations promulgated by the FDA, except for violations which are not reasonably likely to have a Material Adverse Effect. Borrower and each Subsidiary have filed or caused to be filed all tax returns required to be filed, and have paid, or have made adequate provision for the payment of, all taxes reflected therein except those being contested in good faith with adequate reserves under GAAP or where the failure to file such returns or pay such taxes would not reasonably be expected to have a Material Adverse Effect.

5.10 Subsidiaries. Borrower does not own any stock, partnership interest or other equity securities of any Person, except for Permitted Investments and except as permitted under Sections 7.3 or 7.7.

5.11 Government Consents. Borrower and each Subsidiary have obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary for the continued operation of Borrower's business as currently conducted, except where the failure to do so would not reasonably be expected to cause a Material Adverse Effect. Notwithstanding the foregoing, Bank acknowledges that Borrower has not obtained FDA approval or clearance for the OraQuick(R) rapid HIV antibody test, the Uplink(TM) drugs of abuse rapid detection system or other products of Borrower which have not been developed and commercialized, and the failure to do so shall not constitute a breach of this Section 5.11.

5.12 Inbound Licenses. Intentionally omitted.

5.13 Full Disclosure. No representation, warranty or other statement made by Borrower in any certificate or other written statement furnished to Bank taken together with all such certificates and written statements furnished to Bank contains any untrue statement of a material fact or omits to state a material fact necessary in order to make the statements contained in such certificates or statements not misleading, it being recognized by Bank that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not to be viewed as facts and that actual results during the period or periods covered by any such projections and forecasts may differ from the projected or forecasted results.

6. AFFIRMATIVE COVENANTS.

Borrower covenants that, until payment in full of all outstanding Obligations, and for so long as Bank may have any commitment to make a Credit Extension hereunder, Borrower shall do all of the following:

6.1 Good Standing and Government Compliance. Borrower shall maintain its and each of its Subsidiaries' corporate existence and good standing in their respective states of organization, shall maintain its qualification and good standing in each jurisdiction in which the failure to so qualify would reasonably be expected to have a Material Adverse Effect, and shall furnish to Bank the organizational identification number issued to Borrower by the authorities of the state in which Borrower is organized, if applicable. Borrower shall meet, and shall cause each Subsidiary to meet, the minimum funding requirements of ERISA with respect to any employee benefit plans subject to ERISA, except where the failure to meet such requirements would not reasonably be expected to have a Material Adverse Effect. Borrower shall comply, and shall cause each Subsidiary to comply, in all material respects, with all statutes, laws, ordinances and government rules and regulations to which it is subject, including all applicable Environmental Laws, and shall maintain, and shall cause each of its Subsidiaries to maintain, in force all material licenses, permits and approvals, the loss of which or failure to comply with which would reasonably be expected to have a Material Adverse Effect, or a material adverse effect on the Collateral or the priority of Bank's Lien on the Collateral.

6.2 Financial Statements, Reports, Certificates. Borrower shall deliver to Bank:

(a) as soon as available, but in any event within twenty (20) days after the end of each calendar month, a company prepared monthly and year to date consolidated balance sheet and income statement covering Borrower's consolidated operations during such period, in a form reasonably acceptable to Bank and certified by a Responsible Officer (with a comparison to budget);

(b) as soon as available, but in any event within thirty (30) days prior to each fiscal year end, internally prepared quarterly and annual financial projections (for at least 2 forward-looking years);

(c) copies of all statements, reports and notices sent or made available generally by Borrower to its security holders or to any holders of Subordinated Debt, all reports on Forms 10-K and 10-Q filed with the Securities and Exchange Commission ("SEC") within five (5) days after filing and all other documents filed with the SEC within five (5) days after filing;

(d) promptly upon receipt of notice thereof, a report of any legal action pending or threatened (to the extent known to Borrower) against Borrower or any Subsidiary that is reasonably likely to result in damages or costs to Borrower or any Subsidiary of $500,000 or more;

(e) such budgets, sales projections, operating plans or other financial information generally prepared by Borrower in the ordinary course of business as Bank may reasonably request from time to time;

(f) within twenty (20) days after the end of each calendar month Borrower shall deliver to Bank a Borrowing Base Certificate dated as of the end of the immediately preceding month, signed by a Responsible Officer in substantially the form of Exhibit D hereto, together with aged listings of accounts receivable and accounts payable;

(g) at the time Borrower delivers its reports on Form 10-K and 10-Q under Section 6.2(c), Borrower shall also deliver to Bank a Compliance Certificate signed by a Responsible Officer in substantially the form of Exhibit E hereto; and

(h) as soon as possible and in any event within three (3) Business Days after becoming aware of the occurrence or existence of an Event of Default hereunder, a written statement of a Responsible Officer setting forth details of the Event of Default, and the action which Borrower has taken or proposes to take with respect thereto.

6.3 Inventory; Returns. Borrower shall keep all Inventory in good and merchantable condition, free from all material defects except for Inventory for which adequate reserves (in accordance with GAAP) have been made. Returns and allowances, if any, as between Borrower and its account debtors shall be on the same basis and in accordance with the usual customary practices of Borrower, as they exist on the Closing Date. Borrower shall promptly notify Bank of each return, recovery, dispute or claim involving more than $150,000 of Inventory.

6.4 Taxes. Borrower shall make, and cause each Subsidiary to make, due and timely payment or deposit of all material federal, state, and local taxes, assessments, or contributions required of it by law, including, but not limited to, those laws concerning income taxes, F.I.C.A., F.U.T.A. and state disability, and will execute and deliver to Bank, on demand, proof satisfactory to Bank indicating that Borrower or a Subsidiary has made such payments or deposits and any appropriate certificates attesting to the payment or deposit thereof; provided that Borrower or a Subsidiary need not make any payment if the amount or validity of such payment is contested in good faith by appropriate proceedings and is reserved against (to the extent required by GAAP) by Borrower.

6.5 Insurance.

(a) Borrower, at its expense, shall keep the Collateral insured against loss or damage by fire, theft, explosion, sprinklers, and all other hazards and risks, and in such amounts, as ordinarily insured against by other owners in similar businesses conducted in the locations where Borrower's business is conducted on the date hereof. Borrower shall also maintain liability and other insurance in amounts and of a type that are customary to businesses similar to Borrower's.

(b) All such policies of insurance shall be in such form, with such companies, and in such amounts as reasonably satisfactory to Bank. All policies of property insurance shall contain a lender's loss payable endorsement, in a form reasonably satisfactory to Bank, showing Bank as an additional loss payee, and all liability insurance policies shall show Bank as an additional insured and specify that the insurer must give at least thirty (30) days notice to Bank before canceling its policy for any reason. Upon Bank's request, Borrower shall deliver to Bank certified copies of the policies of insurance and evidence of all premium payments. If no Event of Default has occurred and is continuing, proceeds payable under any casualty policy will, at Borrower's option, be payable to Borrower to replace the property subject to the claim, provided that any such replacement property shall be deemed Collateral in which Bank has been granted a first priority security interest. If an Event of Default has occurred and is continuing, all proceeds payable under any such policy shall, at Bank's option, be payable to Bank to be applied on account of the Obligations.

6.6 Primary Depository. Borrower shall open and maintain its primary depository, operating and investment accounts with Bank or Bank's Affiliates on the date hereof and shall terminate the use of all currently existing primary depository and/or operating accounts at other financial institutions as primary accounts as soon as practicable (but in no event more than ninety (90) days) following the date hereof.

6.7 Financial Covenants. Borrower shall maintain the following financial ratios and covenants, reported as of the last day of each calendar quarter, except for the covenants set forth in Section 6.7(b) which shall be maintained at all times and reported monthly and Section 6.7(d) which shall be reported as of December 31, 2003 and as of the end of each fiscal year thereafter:

(a) Quick Ratio. A ratio of Quick Assets to Current Liabilities of at least 2.00 to 1.00.

(b) Minimum Liquidity. A balance of cash, cash equivalents and short-term investments plus Excess Collateral Availability under the Revolving Facility, of not less than $7,500,000, which amount shall include at least $4,000,000 in cash, cash equivalents and short-term investments.

(c) Tangible Net Worth. A Tangible Net Worth of not less than $19,000,000.

(d) Minimum Profitability. Borrower will achieve positive consolidated net income (determined in accordance with GAAP) for the twelve (12) month fiscal period ending December 31, 2003, and for each fiscal year thereafter.

6.8 Registration of Intellectual Property Rights.

(a) Borrower shall register or cause to be registered consistent with its past practices (to the extent not already registered) with the United States Patent and Trademark Office or the United States Copyright Office, as applicable: (i) all registrable intellectual property rights Borrower has developed as of the date of this Agreement but heretofore failed to register, and (ii) those additional registrable intellectual property rights developed or acquired by Borrower from time to time in connection with any product or service, promptly following development or acquisition or initial provision of the related service, except in each case where the failure to register is not reasonably likely to have a Material Adverse Effect.

(b) Borrower shall use commercially reasonable efforts, consistent with its past practices, to (i) protect, defend and maintain the validity and enforceability of the Trademarks, Patents and Copyrights, (ii) detect infringements of the Trademarks, Patents and Copyrights and promptly advise Bank in writing of infringements detected that are reasonably likely to have a Material Adverse Effect and (iii) not allow any Trademarks, Patents or Copyrights to be abandoned, forfeited or dedicated to the public where such abandonment, forfeiture or dedication is reasonably likely to have a Material Adverse Effect.

6.9 Consent of Inbound Licensors. Intentionally omitted.

6.10 Further Assurances. At any time and from time to time Borrower shall execute and deliver such further instruments and take such further action as may reasonably be requested by Bank to effect the purposes of this Agreement.

7. NEGATIVE COVENANTS.

Borrower covenants and agrees that, so long as any credit hereunder shall be available and until payment in full of the outstanding Obligations or for so long as Bank may have any commitment to make any Credit Extensions hereunder, Borrower will not do any of the following without Bank's prior written consent, which shall not be unreasonably withheld or delayed:

7.1 Dispositions. Convey, sell, lease, license, transfer or otherwise dispose of (collectively, to "Transfer"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, other than Permitted Transfers; provided that this Section 7.1 shall not preclude Borrower or any of its Subsidiaries from expending funds in the ordinary course of business.

7.2 Change in Corporate Name, Location or Executive Office; Change in Business; Change in Fiscal Year; Change in Control. Change its corporate name, fiscal year end, the Borrower State, or the Chief Executive Office State without at least thirty (30) days prior written notification to Bank; or engage in any business, or permit any of its Subsidiaries to engage in any business, other than businesses reasonably related or incidental to the businesses engaged in by Borrower on the Closing Date; or have a Change in Control.

7.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with or into any other business organization (other than mergers or consolidations of a Subsidiary into another Subsidiary or into Borrower), except where (i) the surviving entity in such merger or consolidation is Borrower or any such Subsidiary, and (ii) no Event of Default has occurred, is continuing or would exist after giving effect to the transaction.

7.4 Indebtedness. Create, incur, assume, guarantee or become liable with respect to any Indebtedness, or permit any Subsidiary so to do, other than Permitted Indebtedness, or prepay any Indebtedness or take any actions which impose on Borrower an obligation to prepay any Indebtedness, except Indebtedness to Bank or its Affiliates or as permitted under Section 7.9.

7.5 Encumbrances. Create, incur, assume or allow any Lien with respect to any of its property, including, without limitation, its Intellectual Property, or assign or otherwise convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries so to do, except for Liens, assignments or conveyances to Bank or its Affiliates and except for Permitted Liens, or covenant to any other Person that Borrower in the future will refrain from creating, incurring, assuming or allowing any Lien with respect to any of Borrower's property, including, without limitation, its Intellectual Property.

7.6 Distributions. Pay any dividends or make any other distribution or payment on account of or in redemption, retirement or purchase of any capital stock, except that Borrower may (i) repurchase the stock of former employees pursuant to stock repurchase agreements as long as an Event of Default does not exist prior to such repurchase or would not exist after giving effect to such repurchase, and (ii) repurchase the stock of former employees pursuant to stock repurchase agreements by the cancellation of indebtedness owed by such former employees to Borrower regardless of whether an Event of Default exists.

7.7 Investments. Directly or indirectly acquire or own, or make any Investment in or to any Person, or permit any of its Subsidiaries so to do, other than Permitted Investments and Permitted Indebtedness or as permitted under Section 7.3, or maintain or place any of its Investments with a Person other than Bank or Bank's Affiliates, except as disclosed on the Schedule, unless such Person has entered into a control agreement with Bank, in form and substance satisfactory to Bank, or suffer or permit any Subsidiary to be a party to, or be bound by, an agreement that restricts such Subsidiary from paying dividends or otherwise distributing property to Borrower.

7.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower except for transactions that are (i) disclosed in the Schedule or (ii) are in the ordinary course of Borrower's business and are upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's length transaction with a non-affiliated Person. Nothing in this Agreement shall preclude Borrower from paying fees, salaries and bonuses, or granting equity compensation pursuant to stock options or stock purchase plans, to its directors, officers and employees, or reimbursing or paying advances to its directors, officers or employees for relocation or business-related expenditures, in each case in accordance with its usual and customary practices or as approved by Borrower's Board of Directors or a committee thereof.

7.9 Subordinated Debt. Make any payment in respect of any Subordinated Debt, or permit any of its Subsidiaries to make any such payment, except in compliance with the terms of such Subordinated Debt, or amend any provision affecting Bank's rights contained in any documentation relating to the Subordinated Debt without Bank's prior written consent.

7.10 Inventory and Equipment. Except as disclosed in the Schedule, store the Inventory or the Equipment with a bailee, warehouseman, or similar third party unless the third party has been notified of Bank's security interest and Bank (a) has received an acknowledgment from the third party that it is holding or will hold the Inventory or Equipment for Bank's benefit or (b) is in possession of the warehouse receipt, where negotiable, covering such Inventory or Equipment. Except for (i) Inventory or Equipment sold in the ordinary course of business, (ii) Equipment transferred for use by a customer pursuant to a reagent rental agreement or similar arrangement in the ordinary course of business, or (iii) Inventory or Equipment at such other locations as Bank may approve in writing, Borrower shall keep the Inventory and Equipment only at the locations set forth in the Schedule and such other locations which Borrower gives Bank prior written notice.

7.11 No Investment Company. Become or be controlled by an "investment company," within the meaning of the Investment Company Act of 1940, or become principally engaged in, or undertake as one of its primary activities, the business of extending credit for the purpose of purchasing or carrying margin stock, or use the proceeds of any Credit Extension for such purpose.

7.12 Merrill Lynch Investment Account. Acquire with assets from Merrill Lynch, Pierce, Fenner & Smith Incorporated ("Merrill Lynch") Account No. 83807G24 any shares of Merrill Lynch Ready Assets Trust, U.S. Government or U.S. Treasury money market funds, shares of any Merrill Lynch Institutional Funds, non-listed partnership interests, annuities, life insurance contracts or precious metals.

8. EVENTS OF DEFAULT.

Any one or more of the following events shall constitute an Event of Default by Borrower under this Agreement:

8.1 Payment Default.

(a) If Borrower fails to pay any principal of or interest on any Credit Extension when due; or

(b) If Borrower fails to pay any other Obligation (other than principal of or interest on any Credit Extension) when due and such failure continues for at least fifteen (15) days after receipt of written notice thereof by Bank.

8.2 Covenant Default.

(a) If Borrower fails to perform any obligation under Article 6 (other than any obligation under Sections 6.2(a), (b), (c), (f), (g) or (h), 6.6 or 6.7 as to which the cure period shall be fifteen (15) days) or violates any of the covenants contained in Article 7 of this Agreement and such failure or violation shall continue for a period of at least thirty (30) days after written notice thereof by Bank; or

(b) If Borrower fails or neglects to perform or observe any other material term, provision, condition, or covenant contained in this Agreement, or in any other Loan Document, and as to any default under such other term, provision, condition or covenant that can be cured, has failed to cure such default within thirty (30) days after Borrower receives written notice thereof by Bank; provided, however, that if the default cannot by its nature be cured within the thirty (30) day period or cannot after diligent attempts by Borrower be cured within such thirty (30) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional reasonable period (which shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to have cured such default shall not be deemed an Event of Default but no Credit Extensions will be made;

8.3 Defective Perfection. If Bank shall receive at any time following the Closing Date an SOS Report indicating that except for Permitted Liens, Bank's security interest in the Collateral is not prior to all other security interests or Liens of record reflected in the report and Borrower has not restored the priority of Bank's security interest in the Collateral within thirty (30) days after written notice thereof by Bank;

8.4 Material Adverse Change. If there occurs a material adverse change in Borrower's business or financial condition, or if there is a material impairment of the prospect of repayment of any portion of any Credit Extension or a material impairment of the value or priority of Bank's security interests in the Collateral; and Borrower has not corrected such material adverse change or impairment within fifteen (15) days after receipt of written notice thereof by Bank;

8.5 Attachment. If all or a substantial portion of Borrower's assets is attached, seized, subjected to a writ or distress warrant, or is levied upon, or comes into the possession of any trustee, receiver or person acting in a similar capacity and such attachment, seizure, writ or distress warrant or levy has not been removed, discharged or rescinded within thirty (30) days, or if Borrower is enjoined, restrained, or in any way prevented by court order from continuing to conduct all or substantially all of its business affairs, provided that none of the foregoing shall constitute an Event of Default where such action or event is stayed or an adequate bond has been posted pending a good faith contest by Borrower (provided that no Credit Extensions will be required to be made during such cure period);

8.6 Insolvency. If Borrower becomes insolvent, or if an Insolvency Proceeding is commenced by Borrower, or if an Insolvency Proceeding is commenced against Borrower and is not dismissed or stayed within sixty (60) days (provided that no Credit Extensions will be made prior to the dismissal of such Insolvency Proceeding);

8.7 Other Agreements. If there is a default or other failure to perform in any agreement to which Borrower is a party with a third party or parties resulting in the acceleration of any Indebtedness prior to its maturity in an amount in excess of $500,000 or that is reasonably likely to have a Material Adverse Effect;

8.8 Subordinated Debt. If Borrower makes any payment on account of Subordinated Debt, except to the extent the payment is allowed under the terms of such Subordinated Debt or under any subordination agreement entered into with Bank;

8.9 Judgments. If a judgment or judgments for the payment of money in an amount, individually or in the aggregate, of at least $500,000 shall be rendered against Borrower and shall remain unsatisfied, unstayed, unreleased or undismissed for a period of thirty (30) days (provided that no Credit Extensions will be made prior to the satisfaction or stay of the judgment); or

8.10 Misrepresentations. If any warranty or representation set forth herein or in any certificate delivered to Bank by any Responsible Officer pursuant to this Agreement is false or incorrect in any material respect.

9. BANK'S RIGHTS AND REMEDIES.

9.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, at its election, without notice of its election and without demand, do any one or more of the following, all of which are authorized by Borrower:

(a) Declare all Obligations, whether evidenced by this Agreement, by any of the other Loan Documents, or otherwise, immediately due and payable (provided that upon the occurrence of an Event of Default described in Section 8.6, all Obligations shall become immediately due and payable without any action by Bank);

(b) Cease advancing money or extending credit to or for the benefit of Borrower under this Agreement or under any other agreement between Borrower and Bank;

(c) Settle or adjust disputes and claims directly with account debtors for amounts, upon terms and in whatever order that Bank reasonably considers advisable;

(d) Make such payments and do such acts as Bank considers necessary or reasonable to protect its security interest in the Collateral. Borrower agrees to assemble the Collateral if Bank so requires, and to make the Collateral available to Bank as Bank may designate. Borrower authorizes Bank to enter the premises where the Collateral is located, to take and maintain possession of the Collateral, or any part of it, and to pay, purchase, contest, or compromise any encumbrance, charge, or lien which in Bank's determination appears to be prior or superior to its security interest and to pay all expenses incurred in connection therewith. With respect to any of Borrower's owned premises, Borrower hereby grants Bank a license to enter into possession of such premises and to occupy the same, without charge, in order to exercise any of Bank's rights or remedies provided herein, at law, in equity, or otherwise;

(e) Set off and apply to the Obligations any and all (i) balances and deposits of Borrower held by Bank, or (ii) indebtedness at any time owing to or for the credit or the account of Borrower held by Bank;

(f) Ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell (in the manner provided for herein) the Collateral. Bank is hereby granted a license or other right, solely pursuant to the provisions of this Section 9.1, to use, without charge, Borrower's labels, patents, copyrights, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any property of a similar nature, as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Bank's exercise of its rights under this Section 9.1, Borrower's rights under all licenses and all franchise agreements shall inure to Bank's benefit;

(g) Sell the Collateral at either a public or private sale, or both, by way of one or more contracts or transactions, for cash or on terms, in such manner and at such places (including Borrower's premises) as Bank determines is commercially reasonable, and apply any proceeds to the Obligations in whatever manner or order Bank deems appropriate. Bank may sell the Collateral without giving any warranties as to the Collateral. Bank may specifically disclaim any warranties of title or the like. This procedure will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral. If Bank sells any of the Collateral upon credit, Borrower will be credited only with payments actually made by the purchaser, received by Bank, and applied to the indebtedness of the purchaser. If the purchaser fails to pay for the Collateral, Bank may resell the Collateral and Borrower shall be credited with the proceeds of the sale;

(h) Credit bid and purchase at any public sale; and

(i) Apply for the appointment of a receiver, trustee, liquidator or conservator of the Collateral, without notice and without regard to the adequacy of the security for the Obligations and without regard to the solvency of Borrower, any guarantor or any other Person liable for any of the Obligations.

Any deficiency that exists after disposition of the Collateral as provided above will be paid immediately by Borrower. Bank may comply with any applicable state or federal law requirements in connection with a disposition of the Collateral and compliance will not be considered adversely to affect the commercial reasonableness of any sale of the Collateral.

9.2 Power of Attorney. Effective only upon the occurrence and during the continuance of an Event of Default, Borrower hereby irrevocably appoints Bank (and any of Bank's designated officers, or employees) as Borrower's true and lawful attorney to: (a) send requests for verification of Accounts or notify account debtors of Bank's security interest in the Accounts; (b) endorse Borrower's name on any checks or other forms of payment or security that may come into Bank's possession; (c) sign Borrower's name on any invoice or bill of lading relating to any Account, drafts against account debtors, schedules and assignments of Accounts, verifications of Accounts, and notices to account debtors; (d) dispose of any Collateral; (e) make, settle, and adjust all claims under and decisions with respect to Borrower's policies of insurance; (f) settle and adjust disputes and claims respecting the Accounts directly with account debtors, for amounts and upon terms which Bank determines to be reasonable; and (g) file, in its sole discretion, one or more financing or continuation statements and amendments thereto, relative to any of the Collateral without the signature of Borrower where permitted by law; provided Bank may exercise such power of attorney to sign the name of Borrower on any of the documents described in clause (g) above regardless of whether an Event of Default has occurred. The appointment of Bank as Borrower's attorney in fact, and each and every one of Bank's rights and powers, being coupled with an interest, is irrevocable until all of the Obligations have been fully repaid and performed and Bank's obligation to provide Credit Extensions hereunder is terminated.

9.3 Accounts Collection. At any time after the occurrence and during the continuation of an Event of Default, (a) Bank may notify any Person owing funds to Borrower of Bank's security interest in such funds and verify the amount of such Account, and (b) Borrower shall collect all amounts owing to Borrower for Bank, receive in trust all payments as Bank's trustee, and immediately deliver such payments to Bank in their original form as received from the account debtor, with proper endorsements for deposit.

9.4 Bank Expenses. At any time after the occurrence and during the continuance of an Event of Default, if Borrower fails to pay any amounts or furnish any required proof of payment due to third persons or entities, as required under the terms of this Agreement, then Bank may do any or all of the following after reasonable notice to Borrower: (a) make payment of the same or any part thereof; (b) set up such reserves under the Revolving Facility as Bank deems necessary to protect Bank from the exposure created by such failure; or (c) obtain and maintain insurance policies of the type discussed in Section 6.5 of this Agreement, and take any action with respect to such policies as Bank deems prudent. Any amounts so paid or deposited by Bank shall constitute Bank Expenses, shall be immediately due and payable, and shall bear interest at the then applicable rate hereinabove provided, and shall be secured by the Collateral. Any payments made by Bank shall not constitute an agreement by Bank to make similar payments in the future or a waiver by Bank of any Event of Default under this Agreement.

9.5 Bank's Liability for Collateral. Bank has no obligation to clean up or otherwise prepare the Collateral for sale. All risk of loss, damage or destruction of the Collateral shall be borne by Borrower.

9.6 No Obligation to Pursue Others. Bank has no obligation to attempt to satisfy the Obligations by collecting them from any other Person liable for them and Bank may release, modify or waive any collateral provided by any other Person to secure any of the Obligations, all without affecting Bank's rights against Borrower. Borrower waives any right it may have to require Bank to pursue any other Person for any of the Obligations.

9.7 Remedies Cumulative. Bank's rights and remedies under this Agreement and all other Loan Documents shall be cumulative. Bank shall have all other rights and remedies not inconsistent herewith as provided under the Code, by law, or in equity. No exercise by Bank of one right or remedy shall be deemed an election, and no waiver by Bank of any Event of Default on Borrower's part shall be deemed a continuing waiver. No delay by Bank shall constitute a waiver, election, or acquiescence by it. No waiver by Bank shall be effective unless made in a written document signed on behalf of Bank and then shall be effective only in the specific instance and for the specific purpose for which it was given. Borrower expressly agrees that this Section 9.7 may not be waived or modified by Bank by course of performance, conduct, estoppel or otherwise.

9.8 Demand; Protest. Borrower waives demand, protest, notice of protest, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees at any time held by Bank on which Borrower may in any way be liable.

10. NOTICES.

Unless otherwise provided in this Agreement, all notices or demands by any party relating to this Agreement or any other agreement entered into in connection herewith shall be in writing and (except for financial statements and other informational documents which may be sent by first-class mail, postage prepaid) shall be personally delivered or sent by a recognized overnight delivery service, certified mail, postage prepaid, return receipt requested, or by telefacsimile to Borrower or to Bank, as the case may be, at its addresses set forth below:

If to Borrower:	OraSure Technologies, Inc. 150 Webster Street Bethlehem, Pennsylvania 18015-1338 Attn: Ronald H. Spair Chief Financial Officer FAX: (610) 814-2937
With a copy to:	OraSure Technologies, Inc. 150 Webster Street Bethlehem, PA 18015-1338 Attn: Jack E. Jerrett, Esq. General Counsel FAX: (610) 814-2937
If to Bank:	Comerica Bank-California 9920 S. La Cienega Blvd., 14/th/ Floor Inglewood, California 90301 Attn: Manager FAX: (310) 338-6110
with a copy to:	Comerica Bank-California Technology & Life Sciences Division 2701 Renaissance Boulevard, Suite 150 King of Prussia, Pennsylvania 19406 Attn: Michael T. Wilk FAX: (610) 239-7911

The parties hereto may change the address at which they are to receive notices hereunder, by notice in writing in the foregoing manner given to the other.

11. CHOICE OF LAW AND VENUE; JURY TRIAL WAIVER. This Agreement shall be governed by, and construed in accordance with, the internal laws of the Commonwealth of Pennsylvania, without regard to principles of conflicts of law. Each of Borrower and Bank hereby submits to the non-exclusive jurisdiction of the state and Federal courts located in the City of Philadelphia, Commonwealth of Pennsylvania. BANK AND BORROWER EACH ACKNOWLEDGE THAT THE RIGHT TO TRIAL BY JURY IS A CONSTITUTIONAL ONE, BUT THAT IT MAY BE WAIVED. EACH OF THEM, AFTER CONSULTING OR HAVING HAD THE OPPORTUNITY TO CONSULT, WITH COUNSEL OF THEIR CHOICE, KNOWINGLY, VOLUNTARILY AND INTENTIONALLY WAIVES ANY RIGHT ANY OF THEM MAY HAVE TO A TRIAL BY JURY IN ANY LITIGATION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY RELATED INSTRUMENT OR LOAN DOCUMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED BY THIS AGREEMENT OR ANY COURSE OF CONDUCT, DEALING, STATEMENTS (WHETHER ORAL OR WRITTEN), OR ACTION OF ANY OF THEM. THESE PROVISIONS SHALL NOT BE DEEMED TO HAVE BEEN MODIFIED IN ANY RESPECT OR RELINQUISHED BY BANK OR BORROWER, EXCEPT BY A WRITTEN INSTRUMENT EXECUTED BY EACH OF THEM.

12. GENERAL PROVISIONS.

12.1 Successors and Assigns. This Agreement shall bind and inure to the benefit of the respective successors and permitted assigns of each of the parties and shall bind all Persons who become bound as a debtor under this Agreement; provided, however, that neither this Agreement nor any rights hereunder may be assigned by Borrower without Bank's prior written consent, which consent shall not be unreasonably withheld or delayed. Bank shall have the right without the consent of, but with written notice to, Borrower to sell, transfer, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights and benefits hereunder.

12.2 Increased Costs; Increased Capital.

(a) If, due to either (i) the introduction after the date hereof of, or any change after the date hereof in or in the interpretation of, any law or regulation or (ii) the compliance with any guideline or request received from any central bank or other governmental authority after the date hereof (whether or not having the force of law), there shall be any increase in the cost to Bank of agreeing to make or making, funding or maintaining Credit Extensions (other than as a result of an increased capital requirement), then Borrower shall from time to time, upon demand by Bank, pay to Bank additional amounts sufficient to compensate Bank for such increased cost. Increased costs shall not include income, stamp or other taxes, imposts, duties, charges, fees, deductions or withholdings imposed, levied, collected, withheld or assessed by the United States of America or any political subdivision or taxing authority thereof or therein (including Puerto Rico). Bank agrees that, upon the occurrence of any event giving rise to a demand under this Section 12.2(a), it will, to the extent permitted by law or the relevant governmental authority, endeavor in good faith and consistent with its internal policies to avoid or minimize the increase in costs resulting from such event. A certificate as to the amount of and specifying in reasonable detail the basis for such increased cost, submitted to Borrower by Bank, shall constitute such demand.

(b) If either (i) the introduction after the date hereof of, or any change after the date hereof in or in the interpretation of, any law or regulation or (ii) the compliance by Bank with any guideline or request received from any central bank or other governmental authority after the date hereof (whether or not having the force of law), affects or would affect the amount of capital required or expected to be maintained by Bank and Bank determines that the amount of such capital is increased by or based upon the existence of the Credit Extensions or its commitment hereunder, then Borrower shall, from time to time, upon demand by Bank, pay to Bank additional amounts sufficient to compensate Bank for increased costs associated with such capital requirement to the extent that Bank determines such capital requirement to be allocable to the existence of the Credit Extensions or Bank's commitment hereunder. A certificate as to the amount of such increased cost and capital requirement and specifying in reasonable detail the basis therefor, submitted to Borrower, shall constitute such demand. Bank shall use all reasonable efforts to mitigate the effect upon Borrower of any such increased capital requirement and shall assess any cost related to such increased capital on a nondiscriminatory basis among Borrower and other borrowers of

Bank to which it applies, and Bank shall not be entitled to demand or be compensated for any increased capital requirement unless it is, as a result of such law, regulation, guideline or request, Bank's policy generally to seek to exercise such rights, where available, against other borrowers of Bank.

(c) Notwithstanding the foregoing provisions of this Section 12.2, (i) Borrower shall not be required to reimburse Bank for any increased costs incurred more than three months prior to the date that Bank notifies Borrower in writing thereof and (ii) in the event Bank makes an assignment of, or grants a participation in, Bank's obligations, rights or benefits hereunder pursuant to Section 12.1, Borrower shall not be obligated to reimburse for increased costs to the extent that the aggregate amount thereof exceeds the aggregate amount for which Borrower would have been obligated if Bank had not made such assignment or granted such participation. Bank shall notify Borrower of any increased cost or capital requirement that would entitle Bank to compensation hereunder promptly after Bank obtains knowledge hereof.

12.3 Indemnification. Borrower shall defend, indemnify and hold harmless Bank and its officers, employees, and agents against: (a) all obligations, demands, claims, and liabilities (collectively, "Losses") claimed or asserted by any other party in connection with the transactions contemplated by this Agreement; and (b) all Bank Expenses in any way suffered, incurred, or paid by Bank, its officers, employees and agents as a result of or in any way arising out of transactions between Bank and Borrower under this Agreement, (including without limitation reasonable attorneys fees and expenses), except for Losses or Bank Expenses caused by Bank's gross negligence or willful misconduct. The foregoing indemnification shall not cover any Losses or Bank Expenses relating to (i) any income, stamp or other taxes, charges, fees, deductions or withholdings imposed, levied, collected, withheld or assessed by the United States of America or any political subdivision or taxing authority thereof or therein; or (ii) any costs (whenever imposed) to Bank of agreeing to make or making, funding or maintaining any Credit Extensions or resulting from any capital required or expected to be maintained by Bank or any corporation controlling Bank as a result of Bank's commitment hereunder or the Credit Extensions, provided that nothing in this clause (ii) shall affect Bank's rights under Section 12.2 hereof.

12.4 Time of Essence. Time is of the essence for the performance of all obligations set forth in this Agreement.

12.5 Severability of Provisions. Each provision of this Agreement shall be severable from every other provision of this Agreement for the purpose of determining the legal enforceability of any specific provision.

12.6 Amendments in Writing, Integration. All amendments to or terminations of this Agreement must be in writing. All prior agreements, understandings, representations, warranties, and negotiations between the parties hereto with respect to the subject matter of this Agreement, if any, are merged into this Agreement and the Loan Documents.

12.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, shall be deemed to be an original, and all of which, when taken together, shall constitute but one and the same Agreement.

12.8 Survival. All covenants, representations and warranties made in this Agreement shall continue in full force and effect so long as any Obligations remain outstanding. The obligations of Borrower to indemnify Bank with respect to the expenses, damages, losses, costs and liabilities described in Section 12.2 and 12.3 shall survive until all applicable statute of limitations periods with respect to actions that may be brought against Bank have run.

12.9 Confidentiality.

(a) Bank, and all employees and agents (which, for purposes hereof, shall include, but not be limited to, Bank's attorneys and accountants as well as all government regulators) of Bank, shall maintain the confidentiality of and not use (except as permitted under this Agreement) any non-public information relating to Borrower, its Subsidiaries or their businesses received by Bank pursuant to this Agreement or otherwise, except that disclosure of such information may be made (i) to the subsidiaries or affiliates of Bank in connection with their

present or prospective business relations with Borrower, or to prospective transferees or purchasers of any interest in the Credit Extensions, provided that such subsidiaries, affiliates and prospective transferees and purchasers shall have entered into an agreement in favor of Borrower containing confidentiality provisions at least as stringent as those set forth in this Section 12.9 and have delivered a copy thereof to Borrower, (ii) as required by law, regulations, rule, subpoena, judicial order or similar order, (iii) as may be required in connection with the examination, audit or similar investigation of Bank and (iv) as Bank may reasonably determine in connection with the enforcement of any remedies hereunder. Confidential information hereunder shall not include information that either: (a) is in the public domain or in the knowledge or possession of Bank when disclosed to Bank, or becomes part of the public domain after disclosure to Bank through no fault of Bank or any Person to which such information is disclosed in accordance with this Section 12.9; or (b) is disclosed to Bank by a third party, provided Bank does not have actual knowledge that such third party is prohibited from disclosing such information.

(b) In the event that Bank or any Person receiving confidential information from Bank becomes legally compelled to disclose any of the information, Bank shall provide Borrower with notice of such event promptly upon obtaining knowledge thereof so that the Borrower may seek a protective order or other appropriate remedy. Bank shall cooperate with Borrower in seeking any such protective order or remedy. In the event that such protective order or other remedy is not obtained, Bank shall furnish only that portion of the confidential information which in its reasonable opinion it is legally required to disclose and shall disclose such information in a manner reasonably designed to preserve its confidential nature.

(c) Bank acknowledges that the disclosure or use of confidential information in violation of this Section 12.9 could have serious consequences, and agrees that, in the event of any breach of this Section 12.9 by Bank or its subsidiaries, affiliates, or representatives, Borrower will be entitled to seek equitable relief (including injunctive relief and specific performance) in addition to all other remedies available to it at law or in equity.

(d) Bank's obligations and all of the Borrower's rights and remedies under this Section 12.9 shall survive any termination of this Agreement and repayment of the Obligations or the return or destruction of the confidential information, in each case until the date two years after the termination of this Agreement.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the date first above written.

ORASURE TECHNOLOGIES, INC.

By: /s/ Ronald H. Spair

Name: Ronald H. Spair

Title: Chief Financial Officer

COMERICA BANK-CALIFORNIA

By: /s/ Michael T. Wilk

Name: Michael T. Wilk

Title: Vice President

EXHIBIT A

DEFINITIONS

"Accounts" means all presently existing and hereafter arising accounts, contract rights, and all other forms of obligations owing to Borrower arising out of the sale or lease of goods (including, without limitation, the licensing of software and other technology) or the rendering of services by Borrower, whether or not earned by performance, and any and all credit insurance, guaranties, and other security therefor, as well as all goods returned to or reclaimed by Borrower, and Borrower's Books relating to any of the foregoing.

"Affiliate" means, with respect to any Person, any Person that owns or controls directly or indirectly such Person, any Person that is controlled by or is under common control with such Person, and each of such Person's senior executive officers, directors, and partners.

"Bank Expenses" means all: reasonable out-of-pocket costs or expenses (including reasonable attorneys' fees and expenses) incurred in connection with the preparation, negotiation, administration and amendment of the Loan Documents; reasonable out-of-pocket Collateral audit and appraisal fees incurred prior to the date of this Agreement; and Bank's reasonable attorney's fees and expenses incurred in enforcing or defending the Loan Documents (including fees and expenses of appeal), incurred before, during and after an Insolvency Proceeding, whether or not suit is brought.

"Borrower State" means Delaware, the state under whose laws Borrower is organized.

"Borrower's Books" means all of Borrower's books and records including: ledgers; records concerning Borrower's assets or liabilities, the Collateral, business operations or financial condition; and all computer programs, or tape files, and the equipment, containing such information.

"Borrowing Base" means an amount equal to 80% of Eligible Accounts, as set forth in the most recent Borrowing Base Certificate delivered by Borrower, which Certificate shall be conclusive absent manifest error.

"Borrowing Base Certificate" means a certificate substantially in the form set forth in Exhibit D hereto and completed by Borrower.

"Business Day" means any day that is not a Saturday, Sunday, or other day on which banks in the State of California are authorized or required to close.

"CAPEX Budget" means Borrower's 2002/2003 capital expenditure budget dated June 11, 2002 and previously delivered to Bank.

"CAPEX Equipment" means computer equipment, laboratory equipment and manufacturing equipment purchased by Borrower or its Subsidiaries and generally of the type described in the CAPEX Budget.

"Change in Control" shall mean a transaction in which any "person" or "group" (within the meaning of Section 13(d) and 14(d)(2) of the Securities Exchange Act of 1934) becomes the "beneficial owner" (as defined in Rule 13d-3 under the Securities Exchange Act of 1934), directly or indirectly, of a sufficient number of shares of all classes of stock then outstanding of Borrower ordinarily entitled to vote in the election of directors, empowering such "person" or "group" to elect a majority of the Board of Directors of Borrower, who did not have such power before such transaction.

"Chief Executive Office State" means Pennsylvania, where Borrower's chief executive office is located.

"Closing Date" means the date of this Agreement.

"Code" means the Pennsylvania Uniform Commercial Code as amended or supplemented from time to time.

"Collateral" means the property described on Exhibit B attached hereto and all Negotiable Collateral to the extent not described on Exhibit B, except to the extent any such property (i) is nonassignable by its terms without the consent of the licensor thereof or another party (but only to the extent such prohibition on transfer is enforceable under applicable law), or (ii) the granting of a security interest therein is contrary to applicable law, provided that upon the cessation of any such restriction or prohibition, such property shall automatically become part of the Collateral.

"Collateral States" means the state or states where the Collateral is located, which are Pennsylvania and Oregon.

"Committed Mortgage Loan Amount" means $887,210.58.

"Committed Non-Revolving Line Amount" means $3,000,000.00.

"Committed Revolving Line Amount" means $4,000,000.00.

"Committed Term Loan Amount" means $3,000,000.00.

"Contingent Obligation" means, as applied to any Person, any direct or indirect liability, contingent or otherwise, of that Person with respect to (i) any indebtedness, lease, dividend, letter of credit or other obligation of another, including, without limitation, any such obligation directly or indirectly guaranteed, endorsed, co-made or discounted or sold with recourse by that Person, or in respect of which that Person is otherwise directly or indirectly liable; (ii) any obligations with respect to undrawn letters of credit issued for the account of that Person; and (iii) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect that Person against fluctuation in interest rates, currency exchange rates or commodity prices; provided, however, that the term "Contingent Obligation" shall not include endorsements for collection or deposit in the ordinary course of business. The amount of any Contingent Obligation shall be deemed to be an amount equal to the stated or determined amount of the primary obligation in respect of which such Contingent Obligation is made or, if not stated or determinable, the maximum reasonably anticipated liability in respect thereof as determined by such Person in good faith; provided, however, that such amount shall not in any event exceed the maximum amount of the obligations under the guarantee or other support arrangement.

"Copyrights" means any and all of Borrower's copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret, now or hereafter existing, created, acquired or held.

"Credit Extension" means the Mortgage Advance, each Non-Revolving Advance, each Revolving Advance, the Term Advance, or any other cash advance or extension of credit by Bank to or for the benefit of Borrower hereunder.

"Current Liabilities" means, as of any applicable date, all amounts that should, in accordance with GAAP, be included as current liabilities on the consolidated balance sheet of Borrower and its Subsidiaries, as at such date, including all Indebtedness that is payable upon demand or within one year from the date of determination thereof unless such Indebtedness is renewable or extendible at the option of Borrower or any Subsidiary to a date more than one year from the date of determination.

"Eligible Accounts" means those Accounts that arise in the ordinary course of Borrower's business that comply with all of Borrower's representations and warranties to Bank set forth in Section 5.3; provided, that Bank may change the standards of eligibility with respect to certain Accounts if Bank determines, in the exercise of its reasonable business judgment after consultation with Borrower, that such change is necessary due to a change in circumstance occurring after the Closing Date which materially adversely affects the collectibility of such Accounts, and provided further that Bank provides Borrower at least thirty (30) days prior written notice of any such change. Unless otherwise agreed to by Bank, Eligible Accounts shall not include the following:

(a) Accounts that the account debtor has failed to pay in full within 90 days of invoice date;

(b) Accounts with respect to an account debtor, 25% of whose Accounts the account debtor has failed to pay within 90 days of invoice date;

(c) Accounts with respect to which the account debtor is an officer or employee of Borrower;

(d) Accounts with respect to which goods are placed on consignment, guaranteed sale, sale or return, sale on approval, bill and hold, or other terms by reason of which the payment by the account debtor may be conditional;

(e) Accounts with respect to which the account debtor is an Affiliate of Borrower;

(f) Accounts with respect to which the account debtor does not have its principal place of business in the United States, except for Eligible Foreign Accounts;

(g) Accounts with respect to which the account debtor is the United States or any department, agency, or instrumentality of the United States, except for Accounts of the United States if the payee has assigned its payment rights to Bank and the assignment has been acknowledged under the Assignment of Claims Act of 1940 (31 U.S.C. 3727);

(h) Accounts with respect to which Borrower is liable to the account debtor for goods sold or services rendered by the account debtor to Borrower, but only to the extent of any amounts owing to the account debtor;

(i) Accounts with respect to an account debtor, including Affiliates of such account debtor, whose total obligations to Borrower exceed 25% of all Accounts (other than LabOne, Inc. whose sublimit shall be 35%), to the extent such obligations exceed the aforementioned percentages, except as approved in writing by Bank (which approval shall not be unreasonably withheld);

(j) Accounts which have not been invoiced to the applicable account debtor;

(k) Retention billings or similar contract Accounts which have been billed to the account debtor in exchange for future performance by Borrower, but only to the extent Borrower has not performed its required obligations or otherwise provided consideration for such retention billings or Accounts; provided that National Institutes of Health, Small Business Innovation Research or other similar "research" contracts or grants would in all cases be considered to be Eligible Accounts; and

(l) Accounts the collection of which Bank reasonably determines after inquiry and consultation with Borrower to be doubtful.

"Eligible Foreign Accounts" means Accounts with respect to which the account debtor does not have its principal place of business in the United States and that (i) are supported by one or more letters of credit in an amount and of a tenor, and issued by a financial institution, reasonably acceptable to Bank, or (ii) are covered by reasonably acceptable credit insurance, or (iii) that Bank approves on a case-by-case basis; provided that, notwithstanding the foregoing, the Accounts identified in the Schedule shall be deemed to be approved by Bank as Eligible Foreign Accounts.

"Environmental Laws" means all laws, rules, regulations, orders and the like issued by any federal state, local foreign or other governmental or quasi-governmental authority or any agency pertaining to the environment or to any hazardous materials or wastes, toxic substances, flammable, explosive or radioactive materials, asbestos or other similar materials.

"Equipment" means all present and future machinery, equipment, tenant improvements, furniture, fixtures, vehicles, tools, parts and attachments in which Borrower has any interest.

"ERISA" means the Employee Retirement Income Security Act of 1974, as amended, and the regulations thereunder.

"Event of Default" has the meaning assigned in Article 8.

"Excess Collateral Availability" means, as of any applicable date, the lesser of the Committed Revolving Line or the Borrowing Base minus the amount of principal outstanding under the Revolving Facility, as at such date.

"FDA" means the United States Food and Drug Administration or any successor thereto.

"Fixed Rate Advance" means a Credit Extension where the Borrower elects to pay interest on such Credit Extension at a fixed rate of interest pursuant to Section 2.3(a)(ii)(C), 2.3(a)(iii)(C) or 2.3(a)(iv)(B) hereof. "Fixed Rate Interest Period" means (a) with respect to a Non-Revolving Advance, the period commencing on the date of the Non-Revolving Advance and ending on the date which is forty-eight (48) months thereafter, (b) with respect to the Term Advance, the period commencing on the date of the Term Advance and ending on the Term Maturity Date and (c) with respect to the Mortgage Advance, the period commencing on the date of the Mortgage Advance and ending on the fifth (5/th/) anniversary thereof, and the period commencing immediately after the end of such first Fixed Rate Interest Period and ending on the Mortgage Maturity Date.

"GAAP" means generally accepted accounting principles, consistently applied, as in effect from time to time in the United States.

"Indebtedness" means (a) all indebtedness for borrowed money or the deferred purchase price of property or services, including without limitation reimbursement and other obligations with respect to surety bonds and letters of credit, (b) all obligations evidenced by notes, bonds, debentures or similar instruments, (c) all capital lease obligations and (d) all Contingent Obligations.

"Insolvency Proceeding" means any proceeding commenced by or against any person or entity under any provision of the United States Bankruptcy Code, as amended, or under any other bankruptcy or insolvency law, including assignments for the benefit of creditors, formal or informal moratoria, compositions, extension generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

"Intellectual Property" means all of Borrower's right, title, and interest in and to the following:

(a) Copyrights, Trademarks and Patents;

(b) Any and all trade secrets, and any and all intellectual property rights in computer software and computer software products now or hereafter existing, created, acquired or held;

(c) Any and all design rights which may be available to Borrower now or hereafter existing, created, acquired or held;

(d) Any and all claims for damages by way of past, present and future infringement of any of the rights included above, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the intellectual property rights identified above;

(e) All licenses or other rights to use any of the Copyrights, Patents or Trademarks, and all license fees and royalties arising from such use to the extent permitted by such license or rights;

(f) All amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents; and

(g) All proceeds and products of the foregoing, including without limitation all payments under insurance or any indemnity or warranty payable in respect of any of the foregoing.

"Inventory" means all present and future inventory in which Borrower has any interest, including merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products intended for sale or lease or to be furnished under a contract of service, of every kind and description now or at any time hereafter

owned by or in the custody or possession, actual or constructive, of Borrower, including such inventory as is temporarily out of its custody or possession or in transit and including any returns upon any accounts or other proceeds, including insurance proceeds, resulting from the sale or disposition of any of the foregoing and any documents of title representing any of the above, and Borrower's Books relating to any of the foregoing.

"Investment" means any beneficial ownership of (including stock, partnership or limited liability company interest or other securities) any Person, or any loan, advance or capital contribution to any Person.

"LIBOR" means the London Interbank Offered Rate which is a floating annual rate of interest quoted by Bank at approximately 2:00 P.M. Pacific time, two (2) Business Days prior to the first day of any applicable LIBOR Interest Period for the offering to leading banks in the London interbank market of dollar deposits for a period, comparable to the length of the applicable LIBOR Interest Period, and in the amount comparable to the unpaid principal balance of the applicable Credit Extension outstanding at the commencement date of such LIBOR Interest period.

"LIBOR Advance" means a Credit Extension where the Borrower chooses to pay interest on such Credit Extension at a rate pursuant to Sections 2.3(a)(i)(B), 2.3(a)(ii)(B), or 2.3(a)(iii)(B) hereof.

"LIBOR Interest Period" means each consecutive 30-day, 180-day or 360-day period, as applicable, during the term of any LIBOR Advance, commencing on the date the LIBOR Advance is made. Each LIBOR Interest Period shall continue until the earliest to occur of (i) the expiration of such 30-, 180- or 360-day period, (ii) the applicable maturity date of the LIBOR Advance, or (iii) the repayment in full of all amounts due hereunder.

"LIBOR Prepayment Penalty" means, with regard to the prepayment of a LIBOR Advance, the sum of:

(a) to the extent not paid by Borrower, the Prepaid Principal Amount for such LIBOR Advance and interest accruing on such Prepaid Principal Amount up to, but not including, the Prepayment Date; plus

(b) Five Hundred Dollars ($500.00); plus

(c) the present value, discounted at the Reinvestment Rates, of the positive amount, if any, by which (i) the interest Bank would have earned at the applicable LIBOR interest rate had the Prepaid Principal Amount not been paid prior to the last scheduled day of the applicable LIBOR Interest Period exceeds (ii) the interest Bank would earn through the last scheduled day of such LIBOR Interest Period by reinvesting the prepaid Principal Amount at the Reinvestment Rates.

"Lien" means any mortgage, lien, deed of trust, charge, pledge, security interest or other encumbrance.

"Loan Documents" means, collectively, this Agreement, any note or notes executed by Borrower, and any other document, instrument or agreement entered into between Borrower and Bank in connection with this Agreement, all as amended or extended from time to time.

"Material Adverse Effect" means a material adverse effect on (i) the business operations or condition (financial or otherwise) of Borrower and its Subsidiaries taken as a whole or (ii) the ability of Borrower to repay the Obligations or otherwise perform its obligations under the Loan Documents.

"Mortgage Advance" means the cash advance to the Borrower pursuant to Section 2.1(e) hereof.

"Mortgage Maturity Date" means September 10, 2012.

"Negotiable Collateral" means all of Borrower's present and future letters of credit of which it is a beneficiary, drafts, instruments (including promissory notes), securities, documents of title, and chattel paper, and Borrower's Books relating to any of the foregoing.

"Non-Revolving Advance" or "Non-Revolving Advances" means a cash advance or cash advances under the Non-Revolving Facility.

"Non-Revolving Advance Date" means each of three (3) Business Days following the Closing Date, December 10, 2002, March 10, 2003 and June 10, 2003, or any other date occurring after the Closing Date and prior to September 10, 2003 by which Borrower has accumulated invoices for at least $500,000 of CAPEX Equipment eligible for reimbursement under Section 2.1(d) hereof.

"Non-Revolving Facility" means the facility under which Borrower may request Bank to issue, and Bank shall provide, one or more Non-Revolving Advances, as specified in Section 2.1(d) hereof.

"Non-Revolving Maturity Date" means September 10, 2007.

"Obligations" means all debt, principal, interest, Bank Expenses and other amounts owed to Bank by Borrower pursuant to the Loan Documents, whether absolute or contingent, due or to become due, now existing or hereafter arising, including any interest that accrues after the commencement of an Insolvency Proceeding.

"Patents" means all of Borrower's patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

"Periodic Payments" means all installments or similar recurring payments that Borrower may now or hereafter become obligated to pay to Bank pursuant to the terms and provisions of this Agreement.

"Permitted Indebtedness" means:

(a) Indebtedness of Borrower in favor of Bank arising under this Agreement or any other Loan Document;

(b) Indebtedness existing on the Closing Date and disclosed in the Schedule;

(c) Indebtedness not to exceed $1,000,000 in the aggregate in any fiscal year of Borrower secured by a Lien described in clause (c) of the defined term "Permitted Liens," provided such Indebtedness does not exceed the lesser of the cost or fair market value of the Equipment financed with such Indebtedness;

(d) Subordinated Debt;

(e) Indebtedness to suppliers, vendors, trade creditors or other parties incurred in the ordinary course of business; and

(f) Extensions, refinancings and renewals of any items of Permitted Indebtedness, provided that the principal amount is not increased or the terms modified to impose terms upon Borrower or its Subsidiary, as the case may be, which are materially more burdensome than as provided in the terms of Permitted Indebtedness prior to the extension, refinancing or renewal.

"Permitted Investment" means:

(a) Investments existing on the Closing Date and disclosed in the Schedule;

(b) (i) Marketable direct obligations issued or unconditionally guaranteed by the United States of America or any agency or any State thereof, (ii) commercial paper currently having rating of at least A-2 or P-2 from either Standard & Poor's Corporation or Moody's Investors Service, (iii) certificates of deposit of Bank, any Affiliate of Bank or any other bank with a shareholder's equity of at least $50,000,000 in the aggregate, (iv) money market accounts of Bank or any of its Affiliates and (v) any other Investments permitted under Borrower's Investment Guidelines dated March 27, 2002, a copy of which has been provided to Bank and which may be modified by Borrower upon written notice to Bank;

(c) Repurchases of stock from former employees or directors of Borrower under the terms of applicable repurchase agreements (i) in an aggregate amount not to exceed $500,000 in any fiscal year, provided that no Event of Default has occurred, is continuing or would exist after giving effect to the repurchases, or (ii)

in any amount where the consideration for the repurchase is the cancellation of indebtedness owed by such former employees to Borrower regardless of whether an Event of Default exists;

(d) Investments accepted in connection with Permitted Transfers;

(e) Investments of Subsidiaries in or to other Subsidiaries or Borrower and Investments by Borrower in Subsidiaries not to exceed $500,000 in the aggregate in any fiscal year;

(f) Investments consisting of (i) travel advances and employee relocation loans and advances and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock options or stock purchase plan agreements approved by Borrower's Board of Directors or any committee thereof;

(g) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers, suppliers or other parties or in settlement of delinquent obligations of, and other disputes with, customers, suppliers or other parties arising in the ordinary course of Borrower's business;

(h) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers, suppliers or other parties who are not Affiliates of Borrower, in the ordinary course of business, provided that this subparagraph (h) shall not apply to Investments of Borrower in any Subsidiary; and

(i) Joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the licensing of technology, the development of technology or products or the providing of technical support, provided that any cash Investments by Borrower in connection with such joint ventures or strategic alliances do not exceed $500,000 in the aggregate in any fiscal year.

"Permitted Liens" means the following:

(a) Any Liens existing on the Closing Date and disclosed in the Schedule (excluding Liens to be satisfied with the proceeds of the Advances) or the title commitment delivered pursuant to Section 3.1 hereof or arising under this Agreement or the other Loan Documents;

(b) Liens for taxes, fees, assessments or other governmental charges or levies, either not delinquent or being contested in good faith by appropriate proceedings and for which Borrower maintains adequate reserves;

(c) Liens not to exceed $1,000,000 in the aggregate in any fiscal year (i) upon or in any Equipment acquired or held by Borrower or any of its Subsidiaries to secure the purchase price of such Equipment or indebtedness incurred solely for the purpose of financing the acquisition or lease of such Equipment, or (ii) existing on such Equipment at the time of its acquisition, provided that the Lien is confined solely to the property so acquired and improvements thereon, and the proceeds of such Equipment;

(d) Mechanic's, materialmen's, warehousemen's, carriers' or other like Liens occurring in the ordinary course of business of Borrower with respect to obligations which are not overdue for a period longer that thirty (30) days or which are being contested in good faith by appropriate proceedings and for which adequate reserves (in accordance with GAAP) have been recorded on the books of Borrower;

(e) Deposits or pledges to secure the performance of bids, tenders, contracts, public or statutory obligations, or surety or appeal bids or other deposits or pledges for purposes of a like general nature or given in the ordinary course of business by Borrower;

(f) Liens incurred in connection with the extension, renewal or refinancing of the indebtedness secured by Liens of the type described in clauses (a) through (c) above, provided that any extension, renewal or replacement Lien shall be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness being extended, renewed or refinanced shall not increase;

(g) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Sections 8.5 or 8.9;

(h) Liens in favor of other financial institutions arising in connection with Borrower's deposit accounts held at such institutions, provided that Bank has a perfected security interest in the amounts held in such deposit accounts;

(i) Licenses or similar rights to Borrower's Intellectual Property granted to distributors, research and development parties or other Persons in the ordinary course of business; and

(j) Other Liens not described above arising in the ordinary course of business and not having or not reasonably likely to have a Material Adverse Effect.

"Permitted Transfer" means, with respect to Borrower or any Subsidiary, any of the following:

(a) The Transfer of Inventory or Equipment in the ordinary course of business;

(b) The granting of licenses and similar arrangements for the use of the Intellectual Property or other property of Borrower or its Subsidiaries in connection with research, clinical or other testing, the development of any products or new product applications, or otherwise in the ordinary course of business;

(c) The Transfer of worn-out, obsolete or unusable Inventory or Equipment; or

(d) The Transfer of any other assets of Borrower or its Subsidiaries which do not in the aggregate exceed $250,000 during any fiscal year.

"Person" means any individual, sole proprietorship, partnership, limited liability company, joint venture, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or governmental agency.

"PIDA" means the Pennsylvania Industrial Development Authority, or any successor thereto.

"Prepayment Date" means the date Borrower prepays a Credit Extension.

"Prepayment Principal Amount" means the remaining principal amount of a Credit Extension which Borrower has elected to prepay or the principal amount of such Credit Extension which Bank has required Borrower to prepay because of acceleration in accordance with this Agreement.

"Prepayment Penalty" means, with respect to the prepayment of a Fixed Rate Advance, the sum of:

(a) to the extent not paid by Borrower, the Prepaid Principal Amount for such Fixed Rate Advance and interest accruing on such Prepaid Principal Amount up to, but not including, the Prepayment Date; plus

(b) Five Hundred Dollars ($500.00); plus

(c) the present value, discounted at the Reinvestment Rates, of the positive amount, if any, by which (A) the interest the Bank would have earned at the interest rate applicable to such Fixed Rate Advance had the Prepaid Principal Amount not been prepaid prior to the end of the applicable Fixed Rate Interest Period, exceeds (B) the interest the Bank would earn through the end of the applicable Fixed Rate Interest Period, by reinvesting the Prepaid Principal Amount at the Reinvestment Rates.

"Prime Rate" means the variable rate of interest, per annum, most recently announced by Bank, as its "prime rate," whether or not such announced rate is the lowest rate available from Bank.

"Property" means the real property and improvements thereon located at 1745 Eaton Avenue, Bethlehem, Pennsylvania 18018.

"Quick Assets" means, as of any applicable date, the amounts that should, in accordance with GAAP, be included in cash, cash equivalents and short-term investments, and accounts receivable net of the allowance for doubtful accounts, on the consolidated balance sheet of Borrower and its Subsidiaries, as at such date.

"Reinvestment Rates" means the per annum rates of interest equal to the rate of interest reasonably determined by the Bank to be in effect not more than seven (7) Business Days prior to the applicable Prepayment Date (i) in the case of a prepayment of a LIBOR Advance, in the London interbank market, and (ii) in the case of a Fixed Rate Advance, one-half percent (1/2%) above the rate of interest reasonably determined by the Bank to be in effect not more than seven (7) Business Days prior to the applicable Prepayment Date in the secondary market for United States Treasury Obligations, in each case in amount(s) and with maturity(ies) which correspond (as closely as possible) to the principal installment amount(s) and the Payment Date(s) against which the Prepaid Principal Amount will be applied.

"Responsible Officer" means each of the Chief Executive Officer, the President, the Chief Financial Officer, the Controller and the Vice President, Finance of Borrower.

"Revolving Advance" or "Revolving Advances" means a cash advance or cash advances under the Revolving Facility.

"Revolving Facility" means the facility under which Borrower may request Bank to issue, and Bank shall provide, one or more Revolving Advances, as specified in Section 2.1(b) hereof.

"Revolving Maturity Date" means September 9, 2003.

"Schedule" means the schedule of exceptions attached hereto.

"Solvent" means, as to any Person, that such Person (i) owns property whose fair saleable value is, to the best knowledge of such Person, greater than the amount required to pay all of such Person's Indebtedness, (ii) is able to pay all of its Indebtedness as such Indebtedness matures, and (iii) to the best knowledge of such Person, has capital sufficient to carry on its business and transactions and all business and transactions in which it is about to engage.

"SOS Reports" means the official reports from the Secretaries of State of each Collateral States, Chief Executive Office State and the Borrower State and other applicable federal, state or local government offices identifying all current security interests filed in the Collateral and Liens of record as of the date of such report.

"Subordinated Debt" means any debt incurred by Borrower that is subordinated to the debt owing by Borrower to Bank on terms reasonably acceptable to Bank and pursuant to an acceptable subordination agreement (and identified as being such by Borrower and Bank).

"Subsidiary" means any corporation, partnership or limited liability company or joint venture in which (i) any general partnership interest or (ii) more than 50% of the stock, limited liability company interest or joint venture of which by the terms thereof ordinary voting power to elect the Board of Directors, managers or trustees of the entity, at the time as of which any determination is being made, is owned by Borrower, either directly or through an Affiliate.

"Tangible Net Worth" means, as of any applicable date, all amounts that should, in accordance with GAAP, be included in capital stock, partnership interest or limited liability company interest and additional paid-in capital plus retained earnings (or minus accumulated deficit) of Borrower and its Subsidiaries minus intangible assets, plus Subordinated Debt, in the consolidated balance sheet of Borrower and its Subsidiaries, as of such date.

"Term Advance" means the cash advance or cash advances under Section 2.1(c) hereof.

"Term Maturity Date" means March 10, 2006.

"Trademarks" means any of Borrower's trademark and service mark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower connected with and symbolized by such trademarks.

"Treasury Note Rate" means the then current yield to maturity of a United States Treasury security, having a remaining term to maturity nearest to the term (i.e. 3.5, 4 or 5 years, as applicable) applicable to a Fixed Rate Advance pursuant to Section 2.3(a), as reported in the Wall Street Journal on the first day of the applicable Fixed Rate Interest Period.

"Variable Rate Advance" means a Credit Extension where the Borrower elects to pay interest on such Credit Extension at a variable rate of interest pursuant to Section 2.3(a)(i)(A), 2.3(a)(ii)(A), 2.3(a)(iii)(A), or 2.3(a)(iv)(A) hereof.

DEBTOR ORASURE TECHNOLOGIES, INC.

SECURED PARTY: COMERICA BANK--CALIFORNIA

EXHIBIT B

COLLATERAL DESCRIPTION ATTACHMENT
TO LOAN AND SECURITY AGREEMENT

All personal property of Borrower (herein referred to as "Borrower" or "Debtor") whether presently existing or hereafter created or acquired, and wherever located, including, but not limited to:

(a) all accounts (including health-care-insurance receivables), chattel paper (including tangible and electronic chattel paper), deposit accounts, documents (including negotiable documents), equipment (including all accessions and additions thereto), general intangibles (including payment intangibles and software), goods (including fixtures), instruments (including promissory notes), inventory (including all goods held for sale or lease or to be furnished under a contract of service, and including returns and repossessions), investment property (including securities and securities entitlements), letter of credit rights, money, and all of Debtor's books and records with respect to any of the foregoing, and the computers and equipment containing said books and records; and

(b) any and all cash proceeds and/or noncash proceeds of any of the foregoing, including, without limitation, insurance proceeds, and all supporting obligations and the security therefor or for any right to payment. All terms above have the meanings given to them in the Pennsylvania Uniform Commercial Code, as amended or supplemented from time to time.

EXHIBIT C

LOAN PAYMENT/ADVANCE TELEPHONE REQUEST FORM

DEADLINE FOR SAME DAY PROCESSING IS 3:00 P.M., P.S.T.
DEADLINE FOR EQUIPMENT ADVANCES IS 3:00 P.M., P.S.T.*
*Subject to 3 day advance notice.

TO: [_____] DATE: _____

FAX #: [_____] TIME: _____

- ---

FROM: OraSure Technologies, Inc.
CLIENT NAME (BORROWER)
REQUESTED BY: _____
AUTHORIZED SIGNER'S NAME

AUTHORIZED SIGNATURE: _____

PHONE NUMBER: _____

FROM ACCOUNT # _____ TO ACCOUNT # _____

REQUESTED TRANSACTION TYPE	REQUEST DOLLAR AMOUNT
	$_____
PRINCIPAL INCREASE (ADVANCE)	$_____
PRINCIPAL PAYMENT (ONLY)	$_____
INTEREST PAYMENT (ONLY)	$_____
PRINCIPAL AND INTEREST (PAYMENT)	$_____

OTHER INSTRUCTIONS: _____
_____

All representations and warranties of Borrower stated in the Loan and Security Agreement are true, correct and complete in all material respects as of the date of the telephone request for an Advance confirmed by this Borrowing Certificate; provided, however, that those representations and warranties expressly referring to another date shall be true, correct and complete in all material respects as of such date.

- ---

- ---

BANK USE ONLY
TELEPHONE REQUEST:

The following person is authorized to request the loan payment transfer/loan advance on the advance designated account and is known to me.

_____ _____
Authorized Requester Phone #

_____ _____
Received By (Bank) Phone #

_____
Authorized Signature (Bank)

- ---

EXHIBIT D

BORROWING BASE CERTIFICATE

Borrower: OraSure Technologies, Inc. Lender: Comerica Bank-California

Commitment Amount: $4,000,000.00

ACCOUNTS RECEIVABLE			
1.	Accounts Receivable Book Value as of ___		$_____
2.	Additions (please explain on reverse)		$_____
3.	TOTAL ACCOUNTS RECEIVABLE		$_____
ACCOUNTS RECEIVABLE DEDUCTIONS (without duplication)			
4.	Amounts over 90 days from invoice date	$_____	
5.	Balance of 25% over 90 day accounts	$_____	
6.	Concentration Limits		
7.	Foreign Accounts	$_____	
8.	Governmental Accounts	$_____	
9.	Contra Accounts	$_____	
10.	Intercompany/Employee Accounts	$_____	
11.	Other (please explain on reverse)	$_____	
12.	TOTAL ACCOUNTS RECEIVABLE DEDUCTIONS		$_____
13.	Eligible Accounts (#3 minus #12)		$_____
14.	LOAN VALUE OF ACCOUNTS (__% of #13)		$_____
BALANCES			
15.	Maximum Loan Amount		$_____
16.	Total Funds Available [Lesser of #14 or #15]		$_____
17.	Present balance owing on Line of Credit		$_____
18.	Outstanding under Sublimits (Letters of Credit and Credit Card Services)		
19.	Excess Collateral Availability (#19 minus #17 and #18)		$_____

The undersigned represents and warrants that the foregoing is true, complete and correct in all material respects, and that the information reflected in this Borrowing Base Certificate complies with the representations and warranties set forth in the Loan and Security Agreement between the undersigned and Comerica Bank-California.

OraSure Technologies, Inc.

By: _____
Authorized Signer

EXHIBIT E
COMPLIANCE CERTIFICATE

TO: COMERICA BANK--CALIFORNIA

FROM: ORASURE TECHNOLOGIES, INC.

The undersigned authorized officer of OraSure Technologies, Inc. hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement between Borrower and Bank (the "Agreement"), (i) Borrower is in complete compliance for the period ending _____ with all required covenants under the Agreement, except as noted below and (ii) all representations and warranties of Borrower stated in the Agreement are true and correct in all material respects as of the date hereof (except for representations and warranties referring to a prior date which shall be true and correct in all material respects only as of such prior date). Attached herewith are the required documents supporting the above certification. The Officer further certifies that these were prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenant	Required	Complies
Monthly Financial Statements	Monthly within 20 days	Yes No
Annual (CPA Audited) Financial Statements	FYE within 90 days	Yes No
10K and 10Q	(as applicable)	Yes No
A/R Agings and Borrowing Base Cert.	Monthly within 20 days	Yes No
A/R Audit	Initial and Annual	Yes No
Projection	FYE within 30 days	Yes No

Financial Covenant	Required	Actual	Complies
Minimum Quick Ratio	2.00:1.00	_____:1.00	Yes No
Minimum Tangible Net Worth	$19,000,000	$_____	Yes No
Minimum Liquidity	$ 7,500,000*	$_____	Yes No
Minimum Profitability	$_____	$_____	Yes No

_____

* Including $_____ of cash, cash equivalents and short-term investments ($4,000,000 minimum)

Comments Regarding Exceptions: See Attached.

Sincerely,

_____
SIGNATURE

_____
TITLE

_____
DATE

- ---
BANK USE ONLY

Received by: _____
AUTHORIZED SIGNER

Date: _____

Verified: _____
AUTHORIZED SIGNER

Date: _____

Compliance Status Yes No

- ---

SCHEDULE OF EXCEPTIONS

Location of Collateral (Sections 5.3, 7.7 and 7.10)

1. Raw materials, manufacturing and packaging equipment, computer equipment and software, and finished product are maintained at the following location for the manufacture or assembly of Borrower's OraQuick(R) rapid HIV test:

Pacific BioTech
42 Moo 4 Petchaboon-Chalianglub Rd.
Napa, Muang
Petchaboon 67000
Thailand

2. Raw materials, manufacturing and packaging equipment and finished product are maintained at the following location for the manufacture or assembly of Borrower's Intercept(R) and OraSure(R) oral fluid collection devices:

MML Diagnostics Packaging, Inc.
1625 NW Sundial Road
PO Box 458
Troutdale, Oregon 97060

3. From time to time, Borrower may allow its customers to use laboratory and other Equipment pursuant to reagent rental or other arrangements in the ordinary course of business and such Equipment shall be located at specific customer locations. As of the Closing Date, laboratory equipment under reagent rental agreements is located at the following customers of Borrower:

Customer	Location	Equipment
Community BioResources	Birmingham, AL	312e Reader
Alpha Therapeutic	Memphis, TN	312e Reader (two units)
Alpha Therapeutic	Memphis, TN	EL404 Washer (two units)
Alpha Therapeutic	Memphis, TN	Hamilton AT (two units)
Santa Clara Crime Lab	Santa Clara, CA	Hamilton AT Plus
Santa Clara Crime Lab	Santa Clara, CA	Microplate Reader
Santa Clara Crime Lab	Santa Clara, CA	Microplate Washer
Santa Clara Crime Lab	Santa Clara, CA	Omni Processor
Las Vegas Metropolitan Police Department	Las Vegas, NV	PersonalLAB
KS Bureau of Investigation	Topeka, KS	PersonalLAB
ID State Pol./Forensic Serv - C	Coeur D Alene, ID	PersonalLAB
ID State Pol./Forensic Serv - P	Pocatello, ID	PersonalLAB
U MASS Memorial	Worchester, MA	PersonalLAB
New Mexico Dept. of Public Health	Albuquerque, NM	PersonalLAB
Contra Costa County Sheriff's Crime Lab.	Martinez, CA	PersonalLAB
Sacramento County Crime Lab	Sacramento, CA	PersonalLAB (two units)
American Medical Laboratory	Chantilly, VA	PersonalLAB (two units)
LA County Sheriff's Crime Laboratory	Los Angeles, CA	Labotech

4. Intercept(R) and OraSure(R) oral fluid collection devices and reagents and assays are maintained on consignment at the following laboratory distributor:

LabOne, Inc.
10101 Renner Blvd.
Lenexa, Kansas 66219-9752

5. Borrower maintains Permitted Investments with the following financial institutions:

Lafayette Ambassador Bank
3397 Bath pike
P.O. Box 25091
Lehigh Valley, PA 18002-5091

Merrill Lynch Investments
7424 Windsor Drive
Allentown, PA 18106

6. Borrower maintains demand/deposit accounts with the following financial institutions:

Lafayette Ambassador Bank
3397 Bath Pike
P.O. Box 25091
Lehigh Valley, PA 18002-5091

US Bank
P.O. Box 64830
St. Paul, MN 55164-0830

PNC Bank
One PNC Plaza, 9/th/ Floor
Pittsburgh, PA 15265

Rabobank
Fokkerstratt 11-2811 EN Reeuwijk
The Netherlands

7. Collateral is located at the various leased properties identified in this Schedule under "Permitted Liens."

Ownership of Intellectual Property (Section 5.4)

None.

Prior Names (Section 5.5)

1. Epitope, Inc.
2. STC Technologies, Inc.
3. SolarCare Technologies Corporation
4. Epitope KK (Joint Venture in Japan)
5. STC International
6. Epitope, Inc. DBA Epitope Medical Products
7. Epitope, Inc. DBA Immunologic Associates

Litigation (Section 5.6)

None.

Permitted Indebtedness (Section 7.4; Exhibit A)

As of the Closing Date, Borrower had the following Indebtedness:

1. Indebtedness to the Pennsylvania Industrial Development Authority, originally in the amount of $760,611.00 and with a present outstanding balance of $408,893.00, secured by a mortgage on the Property.

Permitted Liens (Section 7.5; Exhibit A)

Borrower is party to the following leases as of the Closing Date:

1. Modified Triple Net Lease, dated September 30, 1999, as amended, between PS Business Parks, L.P. and Epitope, Inc., covering Borrower's office, manufacturing and research and development facilities at 8505 SW Creekside Place, Beaverton, Oregon 97008.

2. Commercial Lease, dated April 30, 1999, as amended, and Right of First Refusal and Purchase Option Agreement, dated April 30, 1999, between Northampton County New Jobs Corp. and STC Technologies, Inc., covering Borrower's office, manufacturing and research and development facilities at 150 Webster Street, Bethlehem, Pennsylvania 18015.

3. Commercial Lease, dated March 1, 2002, as amended, between Tech III Partners, LLC and OraSure Technologies, Inc., covering Borrower's office and manufacturing facilities to be located at 220 East First Street, Bethlehem, Pennsylvania 18015.

4. Lease Agreement, dated as of April 1, 2002, between Westside Warehouse Ltd. and OraSure Technologies, Inc., covering certain warehouse space at 15/th/ and Gary Streets, Bethlehem, Pennsylvania 18018.

5. Lease Agreement, dated November 1, 2001, between HQ Global Workplaces, Inc. and OraSure Technologies, Inc., covering office space at 401 N. Michigan Avenue, Chicago, Illinois 60611.

6. Business Park Lease, dated October 1, 1991, between Petula Associates, Ltd., Knoll Portland Associates and Epitope, Inc., covering warehouse space at 10120 Nimbus Ave., Ste. C/5b, Portland, Oregon 97223.

7. Lease Agreement, dated June 8, 1998, between STC Technologies, Inc. and Billsan BV (succeeded by DeVrind), covering office space at Fokkerstraat 11, 2811 En Reeuwijk, The Netherlands.

Permitted Investments (Sections 5.10, 7.7; Exhibit A)

As of the Closing Date, Borrower held the following Investments:

1. 775,028 shares of capital stock of Altrix HealthCare plc.

2. Investments described in this Schedule under "Location of Collateral."

Transactions with Affiliates (Section 7.8)

Borrower has entered into a Commercial Lease with Tech III Partners, LLC, which provides for the construction of an approximate 48,000 square foot manufacturing, research and development and office facility in Bethlehem, Pennsylvania, and the lease of that facility to Borrower. Tech III Partners, LLC is a limited liability company

owned and controlled by Michael J. Gausling, Borrower's President and Chief Executive Officer, and R. Sam Niedbala, Ph.D., Borrower's Executive Vice President and Chief Science Officer.

Eligible Foreign Accounts

None.

COMERICA BANK--CALIFORNIA
Member FDIC

ITEMIZATION OF AMOUNT FINANCED
DISBURSEMENT INSTRUCTIONS

Name: OraSure Technologies, Inc. Date: September 10, 2002

$3,887,210.58 wired to Commonwealth Land Title to be disbursed in accordance with the settlement sheet.

Upon consummation of this transaction, this document will also serve as the authorization for Comerica Bank-California to disburse the loan proceeds as stated above.

_____ _____

Signature Signature

AGREEMENT TO PROVIDE INSURANCE

TO: COMERICA BANK-CALIFORNIA
Loan Documentation Services Operations
9920 S. La Cienega Blvd.
14/th/ Floor
Inglewood, CA 90301

Date: September 10, 2002

Borrower: ORASURE TECHNOLOGIES, INC.

In consideration of loans in the aggregate amount of up to $10,887,210.58, secured by, among other things, all tangible personal property including inventory and equipment.

Borrower agrees to obtain adequate insurance coverage to remain in force during the term of the loans.

Borrower also agrees to advise the below named agent to add Comerica Bank-California as lender's loss payable on the new or existing insurance policy, and to furnish Bank at above address with a copy of said policy/endorsements and any subsequent renewal policies.

Borrower understands that the policy must contain:

1. Fire and extended coverage in an amount sufficient to cover:

(a) The amount of the loans, OR

(b) All existing encumbrances, whichever is greater,

But not in excess of the replacement value of the improvements on the real property.

2. Lender's "Loss Payable" Endorsement Form 438 BFU in favor of Comerica Bank-California, or any other form acceptable to Bank.

INSURANCE INFORMATION

Insurance Co./Agent: The Addis Group Telephone No.: (610) 279-8550

Agent's Address: 2300 Renaissance Boulevard

King of Prussia, Pennsylvania 19406-2772

Signature of Obligor: _____

Signature of Obligor: _____

- ---

FOR BANK USE ONLY

INSURANCE VERIFICATION: Date: _____

Person Spoken to: _____

Policy Number: _____

Effective From: _____ To: _____

Verified by: _____

COMERICA BANK
California's Business Banks
Member FDIC

AUTOMATIC DEBIT AUTHORIZATION

To: Comerica Bank-California

Re: Loan # _____

You are hereby authorized and instructed to charge account No._____
in the name of OraSure Technologies, Inc.

for principal, interest and other payments due on above referenced loan as set forth below and credit the loan referenced above.

X Debit each interest payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

X Debit each principal payment as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

X Debit each payment for Bank Expenses as it becomes due according to the terms of the Loan and Security Agreement and any renewals or amendments thereof.

This Authorization is to remain in full force and effect until revoked in writing.

Borrower Signature	Date

Exhibit 10.2

Execution Copy

AMENDMENT NO. 1 TO COMMERCIAL LEASE

THIS AMENDMENT NO. 1 TO COMMERCIAL LEASE (this "Amendment") is made this 21st day of October, 2002, by and between TECH III PARTNERS, LLC, a Pennsylvania limited liability company, having an office at 1512 Colesville Road, Bethlehem, Pennsylvania 18015 ("Landlord"), and ORASURE TECHNOLOGIES, INC., a Delaware corporation, having its principal offices at 150 Webster Street, Bethlehem, Pennsylvania 18015 ("Tenant"), with reference to the following background. Capitalized terms used herein have the meanings assigned to them in the Lease (defined below).

WHEREAS, by Commercial Lease dated March 1, 2002 ("Lease"), Landlord demised and leased unto Tenant, and Tenant leased and took from Landlord, for the term, at the rent and upon the terms and conditions therein set forth, certain Leased Premises known as the Bethlehem Technology Center III located in Bethlehem, Pennsylvania, which Leased Premises are more particularly described on Exhibit A annexed to the Lease; and

WHEREAS, Section 1(d) of the Lease provides that when the Final Construction Budget set forth in Exhibit B to the Lease has been agreed to by the parties, Landlord and Tenant shall execute and deliver an Amendment setting forth the Revised Exhibit B containing such Final Construction Budget; and

WHEREAS, Section 2 of the Lease provides that when the Commencement Date and Expiration Date under the Lease have been determined, Landlord and Tenant shall execute and deliver an Amendment setting forth such dates; and

WHEREAS, the parties desire to enter into this Amendment in order to set forth the Final Construction Budget, to amend the Tenant Finish Work Allowance Amount, to amend the Base Rent for the initial ten (10) year term of the Lease and the five (5) year renewal term, to set forth the Commencement Date and the Expiration Date, and to make certain other changes to the Lease.

NOW THEREFORE, Landlord and Tenant, intending to be legally bound, hereby agree as follows:

1. Final Construction Budget. Exhibit B to the Lease is hereby amended and restated as set forth in the Revised Exhibit B attached to this Amendment. The Landlord Equity Contribution, the Landlord Borrowing Amount and the Tenant Finish Work Allowance Amount shall be as set forth in such Revised Exhibit B. The reference to "$4 million" in the last sentence of Section 1(b) is hereby changed to "$6.5 million".

2. Term. The Commencement Date of the Lease is October 21, 2002, and the Expiration Date shall be October 20, 2012, unless the term of the Lease is extended or earlier terminated as provided in the Lease.

3. Rent.

(a) The table in Section 3(a) of the Lease setting forth the Base Rent for the initial term of the Lease is hereby amended and restated in its entirety as follows:

Lease Month	Rentable Sq. Feet	Annualized Base Rent	Monthly Base Rent	Base Rent Rate/SF
1-60	48,000	$780,000.00	$65,000.00	$16.25 sq. ft.
61-72	48,000	$795,840.00	$66,320.00	$16.58 sq. ft.
73-84	48,000	$811,200.00	$67,600.00	$16.90 sq. ft.
85-96	48,000	$827,040.00	$68,920.00	$17.23 sq. ft.
97-108	48,000	$842,400.00	$70,200.00	$17.55 sq. ft.
109-120	48,000	$858,240.00	$71,520.00	$17.88 sq. ft.

(b) Section 3(b) of the Lease is hereby amended and restated in its entirety as follows:

> "(b) In the event that the Commencement Date occurs on a day other than the first day of a calendar month, Tenant shall pay to Landlord a pro rata portion of the monthly installment of Base Rent for such partial month, computed at the monthly Base Rent rate for the first sixty (60) months of the initial term of the Lease, as set forth in Section 3(a)."

4. Tenant Finish Work Allowance Amount. Section 27(c) of the Lease is hereby amended and restated in its entirety as follows:

> "(c) The term "Tenant Finish Work Allowance Amount" shall mean the amount specified as such in the Revised Exhibit B adopted pursuant to Section 1(d) of this Lease."

5. Renewal Rent. Exhibit H to the Lease is hereby amended and restated in its entirety as set forth in the Revised Exhibit H attached to this Amendment.

6. Purchase Option. Sections 33(b) and 33(c) of the Lease are hereby amended and restated in their entirety as follows:

> "(b) The purchase price shall be paid at the closing by certified check, cashier's check or title insurance company check. The purchase price for the Leased Premises shall be calculated as follows: (i) as of the Closing Date, the Option Amount (as defined below); less (ii) the amount of the security deposit then held by Landlord pursuant to Section 47 of the Lease.

(c) For purposes hereof, the term "Option Amount" shall be determined pursuant to the following formula:

OA = $6.5 million - ((DR1x NOD1) + (DR2 x NOD2))

"OA" means the Option Amount payable in connection with the exercise of the Option.

"DR1" shall mean $410.96 per day (representing $150,000 per year divided by 365 days).

"DR2" shall mean $273.97 per day (representing $100,000 per year divided by 365 days).

"NOD1" means the number of calendar days occurring during Lease Years 1 through 5, from and including the Effective Date to but not including the Closing Date or, if the Closing Date does not occur during any such Lease Year, to but including the last day of the fifth (5th) Lease Year.

"NOD2" means the number of calendar days occurring during Lease Years 6 through 10, from including the first day of the sixth (6th) Lease Year to but not including the Closing Date."

The last sentence of Section 33(d) is hereby deleted.

7. Security Deposit. The reference in Section 47 of the Lease to "Forty Thousand Dollars ($40,000)" is hereby changed to "Sixty-Five Thousand Dollars ($65,000)."

8. Amendment. Except as amended hereby, the Lease shall remain in full force and effect. All references to the Lease shall mean the Lease as amended by this Amendment.

9. Governing Law. This Amendment shall be construed, governed and enforced in accordance with the internal laws of the Commonwealth of Pennsylvania, without regard to conflict of law principles.

10. Counterparts. This Amendment may be executed in more than one counterpart and by the parties on separate counterparts, each of which shall be an original and all of which shall together constitute a single instrument.

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be executed by their duly authorized officers or representatives as of the day and year first above written.

WITNESS:	TECH III PARTNERS, LLC
By: /s/ R. Sam Niedbala Name: R. Sam Niedbala	By: /s/ Mike Gausling Name: Mike Gausling Title: Managing Member
ATTEST:	ORASURE TECHNOLOGIES, INC.
By: /s/ Jack E. Jerrett Name: Jack E. Jerrett Title: (Assistant) Secretary	By: /s/ Ronald H. Spair Name: Ronald H. Spair Title: Executive Vice President and Chief Financial Officer

(Corporate Seal)

REVISED EXHIBIT B

(As Revised Pursuant to Section 1(d) of the Lease and Amendment No. 1 to Commercial Lease, dated as of October 21, 2002))

Document Follows

EXHIBIT B

PROJECT BUDGET

Basic Construction		$3,015,000
Land Purchase		436,000
Interest Payments		50,000
Banking - Commitment Fees		16,000
Insurance Expense		8,000
Miscellaneous		25,000
	Subtotal	$3,550,000
Tenant Finish Work Allowance		2,950,000
		$6,500,000
Landlord Equity Contribution		$3,300,000
Landlord Borrowing Amount		$3,200,000
	Total	$6,500,000

REVISED EXHIBIT H

(As Revised pursuant to Amendment No. 1 to Commercial Lease,
dated as of October 21, 2002)

Document Follows

REVISED EXHIBIT H

RENEWAL TERM RENT

LEASE MONTH	RENTABLE SQ. FEET	ANNUALIZED BASE RENT	MONTHLY BASE RENT	BASE RENT RATE/SF
121-180	48,000	$975,360.00	$81,250.00	$20.32

DISTRIBUTION AGREEMENT

This Agreement ("Agreement") is entered into as of October 11, 2002 between bioMerieux, Inc., a Missouri corporation ("BMX"), and OraSure Technologies, Inc., a Delaware corporation ("OSUR").

BACKGROUND

BMX, through its predecessor, Organon Teknika Corporation, a Delaware corporation, and OSUR, through its predecessor, Epitope, Inc., an Oregon corporation, previously entered into a Supply Agreement (the "Original Supply Agreement") and Distribution Agreement (the "Original Distribution Agreement"), each dated as of April 1, 1994. Pursuant to the Original Supply Agreement, BMX agreed to supply all of OSUR's requirements of Antigen (as defined below) in connection with the research and development, manufacture, use and sale of Products (as defined below) to BMX under the Original Distribution Agreement. Pursuant to the Original Distribution Agreement, OSUR appointed BMX and its Affiliates (as defined below) as exclusive distributor of the Products within the Territory (as defined below). BMX and OSUR desire to enter into this Agreement in order to amend and restate the terms of the Original Supply Agreement.

AGREEMENT

In consideration of the mutual covenants contained herein, and the premises set forth above, the parties hereby amend and restate the Original Distribution Agreement in its entirety, as follows:

1. Definitions. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in the Supply Agreement.

1.1 "Affiliate" shall mean any individual or entity that controls, is controlled by, or is under common control with, the specified party. For purposes of this definition, "control" shall mean direct or indirect beneficial ownership of more than 50% of the voting stock, ownership interest or income interest in an entity.

1.2 "Antigen" shall mean the Antigen, as that term is defined in the Supply Agreement (as defined below), which is supplied to OSUR, pursuant to the Supply Agreement, for the production of the appropriate Products.

1.3 "Territory" shall mean the entire world.

1.4 "Products" shall mean oral fluid confirmatory tests for HIV-1 manufactured from time to time during the Term by OSUR using the Antigen. For reference purposes, a list of current Products is contained in Exhibit 1.4 attached hereto.

1.5 "Specifications" shall mean those specifications concerning the Products as set forth in Exhibit 1.5, or such other specifications as may be established pursuant to Article 7 hereof.

1.6 "Supply Agreement" shall mean that certain Supply Agreement entered into by BMX and OSUR as of the date hereof, which amends and restates the Original Supply Agreement.

1.7 "Term" shall have the meaning described in Section 13.1.

1.8 "Transfer Price" shall mean the price per Test set forth on Exhibit 1.8, subject to adjustment as provided in Section 3.1.

1.9 "Test" shall mean an individual confirmatory test strip for HIV-1 contained in a Product kit for HIV-1 testing.

2. Distributorship.

2.1 OSUR hereby appoints BMX and its Affiliates as the exclusive distributor to sell the Products within the Territory. "Exclusive" shall mean that OSUR will not distribute or sell, or appoint any other person or entity to distribute or sell, the Products. OSUR shall not be permitted to appoint any other person or entity to distribute or sell the Products.

2.2 BMX hereby accepts such appointment and shall use its best efforts to promote and sell Products. Notwithstanding the foregoing, if (a) at any time BMX desires to market and sell a confirmatory test that can be used with any specimen type other than oral fluid, or (b) after June 30, 2004, a new confirmatory test becomes available for marketing and sale in the United States that (i) simultaneously confirms the presence of HIV-1 plus HIV-2 or HIV-0 and (ii) has received FDA approval for testing an oral fluid sample collected with an FDA-approved oral fluid collection device, then, upon written notice to OSUR from BMX stating that it desires to market and sell such a confirmatory test or that such an oral fluid confirmatory test has become available, and in each case identifying the specific confirmatory test, BMX may market and sell the confirmatory test which it identified and, during the period in which BMX markets and sells such confirmatory test, BMX shall be relieved of its obligations to use best efforts to promote and sell Products and instead shall use commercially reasonable efforts to sell Products as necessary to satisfy the continuing demand for the Products for the remainder of the Term. BMX represents that it is not aware of any confirmatory test intended for use in detecting any strain of HIV in oral fluid or any oral fluid collection device intended for HIV testing, that are currently in development.

2.3 The parties are independent businesses and neither has nor will have any power, right, or authority, nor will either party represent that it has any power, right, or authority, to bind the other or to assume or to create any obligation or responsibility, express or implied, on behalf of the other. Nothing stated in this Agreement shall be construed as constituting BMX and OSUR as partners or as creating relationships of employer and employee, master and servant, or principal and agent between the parties.

2.4 This Agreement gives BMX and its Affiliates the right to purchase Products from OSUR and to resell them in accordance with the terms and conditions of this Agreement. BMX's compensation, if any, will come solely from the margin between the price it pays for Products and the price at which it sells those Products. Except as may be provided elsewhere herein, BMX has no right to any compensation from OSUR.

2.5 BMX shall maintain records of all sales of Products, which records shall include the name and address of the purchaser, the date of purchase, and quantity and lot number of the Products sold. If required by regulatory authorities, BMX shall furnish, during normal working hours, such information to said regulatory authorities upon OSUR's request at no charge. BMX shall not remove, deface, or otherwise obliterate any labeling placed upon Products by OSUR.

2.6 As consideration for BMX agreeing to amend and restate the Original Supply Agreement and Original Distribution Agreement and entering into this Agreement and the Supply Agreement, OSUR shall pay an aggregate of $750,000 in fees to BMX, as follows:

2.6.1 $250,000 upon BMX's execution and delivery of this Agreement and the Supply Agreement, $250,000 on or before December 31, 2002 and $250,000 on or before March 31, 2003.

2.6.2 Payment of the foregoing fees shall be made by wire transfer by OSUR to an account designated in writing by BMX.

2.6.3 OSUR acknowledges and agrees that the payment of such fees is an irrevocable commitment, and payment thereof is non-refundable and may not be offset, reduced or delayed for any reason whatsoever. In connection therewith, OSUR has agreed to execute and deliver to BMX a Promissory Note in the form attached hereto as Exhibit 2.6.3, to evidence its commitment to make the payments due December 31, 2002 and March 31, 2003.

3. Price; Payment.

3.1 BMX shall pay OSUR an amount equal to the Transfer Price for the Products sold hereunder. Commencing on January 1, 2004 and on each January 1 thereafter during the Term, OSUR may increase the Transfer Price for Products purchased during the calendar year beginning on such January 1, upon sixty (60) days prior written notice to BMX, by an amount equal to the percentage change in the Consumer Price Index published by the United States Bureau of Labor Statistics of the United States Department of Labor during the twelve (12) consecutive calendar months immediately prior to the date of the notice for which data (either preliminary or final) is then available. Comparisons shall be made using the index entitled U.S. City Average - All Items and Major Group Figures for All Urban Consumers (1982-84 = 100), or the nearest comparable data on changes in the cost of living if such index is no longer published. The Transfer Price shall not include sales, use or similar taxes, and BMX shall be responsible for payment of any such taxes.

3.2 BMX shall pay OSUR within thirty (30) days of the date of OSUR's invoice, which invoice shall not be dated earlier than the date of shipment of Products. Amounts not paid when due shall bear interest from the invoice date at one (1) percent per month or, if less, the highest rate of interest permitted under applicable law.

4. Purchase Orders; Forecasts.

4.1 All purchases of Products pursuant to this Agreement shall be effected by BMX's issuance of purchase orders. Each purchase order shall contain the following information: Product(s), quantity, delivery date(s) (in accordance with the applicable forecast unless otherwise agreed), dating, routing instructions, destination and confirmation of price. For accounting convenience, each purchase order may bear a separate number having no numerical relationship to this Agreement. No term or condition contained in any such purchase order shall alter, amend, modify or supplement OSUR's obligations hereunder unless specifically agreed to in writing by OSUR. OSUR shall accept purchase orders by facsimile. BMX shall submit orders at least 90 days in advance of the requested delivery date. OSUR may, but shall not be required to, accept orders placed less than 90 days before the requested delivery date.

4.2 By the last day of each calendar month, BMX shall provide OSUR with a forecast of the quantity of Products that BMX expects to order for shipment for each month during the next 12 months. The forecast shall constitute a binding commitment by BMX to purchase not less than the quantity of Product stated for each of the first three (3) months of the forecast. OSUR shall use its best efforts to meet all delivery dates for Products up to the amounts specified in the applicable forecast and shall use commercially reasonable efforts to meet requested delivery dates for Products ordered by BMX in excess of such quantities.

5. Product Assembly.

5.1 Each unit of Product shall consist of Tests in strips or other components assembled and packaged together in a unit for sale, all as described in the Products' package inserts attached to Exhibit 1.5. With respect to any new Product, its package insert shall be added to and become a part of Exhibit 1.5. OSUR will assemble the Products for BMX and, subject to the provisions of Article 10 hereof, agrees to label the Products with BMX's label in accordance with text supplied by BMX and the Specifications. BMX will supply camera-ready art for such labels. Said labeling shall also contain appropriate lot and kit numbers and product expiration dates, which lot numbers and expiration dates shall be provided by OSUR.

5.2 OSUR shall be responsible for boxing, crating, handling, storage and other packing requirements prior to shipment. All Products shall be packaged, marked and otherwise prepared for shipment in a manner which is (i) in accordance with good commercial practice, (ii) acceptable to common carriers for shipment at the lowest reasonable rate and (iii) adequate to insure safe arrival of the Products. All such costs shall be paid by OSUR.

6. Delivery; Acceptance; Returns.

6.1 All Products shall be delivered EX WORKS (Incoterms 2000) OSUR's facility. Products shall be shipped by air express or air freight. The cost of shipping shall be borne by BMX. In the event any shipment exceeds OSUR's validated transit time (currently 24 hours), BMX may refuse and return the shipment to OSUR, at OSUR's expense. OSUR shall forward to BMX a Certificate of Conformance with each lot of Product certifying that the Products conform to the Specifications, and shall provide a copy of such Certificate to BMX's purchasing agent within 24 hours after shipment. OSUR shall not deliver any Product more than five (5) days in advance of BMX's requested delivery date, and BMX may return any such Product to OSUR at OSUR's expense for subsequent delivery to BMX in conformance with the applicable purchase order.

6.2 OSUR shall inspect all Products prior to shipment to BMX. All Products shall be subject to inspection and acceptance by BMX. BMX shall inspect incoming Product in accordance with the inspection procedures and criteria set forth in Exhibit 6.2 hereto. Any Product which fails to pass the incoming test or inspection requirements (based on the quality control specifications for each Product) may be rejected by BMX. Unless otherwise mutually agreed, BMX shall have 30 days from the receipt of Product to inspect such Product and notify OSUR in writing of BMX's rejection of any Product. Inspection by and acceptance of, or any failure to inspect or accept, any Product by BMX shall in no way relieve OSUR of its obligation to deliver Product in accordance with the warranties set forth in Article 8 or otherwise comply with this Agreement.

6.3 BMX is authorized upon reasonable notice to OSUR and during normal business hours to inspect OSUR's manufacturing facilities and operations and quality control records to review compliance with Product Specifications, FDA Quality Systems Regulations and this Agreement. All such inspection and review shall be subject to the obligations of confidentiality set forth in Article 12 hereof. Any such inspection or right to inspect by BMX shall in no way relieve OSUR of its obligation to deliver conforming Products and shall in no way

waive BMX's rights to inspect and accept or reject Products. OSUR shall advise BMX promptly in writing (including a description of any and all observations or notices made or given) of any inspection of its facilities by any governmental or regulatory agency or authority and of any other governmental or regulatory action, actual or threatened, or any other problem, condition or issue related to the Product, which OSUR's management reasonably believes, or should reasonably believe, may substantially and adversely affect the Products or OSUR's performance of its obligations under this Agreement (including, without limitation, OSUR's obligation to comply with applicable laws and regulations). In addition, at BMX's request, OSUR shall make available for review by the FDA the manufacturing and control documentation required in connection with any FDA approvals, which may be accomplished in any manner acceptable to the FDA, including the filing of a suitable master file.

6.4 OSUR shall retain 3 units from each lot of Product manufactured and shall retain such units as samples for the stated shelf life of the Product. All samples retained shall be stored in accordance with the Specifications and shall be made available for inspection and testing by BMX.

6.5 BMX shall market the Products in accordance with their intended purpose, as specified in the Specifications and any Product inserts. BMX shall not instruct any of its customers to use the Products in any manner inconsistent with such Product's intended purpose or any Product inserts.

7. Changes in Specifications. BMX may, at any time, make written requests for changes in the Specifications as reasonably necessary to meet market demands, provided that such change shall have no effect upon any FDA or other governmental approval. If any requested change causes an increase or decrease in the cost of or time required in the performance for an order, such change shall not be implemented until an equitable adjustment in the price or delivery schedule or both has been agreed upon. OSUR shall notify BMX in writing at least 30 days prior to making any changes in Specifications, and shall not make any changes that would adversely affect Product performance without BMX's prior written approval, unless required by the FDA. Any change in Specifications shall be subject to the warranties given by OSUR as set forth in Article 8 hereof.

8. Warranties.

8.1 OSUR warrants that it has full right and title to the Products and has authority to sell the Products to BMX. OSUR further warrants to BMX that, for the stated shelf-life of the Products, but not less than eight (8) months, such Products will conform to the Specifications; that in the production of the Products OSUR will comply with the FDA Quality System Regulations, as well as the then current good manufacturing practices, good laboratory practices and all other applicable requirements of the FDA, and with all other applicable Federal, state and local laws and regulations; and that for the stated shelf-life of the Products, but not less than eight (8) months, such Products will be free from defects in materials and workmanship. The foregoing warranties as to the quality of the Products shall not apply to any Products that have been subjected to misuse, mishandling, storage in a manner inconsistent with labeling, neglect, modification or unusual physical or chemical stress after delivery to BMX or which are defective because of Antigen supplied by BMX which does not meet the warranties therefore set forth in the Supply Agreement. THE FOREGOING WARRANTIES ARE THE SOLE AND EXCLUSIVE WARRANTIES MADE BY OSUR AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF

MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE EXPRESSLY DISCLAIMED.

8.2 OSUR shall indemnify, defend and hold harmless BMX from all claims, suits, liabilities, damages and expenses (including reasonable attorney fees) incurred on account of any third party product liability claims or recalls, resulting from, arising out of or connected with OSUR's breach of any of the foregoing warranties or its other obligations under this Agreement; provided, however, that the foregoing indemnity shall not extend to any claim, suit, liability, damage or expense of any kind attributable to the negligent conduct of BMX or to a defect in Products resulting solely from defective Antigen supplied by BMX.

8.3 In the event OSUR or BMX, upon advice of legal counsel, determines that a license from a third party or third parties is required to enable OSUR to make and sell the Products without infringing patent rights of any such parties, then OSUR shall use its best efforts to obtain such license. If OSUR is unable or unwilling to obtain such a license within 6 months after such determination is made, then BMX shall be free to negotiate with such third party for a license. In the event neither party obtains a license from the third party, either party shall be entitled to cancel any pending purchase commitments and to terminate this Agreement.

8.3.1 Provided BMX has approved of the license agreement to OSUR , OSUR may add the agreed net royalty which is due the third party to the Transfer Price for each Test, which royalty shall be paid by BMX.

8.4 It shall be a condition to OSUR's indemnification obligation that BMX follow the procedures set forth below:

8.4.1 BMX shall promptly notify OSUR upon learning of any claim for which indemnification may be sought; provided however failure to give such prompt notice shall only relieve OSUR of its obligation to provide indemnification to the extent such failure has a materially adverse effect which limits OSUR from making a proper defense of such claim.

8.4.2 BMX shall permit OSUR to control the response to and any settlement or defense of any claim as to which indemnification may be sought, but may require that any settlement agreement impose no obligation on BMX other than the payment of monetary damages for which OSUR indemnifies BMX. BMX's written consent, not to be unreasonably withheld, shall be required on any term other than the payment of such damages. BMX shall have the right to participate in the response to and any settlement or defense of the claim using its own counsel at its own expense. If OSUR fails within a reasonable time to respond to and undertake a settlement or defense of the claim, BMX shall have the right, but not the obligation, to undertake such response, settlement, and defense, at OSUR's expense and risk.

8.4.3 BMX shall cooperate fully with OSUR with respect to any claim for which indemnification is sought, making available all information and assistance that OSUR may reasonably request and that is under BMX's control.

9. Regulatory Matters.

9.1 OSUR has obtained approval of a Pre-Market Approval Application ("PMA") for the Products from the FDA. If any change to the Specifications requires a supplement to the PMA, OSUR will use commercially reasonable efforts to prepare, file and prosecute the necessary regulatory submission. OSUR shall bear the cost of generating any

supporting clinical data required in connection with the submission unless OSUR is making the change at BMX's request, in which event BMX shall bear such cost.

9.2 No changes or amendments shall be made to OSUR's PMA if such changes or amendments would involve changes to the Specifications or would adversely affect the performance of the Products, unless BMX has given its prior written approval. The parties acknowledge that OSUR intends to change the manufacturing location for the Products from Beaverton, Oregon to Bethlehem, Pennsylvania and nothing in this Agreement shall preclude OSUR from doing so, so long as OSUR manufactures the Products in Bethlehem, Pennsylvania in accordance with this Agreement.

9.3 BMX shall not market the Products in any country in which all appropriate regulatory approvals have not been obtained.

10. Labeling; Trademarks.

10.1 All Products shall be labeled in accordance with BMX's chosen format and specifications (e.g., under BMX's name and trademark(s)), which shall be reasonably acceptable to OSUR and shall include, to the extent required by the FDA or other applicable governmental authority, OSUR's name and other information pertaining to OSUR. A copy of the current Product labeling which is acceptable to BMX is attached as Exhibit 10.1. BMX shall be responsible for ensuring that such labeling conforms to all applicable law in each jurisdiction in which the Products are sold, and shall indemnify and hold harmless OSUR against any and all claims, losses, or damages arising out of or in any way resulting from BMX's failure to do so.

10.2 Neither party shall acquire any right, title or interest in any trademark, trade name, logo or copyright of the other party by reason of this Agreement, except for the rights hereby granted to BMX to use trademarks, trade names, logos and copyrights of OSUR to distribute and promote the Products during the Term. BMX's rights to use OSUR's trademarks, trade names, logos or copyrights shall terminate upon the termination or expiration of this Agreement; provided however, BMX may continue to use them for a reasonable time after such termination or expiration in connection with the promotion and sale of any remaining Products in inventory upon termination or expiration of this Agreement. Each party shall be responsible for registering, as necessary, its own trademarks, trade names, logos and copyrights.

11. Complaints; Recalls. Customer complaints and recalls shall be handled pursuant to the criteria set forth in Exhibit 11.

12. Confidentiality.

12.1 Each party shall take such steps and, when necessary to protect the rights of the other, shall cause its Affiliates to take such steps as are reasonably required to protect and keep confidential, and shall not use, publicize or otherwise disclose to third parties other than Affiliates, Confidential Information (as defined below) of the other party (or its Affiliates), which Confidential Information was acquired from the other party (or its Affiliates) pursuant to this Agreement, including, without limitation, following procedures designed to limit access to such Confidential Information to those persons having the need to know it. The parties shall not disclose or use such Confidential Information except as they may be entitled to do so under this Agreement or if necessary pursuant to or in the performance of this Agreement.

12.2 The obligation of confidentiality and restriction on use imposed by the foregoing Section 12.1 shall not apply to any particular item of Confidential Information that:

12.2.1 is known or generally available, or subsequently becomes known or generally available, to the public, or is otherwise at the time of disclosure or subsequently becomes part of the public domain, whether by printed publication or otherwise, through no fault of the receiving party;

12.2.2 the receiving party can demonstrate by competent evidence, based in substance upon writings and/or physical evidence, (i) was known to the receiving party at the time of receipt or (ii) is furnished to the receiving party without obligation of confidentiality or nonuse by a third party, either before or after the time of its disclosure by the disclosing party, which third party is not restricted by confidential undertaking to the disclosing party at the time of the disclosure;

12.2.3 the receiving party can demonstrate by competent evidence, based in substance upon writings and/or physical evidence, has been developed independently by the receiving party by persons not having access to the Confidential Information; or

12.2.4 is the Confidential Information of the disclosing party that the disclosing party discloses to a non-Affiliate without restriction.

12.3 The obligations of confidentiality and restriction on use under this Article 12 shall continue to be binding upon the parties, for a period of five years following termination or expiration of this Agreement.

12.4 Either party may also disclose Confidential Information disclosed to it by the other party to the extent, and only to the extent, such disclosure is necessary for such party to comply with applicable governmental laws or regulations, including disclosures in any regulatory filings required in connection with the Products. The party that desires to so disclose Confidential Information shall give the other party reasonable advance notice of any such proposed disclosure pursuant to such compliance with law or regulation, shall use its best efforts to secure confidential treatment of the Confidential Information thus disclosed, and shall advise the other party in writing of the manner in which that was done.

12.5 For purposes of this Agreement, Confidential Information shall mean: (a) data, inventions, information, processes, know-how, patent applications, trade secrets and similar intellectual property rights of a party, including, without limitation, the original and copies of all documents, inventions, laboratory notebooks, drawings, specifications, devices, equipment, prototype models and tangible manifestations embodying any technology disclosed hereunder, (b) a party's customer lists and marketing, sales, costs, royalty and similar information related to the manufacture or sale of Antigen, Vironostika Assays or Products, and (c) any other information disclosed in writing and marked as "Confidential Information" or, if disclosed orally, reduced to writing and marked as "Confidential Information" and submitted within thirty (30) days of the original oral disclosure.

13. Term; Termination.

13.1 The initial term of this Agreement shall commence on the date first written above and shall continue until December 31, 2005 (the "Initial Term"), unless terminated earlier as provided below; provided, however, that this Agreement shall automatically renew for successive additional periods of one year each (each a "Renewal Term" and together with the Initial Term, the "Term") unless either party gives the other written notice of its election not to

renew this Agreement, which notice must be given not less than 180 days prior to the expiration of the Initial Term or applicable Renewal Term. In the event FDA approval for the use of BMX's HIV-O-TEK HIV-1 assay to detect HIV-1 in an oral fluid sample collected with an OraSure(R) Oral Specimen Collection Device is received on or before December 31, 2004, the Initial Term shall automatically be extended to December 31, 2007 (notwithstanding either party giving notice of its election not to renew).

13.2 Without waiving any other rights BMX may have hereunder, BMX shall have the right to terminate this Agreement at any time within 90 days following the occurrence of any of the following events:

13.2.1 OSUR fails on more than one occasion in any calendar year to deliver Products within 20 working days after the delivery dates established pursuant to Article 4 unless such failure results from BMX's failure to supply Antigen or Vironostika Assays under the terms of the Supply Agreement or unless BMX elects the remedy provided in Section 13.3 hereof;

13.2.2 The Products delivered do not conform to the applicable Specifications or warranties contained in this Agreement, provided such failure does not result from BMX's failure to supply Antigen or Vironostika Assays which meet the specifications set forth in the Supply Agreement, and OSUR does not provide conforming replacement Products within 10 days after notice of the nonconformity;

13.2.3 OSUR is in material breach of any of the other provisions of this Agreement or of any purchase order issued pursuant to this Agreement and such breach is not cured within 30 days of written notice thereof to OSUR;

13.2.4 OSUR becomes insolvent or files a voluntary petition in bankruptcy; OSUR makes an assignment for the benefit of creditors; a receiver, trustee in bankruptcy or similar officer is appointed to take charge of all or part of OSUR's assets/property; or an involuntary petition of bankruptcy is filed against OSUR and, in the case of any of the foregoing, the same are not removed within 30 days; or

13.2.5 The Supply Agreement expires without being renewed or is terminated other than for default of BMX.

13.3 In the event OSUR is in breach of Section 13.2.1 or Section 13.2.4 hereof and such breach is not promptly remedied, BMX may elect not to terminate this Agreement but may instead assume the manufacture of, or may have manufactured, the Products until such time as OSUR gives 60 days written notice that it is able to resume production and delivery of the Products in accordance herewith; provided, however, BMX may revoke such election at any time and terminate this Agreement by giving written notice thereof to OSUR. If BMX makes such an election, OSUR will provide BMX the know-how, data, documentation and technical assistance, at BMX's expense, which is reasonably necessary for BMX to manufacture the Products. During the time BMX is manufacturing the Products, OSUR shall be relieved of its obligations under Articles 4, 5, 6, 8, 9, 10, 11, and 14 hereof; provided however such obligations shall only be relieved with respect to Products manufactured by BMX or others at BMX's request.

13.4 Without waiving any other rights OSUR may have, OSUR shall have the right to terminate this Agreement at any time within 90 days following the occurrence of any of the following events:

13.4.1 BMX is in material breach of any of the provisions of this Agreement and such breach is not cured within 30 days of written notice thereof to BMX (15 days for breach of payment terms);

13.4.2 BMX becomes insolvent or files a voluntary petition in bankruptcy; BMX makes an assignment for the benefit of creditors; a receiver, trustee in bankruptcy or similar officer is appointed to take charge of all or part of BMX's assets; or an involuntary petition of bankruptcy is filed against BMX, and in the case of any of the foregoing, the same are not removed within 30 days;

13.4.3 The Supply Agreement expires without being renewed or is terminated other than for default of OSUR; or

13.4.4 The regulatory approvals necessary to allow OSUR to manufacture and sell the Products for commercial purposes in the United States are withdrawn, provided OSUR has used its best efforts to maintain such approvals and to prevent such withdrawal.

13.5 Termination or expiration of this Agreement shall not relieve any party from performance of any obligation then due nor affect any rights accrued prior to the effective date of such termination or expiration.

14. Insurance. During the Term of this Agreement, each party shall maintain comprehensive general liability insurance, including product liability insurance, through a carrier reasonably satisfactory to the other, that will adequately insure it against risks associated with the manufacture, use and sale of Products in an amount not less than $4,000,000 per occurrence. Evidence of such insurance shall be furnished to the other party upon request.

15. Taxes and Duties. BMX shall have the sole responsibility to pay all import duties and fees, taxes and other charges levied by government authorities upon or in connection with any transaction covered by this Agreement, including, without limitation, taxes on sales, use, transactions or inventory, and value added taxes.

16. Related Products.

16.1 HIV-O-TEK Assay.

16.1.1 OSUR will conduct, at its cost, the pre-clinical and clinical trials required to obtain a claimed indication for BMX's new HIV-O-TEK HIV-1 assay for testing of an oral fluid sample collected with the OraSure(R) Oral Specimen Collection Device. BMX will provide all HIV-O-TEK HIV-1 assays required for the trials. OSUR shall pay BMX for 50% of BMX's cost for up to the first 25,000 HIV-O-TEK HIV-1 assays required for the pre-clinical and clinical trials, and shall pay BMX's cost for all such additional HIV-O-TEK HIV-1 assays required therefore. For purposes of this Section 16.1.1, BMX's cost shall not exceed $**** per test.

16.1.2 The parties have met and will continue to meet to clarify what FDA submissions will be required and which party will prepare and make such submissions. Subject to further discussions between the parties and with the FDA, OSUR will use its best efforts to complete all pre-clinical and clinical trials and prepare a report of the results of such trials, in a format reasonably acceptable to the parties, by August 31, 2003, so that whichever party must file the submission(s) may do so by September 30, 2003. The foregoing best efforts obligation of OSUR is subject to (i) BMX providing timely cooperation in developing a regulatory filing strategy and clinical trial protocol that

is reasonably acceptable to the parties and acceptable to the FDA, (ii) BMX providing sufficient quantities of its HIV-O-TEK HIV-1 assay in a timely manner as required for the pre-clinical and clinical trials, (iii) the HIV-O-TEK HIV-1 assays provided by BMX performing at a level required to meet the FDA approval requirements for the detection of HIV-1 in an oral fluid sample, and (iv) BMX receiving FDA approval of its current PMA submission for the HIV-0-TEK HIV-1 assay on or prior to September 30, 2003.

16.1.3 OSUR shall be responsible for developing a protocol for conducting the clinical trials in the most economical and expeditious manner possible and BMX will cooperate in developing such protocol. The parties shall also develop an action plan, specifying the respective responsibilities of each party with respect to other requisite actions in seeking regulatory approval. Further, the parties shall agree upon a definition of "intended use" for purposes of presentation to the FDA. Thereafter, the parties shall present the proposed protocol, action plan and definition of intended use to the FDA for its review and concurrence prior to beginning clinical trials. The parties shall use their reasonable best efforts to meet with the FDA regarding these matters. Such modifications as necessary to obtain FDA concurrence will be negotiated between the parties. The party determined to be responsible for preparing an FDA submission and each additional action item, based on discussions between the parties and the FDA, shall use its best efforts to file and prosecute such submission and complete the other actions in as prompt a manner as is reasonably possible. The scope of the pre-clinical and clinical trials shall be determined pursuant to the protocol reasonably developed by the parties and approved by the FDA.

16.2 Vironostika Assay Availability. BMX will use commercially reasonable efforts to continue to make available its Vironostika Assay on commercially reasonable terms to its customers that purchase or use the OraSure(R) Oral Specimen Collection Device until receipt of FDA approval for the use of BMX's HIV-O-TEK HIV-1 assay to detect HIV-1 in an oral fluid sample collected with an OraSure(R) Oral Specimen Collection Device. Notwithstanding the foregoing, in the event the FDA submissions, contemplated by Section 16.1, have not been filed by September 30, 2003, or the FDA approval for HIV-0-TEK referred to in the preceding sentence is not received by December 31, 2004, and in each such case such failure is not attributable solely to the acts or omissions of BMX, then BMX shall have no further obligation pursuant to this Section 16.2.

16.3 New Collection Device. OSUR does not currently plan to commercialize its OraSure(R) II Oral Specimen Collection Device (the "OraSure(R) II Device"). If, at the request of BMX, OSUR elects to seek FDA approval of either the OraSure(R) II Device or an improved version of its OraSure(R) Oral Specimen Collection Device for the detection of HIV-1 in oral fluid (it being understood that such election shall be at OSUR's sole discretion), OSUR and BMX each agree that either of BMX's Vironostika or another of BMX'sHIV-1 assays then available on the market will be included in the clinical trials for qualification with OSUR's new device, provided that (i) OSUR shall have no obligation to make changes to its new device necessary for the Vironostika or other assay to be so qualified; (ii) if the Vironostika or other HIV-1 assay becomes qualified for use with OSUR's new device, BMX shall continue to make the Vironostika or other HIV-1 assay used in such clinical trials available on commercially reasonable terms to customers purchasing OSUR's new collection device for a period of at least 2 years after receipt of FDA approval, (iii) BMX provides all Vironostika or other HIV-1 assays required for the pre-clinical and clinical trials and testing at no cost to OSUR and agrees to use best efforts to file and prosecute, at its cost, any FDA submission which it must file in order to qualify its assays for use with OSUR's new device, and (iv) the parties shall agree in good faith to an equitable sharing of the costs of obtaining FDA approval.

17. Miscellaneous.

17.1 Force Majeure. Neither party shall be liable for any delay or default in such party's performance if such default or delay is caused by any event beyond the reasonable control of such party, including, but not limited to, acts of God; war; insurrection; civil commotion; labor disturbances, epidemic, or destruction of production facilities or materials by earthquake, fire, flood or storm, or other similar event. The party suffering such cause shall immediately notify the other party of the cause and the expected duration of such cause. Neither party shall be liable to the other for any such delay or default.

17.2 Notices. Notices required or permitted hereunder shall be in writing and shall be personally delivered or sent by registered or certified mail, or facsimile (with confirmation by first class mail) or telex to the addresses set forth below or to such other address in the United States that the parties may hereafter specify, and shall be effective upon receipt:

If to BMX:

bioMerieux, Inc.
100 Rodolphe Street
Durham, NC 27712
Attn: President
Copy: General Counsel
Facsimile: (919) 620-2519

If to OSUR:

OraSure Technologies, Inc.

150 Webster Street
Bethlehem, PA 18015
Attn: President
Copy: General Counsel
Facsimile: (610) 882-2275

17.3 Governing Law. The rights of the parties under this Agreement shall be governed by the laws of the State of North Carolina, excluding choice of law rules and excluding the United Nations Convention on the International Sale of Goods.

17.4 Assignment. This Agreement and the rights and obligations arising hereunder may be assigned to an Affiliate, or to a third party, in whole or in part, by either party with the prior written consent of the other. Such consent shall not be unreasonably withheld. Notwithstanding the above, this Agreement may be assigned by either BMX or OSUR to a third party which succeeds to all or substantially all of the assigning party's business, whether by merger, consolidation, sale or otherwise, without the consent of the non-assigning party, except that, in the event of an assignment by OSUR to any party reasonably deemed a competitor of BMX, as defined below, by BMX, BMX retains the right to refuse such assignment. A competitor of BMX shall mean an entity that competes with BMX in the manufacture, distribution or sale of diagnostic products. Subject to the restrictions on assignment set forth herein, this Agreement shall inure to the benefit of and bind the successors and permitted assigns of each of the parties.

17.5 Entire Agreement. From the effective date hereof, this Agreement (together with all Exhibits), the Supply Agreement and that certain Release and Settlement Agreement of even date herewith between the parties (the "Release"), set forth and constitute the entire agreement between the parties with respect to the subject matter hereof, and supersede any and all other prior agreements, understandings, promises and representations made by either party to the other concerning the subject matter hereof; provided, however, that any sales of Products which occurred under the Original Distribution Agreement or which are pending as of the date of this Agreement, and the parties' rights and obligations with respect thereto, shall continue to be governed by the terms of the Original Distribution Agreement. This Agreement may not be released, discharged, amended or modified in any manner except by an instrument in writing, making specific reference to this Agreement, and signed by duly authorized representatives of both parties.

17.6 Waiver. No waiver of any right under this Agreement shall be deemed effective unless contained in writing and signed by the party charged with such waiver, and no waiver of any right arising from any breach or failure to perform shall be deemed to be a waiver of any future right or any other right arising under this Agreement.

17.7 Survival. Articles 8, 11, 12, 17 and Sections 10.1 (indemnity only) and 10.2 shall survive expiration or termination of this Agreement notwithstanding the delivery, acceptance or payment for Products.

17.8 Severability. If any provision of this Agreement is held invalid by any law, rule, order or regulation of any government or by the final determination of any state or federal court, such invalidity shall not affect the enforceability of all other provisions of this Agreement not held to be invalid.

17.9 Compliance with Law. Each party shall comply with all applicable laws, rules and regulations, including FDA regulations, in its performance under this Agreement.

17.10 Captions. Captions and section headings of this Agreement are for convenience of reference only and shall not affect the interpretation or meaning of this Agreement.

17.11 Attorney Fees. In the event suit or action or arbitration is instituted to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to recover from the other party such sum as the court or arbitrator may adjudge reasonable as attorney fees at trial or arbitration, on appeal, and on any petition for review, in addition to all other sums provided by law; provided, however, such sums shall not exceed the damages awarded to the prevailing party.

17.12 Press Release. Neither party shall make any public disclosure (including press releases) of the terms of this Agreement without the prior written consent of the other party, except to the extent required by securities or other laws in the reasonable opinion of such party or its counsel. If a party intends to issue a press release regarding this Agreement, it shall provide the proposed release by facsimile or otherwise to the other party at least twenty-four (24) hours before the release is issued and shall make any changes reasonably requested by the other party before the release is issued.

17.13 Alternate Dispute Resolution. The parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter cannot be resolved in the normal course of business, either party shall give the other party written notice of any such dispute not resolved, after which the dispute shall be referred to senior executives of both parties, who shall likewise attempt to resolve the

dispute. If the dispute has not been resolved by negotiation within forty-five (45) days of the disputing party's written notice or if the parties fail to meet within twenty (20) days from such notice, the parties shall endeavor to settle the dispute by mediation under the supervision of and in accordance with the Center for Public Resources ("CPR") Model Mediation Procedure for Business Disputes. Unless otherwise agreed, both parties and either individual party may request the CPR to appoint an independent mediator. The location of the mediation shall be agreed upon by both parties and, in the event parties do not timely agree, the location will be determined by the mediator. Any dispute not settled by the mediation referenced above within sixty (60) days after appointment of a mediator may, upon the request of either party, be submitted to arbitration in accordance with the CPR Arbitration Rules and Commentary. A single, impartial arbitrator mutually acceptable to the parties shall conduct the arbitration. In the event the parties cannot agree on an arbitrator within twenty-one (21) days after the end of the aforesaid sixty (60) days, either party may have an arbitrator appointed by the CPR. The location of the arbitration shall be agreed upon by both parties. As a condition of appointment of the arbitrator, said arbitrator shall agree to use her/his best efforts to conclude the proceeding within sixty (60) days. Said arbitrator shall further have the authority to limit the volume of evidence and documents to be submitted by the parties. Any court having jurisdiction thereof may enter judgment upon the award rendered by the arbitrator. This Section 17.13 shall, however, not be construed to limit or to preclude either party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief as necessary or appropriate.

17.14 Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be an original and together all such counterparts shall constitute a single instrument. A facsimile transmission of a signed counterpart shall be the same as delivery of an original.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date and year first written above.

bioMerieux, Inc.	OraSure Technologies, Inc.
By: /s/ Brian W. Armstrong	By: /s/ Mike Gausling
Name: Brian W. Armstrong	Name: Mike Gausling
Title: CFO	Title: CEO

EXHIBIT 1.4

PRODUCTS

PRODUCT	OSUR Part Number
ORASURE ORAL FLUID WESTERN BLOT KIT	501-0000

EXHIBIT 1.5

SPECIFICATIONS

HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)

OraSure(R) HIV-1 Western Blot Kit

An Enzyme Immunoassay for the Detection of Antibodies
to Human Immunodeficiency Virus Type 1 (HIV-1)
in Human Oral Fluid Specimens Obtained with
OraSure(R) HIV-1 Oral Specimen Collection Devices

20 Tests

Store at 2-8(degrees)C

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NAME AND INTENDED USE

The OraSure(R) HIV-1 Western Blot Kit is an in vitro qualitative assay for the detection of antibodies to individual proteins of the Human Immunodeficiency Virus Type 1 (HIV-1) in human oral fluid specimens obtained with the OraSure HIV-1 Oral Specimen Collection Device. For convenience, the collection device will hereafter be referred to as "OraSure". The OraSure HIV-1 Western Blot Kit is intended for use as an additional, more specific test for HIV-1 antibodies in OraSure specimens collected from individuals of unknown risk for HIV-1, which are found to be repeatedly reactive by the Oral Fluid Vironostika(R) HIV-1 Microelisa System. The OraSure HIV-1 Western Blot Kit is intended for professional use only.

The OraSure HIV-1 Western Blot Kit is not intended for use with blood, serum/plasma or urine specimens or for screening potential blood donors.

SUMMARY AND EXPLANATION OF THE TEST

Acquired Immunodeficiency Syndrome (AIDS) is caused by at least two etiologic agents which are designated as Human Immunodeficiency Virus Type 1 (HIV-1) and Human Immunodeficiency Virus Type 2 (HIV-2)./1,2/ Infections with HIV-2 are found primarily in parts of West Africa./2/ Current data indicate that HIV infections are transmitted by sexual contact, exposure to blood (including sharing needles and syringes) or certain blood products, and perinatally by mother to infant./3,4/ Published data have established that patients with AIDS and individuals infected with HIV-1 produce antibodies against HIV-1 proteins. Studies have shown that HIV-1 antibodies have been detected in saliva samples of most HIV-infected patients./5-7/

A number of EIA kits are currently available for the screening of serum specimens for HIV-1 antibodies. The Oral Fluid Vironostika HIV-1 Microelisa System manufactured by bioMerieux, Inc. is available specifically for screening OraSure oral fluid specimens. These specimens are obtained using the OraSure HIV-1 Oral Specimen Collection Device which is designed to collect oral HIV-1 antibodies while minimizing problems inherent in saliva samples (namely in high viscosity and instability). Samples found to be repeatedly reactive for HIV-1 antibodies are tested using additional, more specific tests, such as Western blot or immunofluorescence assays. The Western blot assay, as described by Tsang et al,/8/ is useful for elucidating the specificity of the antibody response to HIV-1 (a summary of the principles of the assay is presented on page 2).

Clinical serum samples that are reactive in the screening assays but do not contain HIV-1 antibodies have also been described./9/ Some of these samples possess antibodies to certain Class II HLA histocompatibility antigens that are found in some cell lines used to produce the virus. Other individuals, who have had no known exposure to HIV-1, produce reactive results in the screening test for unknown reasons. Such nonspecific results are found commonly when screening tests are used in low risk populations. Since the psychosocial and medical implications of a positive antibody test may be significant, it is recommended that additional testing be performed on such samples to validate the presence of antibodies specific to HIV-1./10/

The OraSure HIV-1 Western Blot Kit was developed in order to provide an additional, more specific assay for HIV-1 antibody detection in OraSure specimens found to be repeatedly reactive in the screening EIA. The OraSure HIV-1 Western

Blot Kit, when used as directed in this insert, will detect antibodies to HIV-1 when present in human oral fluid samples obtained with the OraSure HIV-1 Oral Specimen Collection Device. The position of bands on the preblotted nitrocellulose strips allows the antibody reactivity to be associated with specific viral antigens. An OraSure sample that is reactive in both EIA screening test and Western blot assay is presumed to be positive for antibodies to HIV-1, indicating infection with this virus except in situations of passively acquired antibody or experimental vaccination. Antibodies to HIV-2 may also react with the protein antigens of HIV-1./11/ Therefore, individuals infected with HIV-2 may have reactive tests in the HIV-1 Western blot assay. Usually, however, the cross-reactivity is incomplete, resulting in an indeterminate test result (see Interpretation of Results section). Absence of antibodies to HIV cannot be taken as absolute proof that an individual is free of HIV-1 or incapable of transmitting the virus. Individuals with positive tests should be referred for medical evaluation.

CHEMICAL AND BIOLOGICAL PRINCIPLES OF THE PROCEDURE

The whole cell viral lysate used in the manufacture of the OraSure HIV-1 Western Blot Kit is manufactured by bioMerieux, Inc. (U.S. license number 956). It is HIV-1 propagated in an H-9/HTLV-IIIB, T-lymphocyte cell line. It is purified by ultracentrifugation and inactivated by treatment with nonionic detergent and heat.

When used to manufacture the preblotted strips, inactivated and denatured proteins of the HIV-1 virus are fractionated by SDS-polyacrylamide gel electrophoresis. The resolved protein bands are electrophoretically transferred to nitrocellulose sheets. These preblotted nitrocellulose sheets are cut into strips.

OraSure HIV-1 specimens, diluted in Sample Buffer, are incubated with the preblotted nitrocellulose strips. If antibodies to specific HIV-1 proteins are present in a specimen, they bind to epitopes contained in the proteins banded on the strip. Any antibody not bound is removed by washing. The conjugate, alkaline phosphatase-labeled goat anti-human immunoglobulin, is then added to the strip and allowed to incubate. It binds to antibodies already bound to viral proteins on the strip. Excess conjugate is removed by washing. The strips are then incubated with a substrate specific to the alkaline phosphatase. The color reaction is stopped by aspiration and washing.

If antibodies to specific HIV-1 proteins (p) or glycoproteins (gp) are present in the specimen in sufficient concentration, purple bands may be visible at one or more of the following positions on the nitrocellulose strip: gp160, gp120, p65, p55, p51, gp41, p31, p24, and p18 (number refers to apparent molecular weight in kilodaltons).

KIT COMPONENTS SUPPLIED
(20 Test Kit)

OraSure(R) HIV-1 Western Blot Strips — 20 strips
Prenumbered nitrocellulose strips, preblotted with resolved HIV-1 proteins; packed in a resealable plastic pouch between buffer-soaked absorbent paper; buffer contains 0.1% sodium azide as a preservative.

Substrate — 1 bottle; 22 mL
BCIP/NBT single reagent substrate in an organic base/TRIS buffer.

Powdered Milk — 1 bottle; 30 g
Non-fat milk solids.

Sample Diluent Concentrate — 1 bottle; 100 mL
Phosphate buffered saline with 3.0% Tween-20; contains 0.01% thimerosal as a preservative.

Conjugate Concentrate — 1 vial; 0.25 mL
Goat anti-human IgG (heavy and light chains) F(ab')\\2\\ fragment, labeled with alkaline phosphatase; contains 0.1% sodium azide as a preservative.

OraSure(R) HIV-1 WB Negative Control — 1 vial; 0.65 mL
Human serum or plasma, nonreactive for antibodies to HIV-1, in OraSure Control Matrix; tested negative for HBsAg and antibodies to HCV; contains a proprietary preservative.

OraSure(R) HIV-1 WB Low Positive Control — 1 vial; 0.65 mL
Human serum or plasma, reactive for antibodies to HIV-1, in OraSure Control Matrix; tested negative for HBsAg and antibodies to HCV; heat-inactivated to render material noninfectious for HIV-1; contains a proprietary preservative.

OraSure(R) HIV-1 WB High Positive Control — 1 vial; 0.65 mL
Human serum or plasma, reactive for antibodies to HIV-1, in OraSure Control Matrix; tested negative for HBsAg and antibodies to HCV; heat-inactivated to render material noninfectious for HIV-1; contains a proprietary preservative.

Reaction Trays — 5 each
Eight lane disposable trays with lids.

Caution: The Negative Control is prepared from human plasma or serum found to be nonreactive for HIV-1 antibodies and tested for Hepatitis B surface antigen (HBsAg) and antibodies to HCV by FDA-licensed methods. The Positive Controls are prepared from anti-HIV-1 positive human plasma or serum, which was heat-inactivated to render it noninfectious for HIV-1. However, as no procedure can offer complete assurance that infectious agents are absent, all specimens of human origin should be considered potentially infectious and handled with care./12/

EQUIPMENT REQUIRED BUT NOT SUPPLIED

1. Centrifuge tube for each sample to be processed
2. Centrifuge
3. Refrigerator (2-8(degree)C)
4. 37(degree)C water bath
5. Graduated cylinders
6. Beaker or appropriate mixing vessel
7. Balance
8. Laboratory timer
9. Magnetic stir plate and stir bar
10. Test Tubes: glass, polypropylene, or polystyrene (12x75 mm) (optional)
11. Precision micropipets to deliver variable volumes from 5 to 1000 (*)L
12. Disposable pipet tips
13. Graduated pipets to deliver volumes to 25 mL
14. Scissors
15. Forceps for strip handling (plastic or Teflon-coated)
16. Transfer pipets
17. Rotary platform, capable of rotating at 50-60 rpm
18. Aspiration system
19. Repeating pipet to deliver 1-2 mL volumes

KIT STORAGE AND STABILITY

1. Store all components at 2-8(degree)C when not in use.
2. Expiration dates printed on the kit and kit components indicate the limits of stability.
3. Stability of the components after reconstitution or dilution is as follows:
   a. Sample Buffer
      Store at room temperature while performing assay. Discard excess buffer at completion of assay.
   b. Sample dilutions
      Test tube sample dilutions must be applied to the strips within one hour of dilution. The dilutions are stored at room temperature during that time.
   c. Conjugate dilution
      Conjugate dilution must be prepared during the last five minute wash and applied immediately after the wash is complete and the wash solution is aspirated. Excess Conjugate dilution must be discarded.
   d. All other kit components are supplied ready to use.
4. Keep strip pouch tightly sealed. Do not let strips dry out.

CHEMICAL OR PHYSICAL INDICATIONS OF INSTABILITY

Alterations in physical appearance of kit materials may indicate instability or deterioration.

Note: Sample Diluent Concentrate may contain crystals. This will not affect essay performance if crystals are dissolved before use (see page 8, step 1.a).

Substrate is pale yellow in color. A fine black precipitate may be observed but its presence does not affect product performance.

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SPECIMEN COLLECTION, STORAGE AND PREPARATION

Note: This test kit may not be used to assay blood specimens. This test kit may only be used to assay OraSure HIV-1 oral fluid specimens obtained using the OraSure HIV-1 Oral Specimen Collection Device.

A. Specimen Collection

1. Refer to the OraSure HIV-1 Oral Specimen Collection Device package insert for instructions on collecting a specimen.
2. OraSure HIV-1 specimens must be transported to the laboratory in the OraSure HIV-1 Specimen Vial.
3. OraSure HIV-1 specimens may be transported to the laboratory at ambient temperature via courier, air freight, or regular mail. OraSure specimens should be protected from impact, direct sunlight, and temperatures exceeding 37(degree)C (98(degree)F). Federal, state and local regulations regarding transportation of diagnostic specimens are applicable to OraSure HIV-1 specimens.

B. Specimen Storage

1. After receipt at the laboratory, OraSure HIV-1 specimens (on or off the collection pad) should be stored at 2-8(degree)C. Specimens may be stored at 4(degree)C to 37(degree)C for a maximum of 21 days from the time of collection, including the time for shipping and testing. If testing of specimens cannot be completed within 21 days, OraSure HIV-1 specimens can be stored frozen at -20(degree)C for a maximum of six weeks.

2. OraSure HIV-1 specimens frozen and thawed once must be tested within the 21 days (see B.1 above). Specimens frozen and thawed twice must be tested within 24 hours, or discarded.

C. Specimen Preparation

1. Record the specimen identification number from the OraSure HIV-1 Specimen Vial.
2. Ensure that the specimen is within acceptable dating for testing, i.e., *21 days from collection. Note: All testing should be completed within 21 days of specimen collection unless stored at -20(degree)C (see B.1 above).
3. Hold the vial with the pointed tip up.
4. Move the pad away from the vial tip by gently tapping the vial.
5. Break the pointed tip of the vial off with the thumb.
6. Place a centrifuge tube over the vial and invert the tube and vial.
7. Centrifuge at 600-800 x g force for 15 minutes.
8. Determine that there is a minimum of 0.75 mL volume of specimen eluate.

If the volume of the centrifuged specimen is less than 0.75 mL, the specimen is unsuitable for testing and a new specimen from the test subject must be obtained. Notify the ordering physician if the volume of specimen is insufficient.

* denotes less than

PRELIMINARY PRECAUTIONS

1. Keep testing area separate from areas where blood or blood products for transfusion are stored.
2. Do not pipet by mouth.
3. Do not smoke, eat, or drink while handling test materials.
4. Wear disposable gloves throughout the specimen processing and testing procedure.
5. Handle all materials used in the test (including specimens, Sample Buffer, reaction trays and pipets) as though capable of transmitting infectious agents./12/
6. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with mucous membranes or breaks in the skin.
7. Immediately clean up any spills containing potentially infectious material with freshly prepared 1:10 dilution of ***5% sodium hypochlorite (bleach) and dispose of the cleaning material by an appropriate method.
8. Dispose of all specimens and materials used to perform the test as if they contain infectious agents. Prior to disposal, treat as follows:

Material	Disposal Procedure
Reusable items	Autoclave for 60 minutes at 121(degree)C.
Disposable items	Incinerate.
Liquid waste	Mix with bleach to yield a final ratio of one part bleach to nine parts waste (1:10). Allow the mixture to stand 30 minutes before flushing down the drain.

PROCEDURAL NOTES AND PRECAUTIONS

Note: This test kit may only be used to assay OraSure HIV-1 oral fluid specimens obtained using the OraSure HIV-1 Oral Specimen Collection Device. Do not test any specimens other than OraSure oral fluid specimens with this kit.

1. Do not interchange or combine any kit component, including strips, with components of another kit lot.
2. The OraSure Low Positive and Negative Controls must be assayed with each run. The OraSure High Positive must be assayed with the first run of every package of strips, but is optional in subsequent runs. This High Positive Control strip should be retained as a reference. It will be compared to the test strips run from that package to determine band identification and placement.
3. Do not perform the test in the presence of reactive vapors (e.g., from acids, alkalis, or aldehydes), dust, or residual bleach or bleach fumes; the enzymatic activity of the conjugate may be affected or reactivity may be decreased.
4. Prepare an assay worksheet, ensuring that the patient sample and control identification is linked to the number embossed on the nitrocellulose strip.
5. For sample dilution and addition to nitrocellulose strips, two options are offered (explained in detail on pages 8 and 9).
   a. The first involves preparing the dilutions in test tubes and adding them to the strips.
   b. The second involves adding the sample directly into the trough which contains the strip and Sample Buffer.

*** denote greater tnan equals to

6. Avoid contamination of the strips and/or the buffer-soaked absorbent paper in the resealable pouch during handling (this may cause false reactivity in subsequent assays).
   a. Prior to removing the strips from the pouch, clean the work surface and forceps with isopropyl alcohol.
   b. Change gloves prior to opening the pouch.
   c. Always use clean forceps when handling strips.
   d. For initial use of strips, cut pouch below the seal line, keeping upper portion of pouch intact including seal line.
   e. It is recommended that the lower portion of the strip pouch be cut on the remaining two sides (dotted lines as shown in diagram to the right).
   f. Fold the plastic down, which acts as a protective barrier, to expose the strips.

[DIAGRAM APPEARS HERE]

7. Place each prenumbered strip, with the green indicator line facing up, in the reaction trays in numerical order. This facilitates band alignment, for ease of reading results.
8. Do not allow strips to dry out prior to sample addition. If diluting the samples in test tubes, place strips into trays only after dilutions have been made.
9. As soon as the sample dilutions have been added to all strips in a tray, cover the tray with a lid.
10. It is essential to avoid cross-contamination between troughs, especially prior to and during sample incubation.
    a. Add sample to the trough of the reaction tray, using a transfer pipet for diluted samples or a pipet for undiluted samples.
    b. It is suggested that an additional precaution be taken by positioning the strips in every other trough of a tray.
    c. Avoid delivering bubbles to the liquid in the troughs.
    d. Be careful to avoid dislodging fluid from the troughs when transferring trays.
    e. Liquid in the troughs should not contact tray lids (if liquid should contact tray lids, immediately remove the material with a lab wipe).
11. It is important that the items used to prepare and dispense Sample Buffer be scrupulously clean (a repeating pipet is preferable for dispensing the 1-2 mL of Sample Buffer).
12. Prime the pipet tip when measuring samples or reagents.
13. A rotation speed of 50-60 rpm is recommended for each rotation step. 14. Be certain that each strip is immersed in the liquid and moves freely; however, liquid must not contact the tray lid during rotation.
15. Incomplete or ineffective washing will compromise the assay; it is imperative to follow the wash procedure carefully.
16. Discard used disposable reaction trays as biohazardous waste. Reuse of the trays and lids is not recommended.
17. Samples must be at room temperature (20-25(degree)C) before starting the test.

18. Reagents should be at room temperature (20-25(degree)C) before beginning the assay except for Conjugate Concentrate and Substrate, which must both remain refrigerated (2-8(degree)C) until just prior to use. Return all reagents to 2-8(degree)C after use.

CAUTION: The Conjugate Concentrate and the buffer in the absorbent paper surrounding the strips contain sodium azide. If discarding into the sewer system, flush copiously with water. This helps prevent formation of metallic azides which, when highly concentrated in metal plumbing, may be potentially explosive. Decontaminate plumbing according to CDC guidelines./13/

ORASURE HIV-1 WESTERN BLOT TEST PROCEDURE

1. Prepare Sample Buffer as follows:
   a. Check Sample Diluent Concentrate for crystals.
      i. If crystals have formed, dissolve them by warming the entire bottle and its contents in a 37(degree)C water bath for 10 minutes or until crystals are completely dissolved.
      ii. Allow the material to reach room temperature before use.
   b. Determine the volume of Sample Buffer to be prepared and quantity of each constituent required from the chart below.

Total number of strips to be assayed+	mL of Sample Buffer to prepare*	mL of Deionized H2O required**	mL of Sample Diluent Conc. required**	g of Powdered Milk required***
3 - 6	200	180	20	6
7 - 9	300	270	30	9
10 - 13	400	360	40	12
14 - 16	500	450	50	15
17 - 20	600	540	60	18

+ Include strips for controls.
* 30.0 mL of Sample Buffer is required for each strip assayed.
** Sample Diluent Concentrate is diluted 1:10 in deionized water.
*** 3 g of Powdered Milk is required for every 100 mL of diluted Sample Diluent Concentrate.

   c. Combine the required amounts of deionized water, Sample Diluent Concentrate and Powdered Milk.
   d. Mix the solution for a minimum of 15 minutes (ensure the Powdered Milk is completely dissolved).
   e. Store at room temperature while performing assay. Discard excess buffer at completion of assay.
2. Prepare an assay worksheet, ensuring that the patient sample and control identification is linked to the number embossed on the nitrocellulose strip.
3. Both the OraSure Low Positive and Negative Controls must be assayed with each run. The OraSure High Positive must be assayed with the first run of every package of strips, but is optional in subsequent runs. This High Positive Control strip should be retained as a reference. It will be compared to the test strips run from that package to determine band identification and placement.
4. Add controls and patient specimens to nitrocellulose strips by one of the following methods:

a. METHOD I: Test Tube Dilution
   i. Into appropriately labeled test tubes, add 150 (*)L of each specimen or control to 1.0 mL of Sample Buffer and mix well. These dilutions must be tested within an hour.
   ii. Place one prenumbered strip with green indicator line facing up into each trough as follows, ensuring the strips do not dry out:
      a) For initial use of strips, cut pouch below the seal line, keeping upper portion of pouch intact including seal line.
      b) Cut the lower portion of the pouch on the two remaining sides (see page 7, step 6.d).
      c) Fold the packaging back to expose strips.
      d) Beginning with the left side of the series (strip #1), remove strips to be assayed and place them in numerical order.
      e) Grasp the strip at the green indicator line with forceps.
      f) Transfer the strips, avoiding contact with contaminated surfaces, into the troughs of the reaction tray(s).
      g) Place any remaining strips (still encased in moist blotting paper and contained in the lower portion of the pouch) in the upper portion of pouch, seal using zip closure, and return to storage at 2-8(degree)C.
   iii. Transfer the contents of each tube (~1.1 mL) into the corresponding trough using a transfer pipet.

b. METHOD II: On-Strip Dilution
   i. Add 1.0 mL Sample Buffer to each trough to be used.
   ii. Place one prenumbered strip with green indicator line facing up into each trough as follows, ensuring the strips do not dry out:
      a) For initial use of strips, cut pouch below the seal line, keeping upper portion of pouch intact including seal line.
      b) Cut the lower portion of the pouch on the two remaining sides (see page 7, step 6.d).
      c) Fold the packaging back to expose strips.
      d) Beginning with the left side of the series (strip #1), remove strips to be assayed and place them in numerical order.
      e) Grasp the strip at the green indicator line with forceps.
      f) Transfer the strips, avoiding contact with contaminated surfaces, into the troughs of the reaction tray(s).
      g) Place any remaining strips (still encased in moist blotting paper and contained in the lower portion of the pouch) in the upper portion of pouch, seal using zip closure, and return to storage at 2-8(degree)C.
   iii. Add 150 (*)L of each OraSure specimen or control to the corresponding trough.

5. Cover each tray with a lid and mix by gentle rotation (50-60 rpm) on a rotator for 180 minutes (3 hours) at room temperature.
6. After incubation, completely aspirate the liquid from troughs (do not allow the strips to dry).

(*) Umalut

7. Wash the strips as follows:
   a. Add 2.0 mL Sample Buffer to each strip.
   b. Immediately aspirate all liquid from each trough.
   c. Repeat steps a and b two more times.
   d. Add 2.0 mL Sample Buffer to each strip and replace the lid(s).
   e. Place the tray(s) on the rotator (at 50-60 rpm) for 5 minutes.
   f. Aspirate the Sample Buffer completely.
   g. Repeat steps d and e one more time.
8. Prepare diluted Conjugate during the final wash step (step 7.g) above):
   a. Conjugate dilution must be prepared during the last five minute wash and applied immediately after the wash is complete and the wash solution is aspirated. Excess Conjugate dilution must be discarded.
   b. Remove Conjugate Concentrate from the refrigerator.
   c. Determine volumes required of Sample Buffer and Conjugate Concentrate from the following chart:

Total number of strips being assayed+	mL of Sample Buffer required*	(*)L of Conjugate Concentrate required**	Total number of strips being assayed+	mL of Sample Buffer required*	(*)L of Conjugate Concentrate required**
3	8	40	12	26	130
4	10	50	13	28	140
5	12	60	14	30	150
6	14	70	15	32	160
7	16	80	16	34	170
8	18	90	17	36	180
9	20	100	18	38	190
10	22	110	19	40	200
11	24	120	20	42	210

(*) Umalut
+ Include strips for controls.
* Prepare 2.0 mL of diluted Conjugate for each strip assayed (a small excess has been incorporated for pipetting ease).
** Conjugate Concentrate is diluted 1:201.

   d. Prepare Conjugate dilution by combining required amounts of Conjugate Concentrate and Sample Buffer, and mix well.
   e. Return the remaining Conjugate Concentrate to storage at 2-8(degree)C.
9. Aspirate the Sample Buffer from the troughs and add 2.0 mL diluted Conjugate to each strip.
10. Replace each lid and incubate on the rotator (at 50-60 rpm) for 45 minutes at room temperature.
11. Repeat wash procedure from steps 6 and 7.
12. Completely aspirate the Sample Buffer and add 2.0 mL of deionized water to each strip.
13. Replace each lid and place on rotator (at 50-60 rpm) for 5 minutes.
14. Remove Substrate from refrigerator during final wash (step 13).
15. Aspirate deionized water from each strip.
16. Add 1.0 mL of Substrate to each strip.

17. Replace each lid and gently move trays back and forth 2-3 times by hand on work surface to ensure strips are completely immersed in Substrate.
18. Incubate for exactly 10 minutes at room temperature without rotation. Note: It is important not to exceed the 10 minute Substrate incubation time.
19. Stop the color development of the strips as follows:
    a. Aspirate the Substrate.
    b. Add 2.0 mL of deionized water to each strip.
    c. Immediately aspirate the contents of the tray(s).
    d. Repeat steps b and c two more times.
    e. Add 2.0 mL deionized water to each strip and replace the tray lid(s).
    f. Place on rotator for 5 minutes.
    g. Aspirate water completely.
20. Allow the developed strips to air dry in the tray(s).
21. Handle the strips carefully; use clean forceps to remove from troughs.
22. Read and interpret the dry strips as soon as possible, since developed strips exposed to light may experience fading of bands. Store developed strips in the dark at room temperature.

QUALITY CONTROL

Both the OraSure Low Positive and Negative Controls must be assayed regardless of the number of samples tested. The OraSure High Positive must be assayed with the first run of every package of strips, but is optional in subsequent runs. This High Positive Control strip should be retained as a reference. It will be compared to the test strips run from that package to determine band identification and placement.

The following conditions must be met for the assay to be considered valid:

1. Negative Control: No bands are observed on the strip.
2. Low Positive Control: (Weakly Reactive) Bands are present (P) at gp160, gp41, and p24. Other bands may or may not be visible.
3. High Positive Control: (Strongly Reactive) Bands are present (P) at gp160, gp41 and p24. Bands are visible at gp120, p65, p51, p31, and p18. The p55 band may or may not be visible (see Figure 1, page 12).

INTERPRETATION OF RESULTS

1. Band Identification
   a. Correlate the band position of the OraSure High Positive Control strip with Figure 1 on page 12 to identify the HIV-1 viral bands and their positions.
   b. Compare each test strip to the OraSure High Positive Control strip for identification of reactive bands.
2. Band Intensity
   a. Compare the bands of each strip and control to the gp41 band on the OraSure Low Positive Control strip and assign a level of intensity as follows:

Assignment	Definition
Present (P)	The band intensity is greater than or equal to the gp41 band on the OraSure Low Positive Control strip.
Indeterminate (I)	The band is visible but intensity is less than the gp41 band on the OraSure Low Positive Control strip.
Absent (A)	No reactivity is observed.

3. Strip Interpretation
   a. Based on band position and reactivity, analyze the results and assign each strip a final result.

Test Result	Definition
Positive	Any two of the three major bands of diagnostic significance below must be Present. gp160 and/or gp120 — gp41 — p24 Other bands may or may not be present.
Indeterminate	Any visible band reactivity which does not meet the criteria for a Positive result as described above.
Negative	Band reactivity is Absent.

Figure 1: Protein Band Identification on an OraSure(R) HIV-1 Western Blot Strip

On the left is a representation of an OraSure Western blot strip developed with OraSure High Positive Control. The illustration is a reference for band identification and position (see Interpretation of Results, page 11, step 1).

On the right is a representation of the HIV-1 virus. The bands correlate to corresponding viral subpart origin.

[DIAGRAM]

Viral Origin of HIV-1 Associated Bands

Virus Gene	Gene Product	Description
env	gp160	env protein precursor
	gp120	outer env protein
	gp41	transmembrane protein
pol	p65	reverse transcriptase
	p51	reverse transcriptase
	p31	endonuclease
gag	p55	core protein precursor
	p24	core
	p18	core

LIMITATIONS OF THE PROCEDURE

1. The assay must be performed in strict accordance with these instructions to obtain accurate, reproducible results.
2. Although a Positive result may indicate infection with the HIV-1 virus, a diagnosis of Acquired Immunodeficiency Syndrome (AIDS) can be made only if an individual meets the case definition of AIDS established by the Centers for Disease Control./10/ A repeat test on an independent sample should be considered to control for sample mix-up or operator error, and to verify a positive test result.
3. Individuals may present incomplete banding patterns due to the natural history of AIDS or other immunodeficiency states, e.g.:
   a. AIDS patients may lose antibody reactions to p24 and p31;
   b. Infants born to HIV-1 infected mothers, but who are uninfected may display incomplete patterns as passively acquired maternal antibodies begin to disappear;
   c. Individuals who have recently seroconverted may display incomplete band patterns;
   d. Infected patients with malignancies and individuals receiving immunosuppressive drugs may fail to develop a Positive result;
   e. Individuals infected with HTLV-I/II or HIV-2, may exhibit cross-reactivity;
   f. Individuals may develop incomplete patterns that reflect the composition of experimental HIV sub-unit vaccines that they may have received.
4. A person who has antibodies to HIV-1 is presumed to be infected with the virus, except that a person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.
5. Since reactivity of any degree with any of the proteins present on the strip results in an indeterminate result, all samples interpreted as Indeterminate should be repeated using the original specimen. In addition, individuals with indeterminate results should be followed for up to six months./14/
6. Do not use this kit as the sole basis of diagnosis of HIV-1 infection.
7. A Negative result does not exclude the possibility of HIV-1 infection.
8. The OraSure HIV-1 Western Blot Kit is a biological product which, although highly consistent, does display variation from lot to lot. Examples of these variations include bands which have a slightly wavy or slanted appearance, small artifacts within the banding area, and a light smearing pattern across a set of strips. These are considered normal assay variations which infrequently affect assay interpretation. However, if they do interfere with the assay interpretation, call the assay invalid and repeat.

PERFORMANCE CHARACTERISTICS

The performance of the OraSure HIV-1 Western Blot Kit was evaluated by comparison of OraSure results with those obtained from matched serum specimens tested by a licensed HIV-1 Western blot. These specimens were collected prospectively in a clinical study of low risk (n = 2,382), high risk (n = 698), and AIDS (n = 242) populations. In addition, non-specificity specimens (n = 248) were obtained from subjects with non-HIV-1 related medical conditions that might result in antibodies cross-reactive with HIV-1 proteins. All of the high risk and AIDS subjects, and 495 of the low risk subjects were tested by Western blot irrespective of their EIA results. EIA testing of an additional 1,887 "screen only" low risk subjects was carried out using the bioMerieux Oral Fluid Vironostika HIV-1 Microelisa System in an effort to find EIA repeatedly reactive samples (from uninfected individuals) with which to challenge the OraSure Western blot. Testing of the 1,887 "screen only" subjects identified 14 OraSure specimens as repeatedly reactive.

These 14 OraSure specimens and their matching sera were also advanced to Western blot testing. Thus, a total of 1,697 matched OraSure and serum specimens were tested by Western blot at five testing laboratories throughout the United States.

Low risk subjects, primarily normal blood donors, were persons with no known risk factors. Of the 698 high risk specimens, 363 were from homosexuals, 116 from injection drug users (IDUs), 83 from persons with multiple heterosexual contacts, and 44 from hemophiliacs. The remaining 92 high risk subjects included bisexuals, prostitutes, and individuals with other acknowledged risk factors. Specimens from 242 persons with clinically diagnosed AIDS were also tested.

The frequency of virus-specific bands and interpretation by risk group using the OraSure HIV-1 Western Blot Kit are presented in Table 1.

Table 1. Frequency of Virus-Specific Bands ("Present" or "Indeterminate") and Interpretation of Specimens Tested by the OraSure HIV-1 Western Blot Kit

Low Risk/a/	OraSure HIV-1 WB Result	Band Specificities (# and % of samples)/g/ gp160	gp120	p65	p55	p51	gp41	p31	p24	p18	Non-Viral
EIA neg.	POS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
n=495	IND	100/b/ (20.2)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	5 (1.0)	0 (0.0)	13 (2.6)	2 (0.4)	87 (17.6)
EIA RR/h/	POS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
n=14	IND	3/c/ (21.4)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.1)	0 (0.0)	2 (14.3)

High Risk/d/	OraSure HIV-1 WB Result	Band Specificities (# and % of samples)/g/ gp160	gp120	p65	p55	p51	gp41	p31	p24	p18	Non-Viral
EIA neg.	POS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
n=264	IND	45/e/ (17.0)	4 (1.5)	0 (0.0)	6 (2.3)	0 (0.0)	5 (1.9)	0 (0.0)	0 (0.0)	8 (3.0)	0 (0.0)	33 (12.5)
EIA RR/h/	POS	429 (98.8)	429 (98.8)	427 (98.4)	417 (96.1)	160 (36.9)	412 (94.9)	427 (98.4)	394 (90.8)	410 (94.5)	238 (54.8)	1 (0.2)
n=434/i/	IND	3 (0.7)	3 (0.7)	2 (0.5)	2 (0.5)	0 (0.0)	2 (0.5)	1 (0.2)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.2)

AIDS/f/	OraSure HIV-1 WB Result	Band Specificities (# and % of samples)/g/ gp160	gp120	p65	p55	p51	gp41	p31	p24	p18	Non-Viral
EIA neg.	POS	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
n=1	IND	1 (100.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)
EIA RR/h/	POS	236 (97.9)	236 (97.9)	236 (97.9)	211 (87.6)	35 (14.5)	207 (85.9)	236 (97.9)	190 (78.8)	189 (78.4)	87 (36.1)	0 (0.0)
n=241	IND	5 (2.1)	5 (2.1)	4 (1.7)	1 (0.4)	0 (0.0)	1 (0.4)	4 (1.7)	1 (0.4)	0 (0.0)	1 (0.4)	0 (0.0)

a. Persons with no known risk factors; primarily normal blood donors.
b. 80 of 100 results Indeterminate due to non-viral bands only.
c. 2 of 3 results Indeterminate due to non-viral bands only.
d. Homosexuals, IDUs, and other accepted risk designations.
e. 32 of 45 results Indeterminate due to non-viral bands only.
f. CDC Classification; MMWR 1982; 31: 507-508.
g. Band patterns for negative samples do not appear in this table. By definition, negative samples show no reactivity.
h. RR indicates repeatedly reactive OraSure EIA results.
i. Includes two EIA false positive individuals whose OraSure Western blots were negative.

Sensitivity Studies

The performance of the OraSure Western blot in seropositive subjects was evaluated by comparing results to those obtained by testing matched serum samples collected from individuals at high risk for HIV infection and from clinically diagnosed AIDS patients. A comparison of OraSure and serum results is presented in Table 2.

Table 2. OraSure and Serum Western Blot Results for Confirmed Positive High Risk and AIDS Populations

		Orasure Specimen Results				Serum Results		
Risk	Confirmed	EIA	Western Blot			Western Blot		
Category	Positives	RR	P	I	N	P	I	N
AIDS	242	241/a/	236	6/a,b/	0	241	1	0
High Risk	431	431	429	2/c/	0	431	0	0
Total	673	672	665	8	0	672	1	0

a. One OraSure sample was EIA false negative, Western blot indeterminate (gp160+, p24+/-); the matching serum sample was EIA repeatedly reactive and Western blot positive (gp160+, pg120+, p65+, p51+, p24+).
b. One of the six Western blot indeterminate OraSure samples was repeatedly reactive on EIA and concordant on Western blot with an indeterminate result for the matching serum specimen. The remaining five OraSure specimens were discordant (indeterminate) with the matching serum specimens (positive) due to the required cardinal bands being visible but of insufficient intensity to be scored as Present.
c. One OraSure sample was discordant due to the intensity of bands on the OraSure Western blot (gp160+, gp120+/-, p65+/-, p51+/-, gp41+/-). The banding pattern of the second indeterminate OraSure sample was gp160+, gp120+/-. The matching serum specimens' banding patterns were gp160+, gp120+, p65+, p51+/-, gp41+, p24+/-, p18+/-, and gp160+, gp120+, p65+/-, gp41+, p24+/-, p18+/-, respectively.

RR = Repeatedly Reactive; P = Positive; I = Indeterminate; N = Negative.

In this study, the sensitivity of the OraSure Western blot testing of oral specimens from the 242 confirmed positive AIDS subjects was 97.5% (236/242) with 2.5% (6/242) indeterminate, and from the 431 confirmed high risk subjects was 99.5% (429/431) with 0.5% (2/431) indeterminate, with no OraSure Western blot false negatives in either group. All OraSure indeterminate blots showed the gp160 band as present and at least one additional cardinal band (gp120, gp41, p24) as visible, but of insufficient intensity to be called present. One of the OraSure indeterminate blots corresponded to the Western blot indeterminate serum specimen.

Specificity Studies

The performance of the OraSure Western blot in documented seronegative subjects was evaluated by testing specimens from 495 EIA negative subjects (using oral fluid) at low risk for HIV-1 infection, 14 EIA repeatedly reactive specimens found by screening 1,887 persons at low risk for HIV-1 infection, 248 subjects with non-HIV related medical conditions (non-specificity subjects), and 267 specimens from high risk seronegative subjects. Thus, a total of 1,024 OraSure HIV-1 Western blots and serum Western blots were performed on these individuals. The results of this testing are presented in Table 3.

Table 3. Comparative Study of Western Blot Results in Low Risk, Non-Specificity, and High Risk, HIV-1 Negative Populations

EIA Result for OraSure Specimens	OraSure HIV-1 Western Blot Interpretation	Licensed Serum HIV-1 Western Blot Interpretation			
		Positive	Ind.	Negative	Totals
EIA Negative (n=1,007)	Positive	0	0	0	0
	Indeterminate	0	96	111	207
	Negative	0	295	505	800
EIA RR (n=17)	Positive	0	0	0	0
	Indeterminate	0	3	1	4
	Negative	0	7	6	13
	Totals	0	401	623	1,024

Seventeen OraSure specimens (14 low risk and 3 high risk) were EIA repeatedly reactive. Thirteen of the 17 EIA false positive specimens were correctly identified as negative by the OraSure HIV-1 Western blot. Thus 2,893 out of 2,897 subjects (99.9%) were correctly identified as HIV-1 antibody negative by a combination of EIA and Western blot testing of OraSure samples. The four remaining specimens were indeterminate by OraSure HIV-1 Western blot (two of the four due to non-viral bands only). The indeterminate rate for uninfected persons who are EIA repeatedly reactive by OraSure was 23.5% (4/17) as compared to 58.8% (10/17) for serum.

Western blot was also performed on serum and OraSure specimens from 1,007 EIA negative subjects (using oral fluid). This testing identified 20.6% of OraSure specimens and 39.2% of sera as indeterminate. The overall concordance between the two types of specimens was 59.6%. Differences were largely due to non-viral bands that were present for one type of sample but not the other for individual subjects.

Analytical Sensitivity

Titration of Matching OraSure and Serum Specimens

Fifteen randomly selected matching OraSure and serum repository specimens that had been obtained from HIV-positive individuals were titrated. Titrated serum specimens were tested with the licensed serum HIV-1 Western Blot Kit and matching titrated OraSure specimens were tested in parallel with the OraSure HIV-1 Western Blot Kit. The assay endpoint in this study was the last dilution at which a positive Western blot result was observed for each specimen. The results of this study are shown in Table 4.

Endpoints were obtained for all serum specimens and for 14 of the 15 OraSure specimens tested. The one specimen not yielding an endpoint (ID# 19052) had an indeterminate result when the neat OraSure specimen was tested. This assignment was based on positive reactivity for the gp160 and gp120 bands, and an indeterminate reactivity for the gp41 band. The corresponding serum specimen for subject 19052 also had a comparatively low titer (1:4). A review of medical records revealed that this individual was severely immunocompromised at the time of specimen acquisition (CD4+ count = 18/mm/3/).

The average ratio of the serum endpoints to the OraSure endpoints was 5.7:1. The difference in analytical sensitivity between the licensed serum Western Blot Kit and the OraSure Western Blot Kit ranged from a ratio of 12.8 to 0.40.

Table 4. Highest Dilution Yielding Positive
Western Blot Results for 15 Matching OraSure and Serum Specimens

Specimen Number	Highest OraSure Dilution/a/	Highest Serum Dilution/a/	Ratio/b/
19026	1:20	1:256	12.8
19027	1:20	1:256	12.8
19078	1:20	1:256	12.8
19095	1:20	1:256	12.8
19105	1:5	1:64	12.8
19079	1:10	1:64	6.4
19032	1:10	1:16	1.6
19059	1:10	1:16	1.6
19066	1:50	1:64	1.28
19069	1:50	1:64	1.28
19080	1:250	1:256	1.02
19044	1:5	1:4	0.8
19101	1:100	1:64	0.64
19033	1:10	1:4	0.40
Mean ratio			5.7
19052	Neatc	1:4	-

/a./ Beyond standard specimen dilution per assay protocol.

/b./ Ratio of serum endpoint dilution/OraSure endpoint dilution.

/c./ Specimen #19052 was indeterminate (with viral bands) when the undiluted OraSure specimen was tested.

Titration of OraSure Seroconversion Specimens

Repository OraSure and plasma specimens from an earlier seroconversion study were used to assess the analytical sensitivity of the OraSure HIV-1 Western Blot.

OraSure specimens were diluted and each dilution was assayed by EIA and Western blot. The objective of this study was to determine the highest dilution of the OraSure specimen that would produce a repeatedly reactive EIA result, based on product insert criteria, and would demonstrate viral band reactivity in the OraSure HIV-1 Western Blot Kit.

Table 5 shows the results of this testing. For each of the four time points, the OraSure Western Blot demonstrated viral bands at dilutions which produced non-reactive EIA results, yielding an average of **10-fold enhanced sensitivity over the EIA for OraSure specimens.

Table 5. Reactivity of OraSure HIV-1 Seroconversion Specimens in the Oral Fluid Vironostika HIV-1 Microelisa System and the OraSure HIV-1 Western Blot Kit

ID#	Highest EIA Dilution	Highest WB Dilution	Blot to EIA Sensitivity
01SC052591	Negative at Neat	Positive at 1:10*	** 10
01SC052691	RR at Neat	Positive at 1:5*	** 5
01SC052791	RR at Neat	Positive at 1:5*	** 5
01SC052991	RR at Neat	Positive at 1:20*	** 20

* Indicates the highest dilution tested RR = Repeatedly Reactive Reproducibility
** Less than or equal to

Reproducibility

The reproducibility of the OraSure HIV-1 Western Blot Kit was evaluated at three separate test laboratories. The study included testing a three-member panel of pooled OraSure specimens with the OraSure HIV-1 Western Blot Kit. The

OraSure reproducibility panel consisted of an HIV-1 antibody positive specimen, an HIV-1 antibody negative specimen, and an HIV-1 Western blot indeterminate specimen.

The panel members were tested on three separate days, using three separate OraSure HIV-1 Western Blot Kit production lots, resulting in a total of 27 test results being generated for each panel member. The percentage of times each band was scored reactive is presented in Table 6.

Table 6. Reproducibility of the OraSure HIV-1 Western Blot Kit

Specimen #	Specimen Reactivity	Percent Frequency of Visible Bands/c/ gp160	gp120	p65	p55	p51	gp41	p31	p24	p18
1	Positive/a/	100	100	100	0	100	100	100	100	18.5
2	Negative	0	0	0	0	0	0	0	0	0
3	Indeterminate/b/	100	100	100	0	100	100	3.7	70.4	0

/a./ Positive specimen known banding pattern: reactivity for gp160, gp120, p65, p51, gp41, p31, p24 and no reactivity for p55, p18.
/b./ Indeterminate specimen known banding pattern: reactivity for gp160, gp120, p65, p51, gp41, p24; and no reactivity for p55, p31, p18.
/c./ Frequency of visible bands (either Indeterminate or Present).

The results demonstrate that for positive specimens, negative specimens, and indeterminate specimens with known banding patterns, reproducibility is high.

Reactivity in Other Disease Conditions

Matching OraSure and serum specimens were obtained at three sites from 248 subjects who were enrolled in the clinical trial because they had non-HIV-1 medical conditions that might result in antibodies cross-reactive with HIV-1 proteins or other potentially interfering factors. Specimens studied included 89 from multiparous women, 69 from subjects with non-HIV viral infections, 50 receiving anticoagulation therapy, 26 with autoimmune diseases other than AIDS, 11 with oral pathology, and 3 with polyclonal or monoclonal gammopathy. Although bands were present at viral band locations for four samples (1.6%), none of the strips could be interpreted as positive. Results are presented in Table 7.

Table 7. Results of OraSure Western Blot Testing on Samples from Subjects with Non-HIV Disease Processes or Other Potentially Interfering Factors

OraSure HIV-1 WB Result		Band Specificities (# and % of samples) gp160	gp120	p65	p55	p51	gp41	p31	p24	p18	Non-viral
NEG	186	0	0	0	0	0	0	0	0	0	0
	(75.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)
IND	62/a/	0	0	0	0	0	2	0	2	1	58
	(25.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(3.2)	(0.0)	(3.2)	(1.6)	(93.5)
Total	248	0	0	0	0	0	2	0	2	1	58
	(100.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.8)	(0.0)	(0.8)	(0.4)	(23.4)

/a./ 58 of 62 results Indeterminate due to non-viral bands only.

Testing of specimens from this population revealed that the number of OraSure indeterminates (62; 25.0%) was substantially less than the number of serum indeterminates (121; 48.8%). The number of serum indeterminates due to the presence of viral bands (27; 10.9%) was substantially greater than the number of OraSure indeterminates due to the presence of viral bands (4; 1.6%).

Summary

In this clinical trial using the recommended OraSure algorithm, 3,558/3,570 subjects received the correct HIV-1 antibody results from a single OraSure sample the first time it was tested. In 11 of the remaining subjects, the Western blot was indeterminate: for these 11, the algorithm would lead to appropriate follow-up testing. Thus, in 3,569/3,570 (99.97%) subjects either the correct result was reached or appropriate follow-up testing would be triggered. It is concluded that OraSure testing is a highly accurate alternative to serum testing.

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KIT AVAILABILITY

OraSure(R) HIV-1 Western Blot Kit

20 Tests

Product Number 501-0000

Manufactured by

OraSure Technologies, Inc.
8505 SW Creekside Place
Beaverton, Oregon USA 97008

Distributed by

bioMerieux, Inc.
Box 15969
Durham, North Carolina 27704-0969

For technical assistance,
contact bioMerieux Customer Support Services
at 1-800-682-2666

Printed in USA

101-0004-6

Human Immunodeficiency Virus Type 1 (HIV-1)

Oral Fluid Vironostika(R) HIV-1 Microelisa System 43-01812

For in vitro diagnostic use. [LOGO OF BIOMERIEUX]

Store between 2-8(degrees)C.

INTENDED USE
Oral Fluid Vironostika(R) HIV-1 Microelisa System is an enzyme-linked immunosorbent assay (ELISA) from bioMerieux, Inc. for the qualitative determination of antibody to HIV-1 only with oral fluid specimens obtained using the OraSure(R) HIV-1 Oral Specimen Collection Device manufactured by Epitope, Beaverton, Oregon. The assay is intended to be used as an aid in the diagnosis of HIV-1 infection and must not be used to qualify blood donors or units of blood.

Note: See Warnings, Interpretations of results, Limitations and Performance characteristics sections for information on:

1. Reduced sensitivity and specificity of testing with OraSure HIV-1 specimens compared with testing blood specimens.

2. The need for follow up testing with a blood specimen when subjects have repeatedly reactive ELISA results using OraSure HIV-1 specimens.

3. Reporting test results to the ordering physician or someone under the supervision of the ordering physician.

SUMMARY AND EXPLANATION OF THE TEST
Available data indicate that the acquired immunodeficiency syndrome (AIDS) is caused by a virus transmitted by sexual contact, exposure to blood (including sharing contaminated needles and syringes) or certain blood products, or transmitted from an infected mother to her fetus or child during the perinatal period./1/ Human Immunodeficiency Virus Type 1 (HIV-1) has been isolated from patients with AIDS and AIDS-related complex (ARC), and from healthy persons at high risk for AIDS./2/ The incidence of antibodies specific for HIV-1 in AIDS and ARC patients and persons at increased risk for AIDS is high. The prevalence of HIV-1 infection in people not known to be at increased risk is not known.

The HIV-1 enzyme-linked immunosorbent assay (ELISA) was developed to detect antibodies to HIV-1 and to identify potentially infectious units of donated blood and plasma. Early experience using oral fluid for HIV-1 testing/3/ suggested that there was a problem of specimen instability and assay insensitivity. Saliva is a complex mixture of parotid, submandibular, sublingual and minor salivary gland secretions mixed with mucin, bacteria, leukocytes, sloughed epithelial cells and gingival crevicular fluid. Gingival crevicular fluid, or mucosal transudate, is the fluid derived from the passive transport of serum components through the oral mucosa into the mouth. The OraSure HIV-1 Specimen Collection Device enhances the flow of mucosal transudate across the mucosal surfaces onto an absorptive cotton pad. Antibodies are among the serum components in mucosal transudate and OraSure HIV-1 specimens. Oral fluid contains a number of enzymes (proteases) which degrade antibodies. The OraSure HIV-1 device includes preservatives that are effective in protecting anitbodies from degredation.

The ELISA was designed to be extremely sensitive in order to afford maximum protection of the blood supply. The sensitivity of the ELISA test using OraSure HIV-1 specimens is reduced compared with testing blood specimens (see Performance Characteristics section). Non specific ELISA reactions may be seen in specimens from some people who, for example, due to prior pregnancy, blood transfusion, or other exposure, have antibodies to the human cells or media in which the HIV-1 is grown for manufacture of the ELISA./4/ Because of nonspecific reactions, it is appropriate to investigate specimens found to be reactive by ELISA in a manner that gives improved predictability that HIV-1 antibody, in fact, is present. When a specimen reacts in an initial test (is initially reactive), the ELISA should be repeated in duplicate on the same specimen. Reactivity in either or both of these duplicate tests (repeatedly reactive) is highly predictive of the presence of HIV-1 antibody. Repeatedly reactive specimens obtained from people at high risk for HIV-1 infection (e.g. homosexual men, hemophiliacs, or intravenous drug users) are usually found to contain antibodies by additional more specific, or supplemental, testing. Currently, there is no supplemental assay that is FDA-licensed for use with OraSure HIV-1 specimens. When the ELISA is used to screen populations in which the prevalence of HIV-1 infection is low, repeatedly reactive specimens may be found not to contain antibodies to HIV-1 by additional more specific assays. The frequency of nonspecific reactivity using OraSure HIV-1 specimens is increased compared with using blood specimens (see Performance characteristics section). Information about prevalence of HIV-1 infections in persons in various categories of risk, as well as clinical and public health guidelines, are available in the publication Morbidity and Mortality Weekly Reports.

Although for all clinical and public health applications of the ELISA, both the degree of risk for HIV-1 infection of the person studied and the degree of reactivity of the specimen may be of value in interpreting the test, these correlations are imperfect. Therefore, in most settings it is appropriate to investigate repeatedly reactive specimens by additional more specific, or supplemental, tests. Due to the fact that, at this time, there is no FDA-licensed additional more specific test for HIV-1 antibodies in an OraSure HIV-1 specimen, subjects whose OraSure HIV-1 test result is repeatedly reactive should be advised to have a blood specimen tested with a licensed screening test for HIV-1 antibodies, and a licensed supplemental test when appropriate.

PRINCIPLE OF THE TEST

HIV-1 antigen is derived from HIV-1 virus propagated in T-lymphocyte culture as reported by Popovic, et al./5/ The virus is purified by ultracentrifugation and inactivated by disruption and is coated onto the microelisa wells contained in the Oral Fluid Vironostika HIV-1 Microelisa System.

To process the oral fluid specimen, the OraSure HIV-1 Specimen Vial is centrifuged and specimen is eluted from the collection pad. A minimum volume of eluate is required to assess if an oral fluid specimen was collected. The eluate is diluted and added to microelisa wells. During incubation, HIV-1 antibodies in a test specimen form immune complexes by interacting with the HIV-1 antigens of the solid phase. Following incubation, the specimen is aspirated and the well is washed with buffer. Antibodies to human immunoglobulin (goat) conjugated with horseradish peroxidase (HRP) are added and bind to the antibody-antigen complex of the solid phase during a second incubation. Following a wash and incubation with ABTS (2,2'-azino-di-[3-ethylbenzthiazoline-6-sulfonate]) substrate, a green color is produced. The enzyme reaction is stopped by the addition of a fluoride solution./6/ The amount of anti-HIV-1 present in the specimen is proportional to color development.

REAGENTS
For in vitro diagnostic use.

Components in each Oral Fluid Vironostika(R) HIV-1 Microelisa System

192 Test	9600 tests	
2 stripholders	100 stripholders	HIV-1 Microelisa Strips - Eight per holder, each containing 12 HIV-1 antigen (inactivated) coated wells; contained in a foil pack with silica gel desiccant.
1 vial (50 ml)	16 vials (50 ml ea.)	Diluent Concentrate, 5x - Normal goat serum in phosphate buffered saline; contains 0.05% Thimerosal as a preservative.
1 bottle (2.5 ml)	16 bottles (2.5 ml ea.)	Tween-20, 5% - Contains 0.1% Thimerosal as a preservative.
1 bottle (200 ml)	16 bottles (200 ml ea.)	Diluent Reagent Water.
1 vial	3 vials	Positive Control Serum (Inactivated) - Lyophilized human serum with protein stabilizers; reactive for anti-HIV-1.
1 vial	8 vials	Negative Control Serum - Lyophilized human serum with protein stabilizers; nonreactive for anti-HIV-1.
2 bottles	15 bottles	Dilsim(TM) - Lyophilized specimen inactivator medium; contains bovine proteins, salt, and surfactant.
2 bottles (60 ml ea.)	15 bottles (60 ml ea.)	Wash Concentrate 50X - Contains 2.5% surfactant.
1 vial	32 vials	Peroxidase Conjugated Goat Anti-human Immunoglobulins (EnzAbody(R)-O) - Lyophilized with protein stabilizers.
2 bottles	30 bottles	ABTS Substrate - Lyophilized 2,2'-azino-di-[3-ethylbenzthiazoline-6-sulfonate].
2 bottles (62 ml ea.)	30 bottles (62 ml ea.)	ABTS Diluent - Contains hydrogen peroxide in citric acid buffer.
1 bottle (120 ml)	15 bottles (120 ml ea.)	Stop Solution - Contains 0.28% sodium fluoride.
1 each	5 each	Clamp and rod - Closure of foil pack.
10 sheets	300 sheets	Plate sealers - Perforated, adhesive.

WARNINGS

1. Laboratories must successfully complete training and testing of the OraSure HIV-1 Laboratory Qualification Panel prior to testing OraSure HIV-1 oral fluid specimens.

2. A minimum of 0.75 ml volume of processed OraSure HIV-1 specimen is required to assure that a specimen was collected.

3. HIV-1 antibody testing of OraSure HIV-1 specimens has reduced sensitivity and specificity compared with HIV-1 antibody testing of blood specimens (see Performance characteristics section for details).

4. Due to the possibility of false positive HIV-1 test results and the lack of an FDA licensed supplemental test for HIV-1 antibodies in OraSure HIV-1 specimens, subjects whose OraSure HIV-1 specimen is repeatedly reactive on the Oral Fluid Vironostika Microelisa System should be advised to have a blood specimen tested by a licensed screening test and a licensed supplemental test for HIV-1 antibodies, as appropriate.

PRECAUTIONS

For in vitro diagnostic use only.

Note: The HIV-1 Microelisa Strips are marked with the product-specific code, E1.

1. Caution: Handle all Oral Fluid Vironostika HIV-1 Microelisa System biological materials though capable of transmitting infectious agents. The antigen used to coat the microelisa wells has been inactivated and the positive control serum has been treated for inactivation of HIV-1; nevertheless, both should be handled as though they contain potentially infectious agents. Other components prepared from human serum or plasma have been tested using FDA-licensed methods and found to be nonreactive for the presence of HIV-1 antibody, hepatitis B surface antigen (HBsAg) and anti-HCV. However, as no test method can offer complete assurance that infectious agents are absent, all materials of human origin should be handled as though they contain infectious agents.

2. Handle specimens and materials contacting specimens as if potentially infectious biological materials in accordance with "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and other Bloodborne Pathogens in Health-Care Settings" (CDC, MMWR, June 24, 1988). It has been reported that infectious HIV-1 can be isolated from the oral fluid of some infected patients./7/ When detectable in oral fluid specimens, infectious virus is present at low levels compared with blood and may be inactivated by salivary inhibitors./8/

3. All test operators should adhere to the Occupational Safety and Health Administration (OHSA) regulations (29 CFR 1910).

4. OraSure HIV-1 Specimen vials are breakable and should be handled with care.

5. Keep testing area separate from areas in which blood or blood products for transfusion are stored.

6. Do not pipet any of the materials by mouth. Do not smoke, eat, or drink in areas where specimens or kit reagents are handled.

7. Do not perform the test in the presence of reactive vapors (e.g., from sodium hypochlorite, acids, alkalis, or aldehydes) or dust, because the enzymatic activity of the conjugate may be affected.

8. Use disposable gloves and handle all materials used in the test including specimens, wash solution, reaction trays, and pipets, cautiously as though capable of transmitting infectious agents. Consult a physician immediately in the event that contaminated materials are ingested or come in contact with open lacerations, lesions, or other breaks in the skin.

9. Immediately clean up any spillage of materials containing antigen or antibody with a 1:10 dilution of 5% sodium hypochlorite. Dispose of the cleaning material by an acceptable method.

10. Treatment prior to disposal

    a. Autoclave for 60 minutes at 121(degrees)C.

    b. Incinerate disposable materials.

    c. Mix liquid waste with 5% sodium hypochlorite solution so that the final concentration is approximately 0.5% sodium hypochlorite. Allow to stand 30 minutes before disposal.

11. Do not use reagents beyond their expiration date.

12. Do not mix microelisa plates, EnzAbody-O and serum control reagents from different kit lots.

13. Use a clean pipet for dispensing specimens and reagents.

14. If a specimen is inadvertently not added in this assay, i.e., a well is missed, the assay results will read negative.

15. Use accurately calibrated equipment.

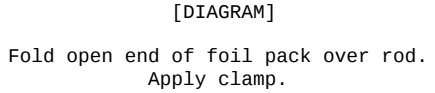
16. Consider using dedicated equipment when cross contamination is a possibility.

17. Inadequate adherence to package insert instructions may result in erroneous results.

Reagent preparation
Prepare all reagents before beginning assay procedure. Reagents and specimens should be at room temperature (15-30(degrees)C) before beginning the test and can remain at room temperature during testing. Return reagents to 2-8(degrees)C after use.

HIV-1 Microelisa Strips.
The foil packs should be brought to room temperature (15-30(degrees)C) before opening to prevent condensation on the HIV-1 Microelisa Strips. After the airtight foil pack has been opened, place unused strips back into the foil pack and seal as shown in Figure 1. The Strips are stable for 4 weeks at 2-8(degrees)C if the foil pack is resealed with the clamp and rod provided. The silicia gel bag must not be removed.

Figure 1: Foil Pack Closure.



Diluent
1. check Diluent Concentrate for the presence of crystals. If crystals have formed, resolubilize by warming at 37(degrees)C until crystals dissolve.

2. Add 1 vial of Diluent Concentrate and 1 bottle of Tween-20 to 1 bottle of Diluent Reagent Water. Mix by inverting several times. Avoid excessive foaming.

Positive and Negative Kit Controls
1. Pipet 500 (*)l prepared Diluent into each Positive and Negative Control Serum vial to be reconstituted. Mix contents thoroughly.

2. Add 28 days to date of reconstitution and record date on vial label.

(*) denote umalut

Dilsim

1. Fill Dilsim bottle to the neck with prepared Diluent (60 ml). Cap bottle tightly and warm at 40-50(degrees)C in a water bath or under a stream of hot water for 20 30 minutes.

2. After warming, vortex bottle vigorously until cake is completely solubilized.

3. Add 28 days to date of reconstitution and record date on bottle label.

   Note: Reconstituted Dilsim has been shown to inactive HIV-1 in serum and plasma preparations.

Wash Solution

1. Dilute the Wash Concentrate 1:50 with purified water in a clean container. Prepare at least 50 ml of diluted Wash Solution for each HIV-1 Microelisa Strip.

2. Label the container "Wash Solution." Add 28 days to date of preparation and record date on container label.

EnzAbody(R)-O

Prepare the EnzAbody-O using one of the following methods.

If the entire EnzAbody-O will be used within one day following reconstitution:

Pipet 50 ml prepared Diluent to 1 vial EnzAbody-O. Mix by inverting several times. Avoid excessive foaming. Add 1 day to the date and time of reconstitution and record the date and time on the vial label.

If EnzAbody-O will be used for more than one day following reconstitution:

1. Pipet 5 ml prepared Diluent to 1 vial of EnzAbody-O. Mix by inverting several times. Avoid excessive foaming. Label the vial as "concentrate." Add 28 days to the date of reconstitution and record date and time on the vial label.

2. On day of use, prepare a 1:10 dilution of the prepared EnzAbody-O "concentrate" with Diluent. For each test strip used, prepare 2.0 ml of EnzAbody-O working solution (0.2 ml EnzAbody-O concentrate to 1.8 ml Diluent). Discard any unused working solution each day.

ABTS Substrate

1. Add ABTS Diluent (1 bottle) to 1 bottle of ABTS Substrate. Mix by inverting several times.

   Caution: To minimize auto-oxidation of ABTS, reconstitute with ABTS Diluent that has been warmed to ambient temperature (15-30(degrees)C). Do not add cold (2.8(degrees))C ABTS Substrate to the wells.

2. Add 14 days to the date of reconstitution and record date on bottle label.

   Note: Do not reconstitute second bottle of ABTS Substrate until first has been depleted.

Stop Solution

Contains sodium fluoride. Avoid contact with skin. If contact is made, wash area with water.

Kit storage instructions

Store all components at 2-8(degrees)C when not in use. Expiration date printed on the kit indicates date beyond which product should not be used.

Chemical or physical indications of instability

Alterations in the physical appearance of test kit material may indicate instability or deterioration. The expiration date shown on component labels indicates the date beyond which product should not be used.

INSTRUMENTS

1. A microelisa plate reader is required which has a single wavelength capacity for 405 nm with a linear absorbance range of 0 to 2.000, a drift of less than 0.005% AU/hr and a bandwidth of 10 nm.

2. The aspiration/wash system must be capable of containing aspirated waste in a closed system and capable of dispensing a 300 (*)l volume.

3. An incubator capable of maintaining 37 + 2(degrees)C.
-

4. A centrifuge capable of 600-800 x g force.

For any instrument, the manual provided by the manufacturer should be reviewed for additional information regarding the following:

a) Installation and special requirements

b) Operation principles, instructions, precautions, and hazards

c) Manufacturer's specifications and performance capabilities

d) Service and maintenance information

SPECIMEN COLLECTION, STORAGE AND PREPARATION (ORASURE HIV-1 SPECIMEN)

Note: This test kit may not be used to assay blood specimens. This test kit may only be used to assay OraSure HIV-1 oral fluid specimens obtained using the OraSure HIV-1 Oral Specimen Collection Device manufactured by Epitope, Beaverton, Oregon.

1. Refer to the OraSure HIV-1 Oral Specimen Collection Device package insert for instructions on collecting a specimen.

2. OraSure HIV-1 specimens must be transported to the laboratory in the OraSure HIV-1 Specimen Vial.

3. OraSure HIV-1 specimens may be transported to the laboratory at ambient temperature via courier, air freight, or regular mail in accordance with applicable Federal, state and local regulations which apply to the transportation of OraSure HIV-1 specimens which may contain etiologic agents (39 CFR 111).

4. OraSure HIV-1 specimens (on or off the collection pad) may be stored at 4(degrees)C to 37(degrees)C for a maximum of 21 days from the time of collection, including the time for shipping and testing. If testing of specimens cannot be completed within 21 days, OraSure HIV-1 specimens can be stored frozen at -20(degrees)C for a maximum of six weeks.

5. OraSure HIV-1 specimens frozen twice and thawed a second time must be tested within 24 hours, or discarded.

6. Record the specimen identification number from the OraSure HIV-1 Specimen Vial.

7. Ensure that the specimen is within acceptable dating for testing, i.e. * 21 days from collection.

   Note: All testing should be completed within 21 days of specimen collection unless stored at -20(degrees)C (see Number 4 above).

8. Hold the vial upright with the pointed tip up.

9. Move the pad away from the vial tip by gently tapping the vial.

10. Break the pointed tip of the vial off with your thumb.

11. Place a tube over the vial and invert the tube and vial.

12. Centrifuge at 600-800 x g force for 15 minutes.

13. Determine that there is a minimum of 0.75 ml volume of specimen eluate.

    If the volume of the centrifuged specimen is less than 0.75 ml, the specimen is unsuitable for testing and a new specimen for the test subject must be obtained. Notify the ordering physician if the volume of specimen is insufficient.

* Denotes less than

ORAL FLUID VIRONOSTIKA HIV-1 MICROELISA SYSTEM TEST PROCEDURE
Materials provided
See Reagents Section

Additional materials required but not provided
Instruments/Equipment
- Automated diluter/dispenser system or test tubes (12x75mm)
- Aspiration/wash system connected to a waste trap and vacuum source
- 12-channel variable volume pipet system (50 to 300 (*)l) and suitable tips
- Micropipet(s) capable of handling of 3(*)l, 75(*)l, and 500(*)l, and suitable disposable tips
- Graduated cylinder, 50 ml
- Incubator, 37 + 2(degrees)C
-
- Microelisa plate reader, single wavelength capacity for 405 nm with a linear absorbance range of 0 to 2.000, with a drift of less than 0.005% AU/hr and a bandwidth of 10 nm
- Timer
- Centrifuge capable of 600-800 x g force

Reagents/Disposables
- Purified water, USP or equivalent
- Absorbent paper
- V-shaped troughs
- Disposable gloves
- Sodium hypochlorite solution (5%) or liquid bleach
- Appropriate biohazard waste containers for materials potentially contaminated with infectious agents
- Tubes suitable for centrifuging OraSure HIV-1 specimen containers
- OraSure HIV-1 Laboratory Qualification Panel (manufactured by Epitope, Inc., Beaverton, Oregon). This panel must be used to qualify a testing laboratory prior to the initial use of the Oral Fluid Vironostika HIV-1 Microelisa with OraSure Hiv-1 Specimens.

Materials available from bioMerieux
- Incubator
- Microelisa washer
- Microelisa reader
- Stripholder with uncoated well (Product No. 259576)
- 12-channel pipet and tips
- Micropipet and tips
- Microprocessor-controlled diluter/dispenser
- OraSure HIV-1 Laboratory Qualification Panel (manufactured by Epitope, Inc., Beaverton, Oregon)

Procedural notes and precautions
1. HIV-1 Microelisa Strips, EnzAbody-O, and Controls used in an assay must be of the same kit lot number and the HIV-1 Microelisa Strips and Controls must be identified with a green sticker "For Oral Fluid Vironostika HIV-1 Only." Materials should not be used after the expiration date shown on the package label. Components and test specimens should be at ambient temperature (15-30(degree)C) before testing begins. Return the reagents to 2-8(degree)C after use.

2. Strips of the microelisa plate are removable. Remove Strips not needed and replace with uncoated strips. Store unused Strips as described in the Reagent preparation section under "HIV-1 Microelisa Strips." Before testing begins, inspect the microelisa stripholder and ensure that all wells are secure. Stripholders should be handled with care to ensure that no Strip is dislodged during testing.

3. HIV-1 Microelisa Strips may be used only once.

4. Do not touch the top or bottom of strips, or the edge of wells with fingers or pipet tips.

5. All reagents and specimens must be mixed well before use.

(*) denote umalut

6. Do not allow the microelisa wells to dry once the assay has begun. Fill the wells with the next required reagent immediately after washing; if this is not possible, fill the wells within 10 minutes.

7. All pipetting steps should be performed with the utmost care and accuracy. Cross-contamination between reagents will invalidate test results. Use micro-pipets for quantitative delivery of specimens and reagents. Avoid microbial or any other contamination of reagents.

8. Refrain from opening the door of the incubator (37(degree)C) during the incubation time.

9. Routine maintenance of the aspiration/wash system is strongly recommended to prevent carryover from highly reactive specimens to nonreactive specimens.

10. The aspiration/wash system should be flushed with copious amounts of water upon completion of the final wash of the assay.

11. Dispose of all used materials as biohazardous waste.

12. Sensitivity and specificity using OraSure HIV-1 specimens are not equivalent to serum or plasma.

Wash procedure

1. Incomplete washing will adversely affect the test outcome.
2. Aspirate well contents into a waste flask. Then fill the wells (approximately 0.3ml) with diluted Wash Solution. Aspirate and fill the wells four times.
3. After the last aspiration, invert stripholder and tap firmly on absorbent paper taking not to dislodge any Strips. Remove any excess Wash Solution by blotting with absorbent tissue. Note precaution Number 9 above.

Test procedure

Once the OraSure HIV-1 specimen is processed following the manufacturer's procedures (see Specimen collection, storage and preparation), continue with the steps listed below.

1. Fit stripholder with the required number of HIV-1 Microelisa Strips. If less than eight Strips are needed, use uncoated strips to complete the plate when using a 96-well washer.

2. Prepare dilutions of each control and OraSure HIV-1 specimen. Include three Negative Controls and one Positive Control on each plate.

   Caution: Use a clean tip for each specimen. Do not pipet specimen into an empty well without Dilsim. Do not allow the microelisa wells to dry once the assay has bagun.

   Control dilution

   A. Automated diluter/dispenser: Pipet 3 (*)l of Control with 225 (*)l Dilsim into the designated microelisa well.

   B. Premixed manual method: Pipet 5 (*)l Control into a clean test tube containing 375 (*)l Dilsim. Mix well. Pipet 225 (*)l of the diluted control into the designated microelisa well.

   C. Direct manual method: Using a multichannel pipet, add 125 (*)l Dilsim to each control microelisa well. Pipet 3 (*)l Control into the designted wells. Using a multichannel pipet and clean tips, add 100 (*)l Dilsim to each control well and repeatedly aspirate and dispense to mix.

   OraSure HIV-1 specimen dilution

   A. Automated diluter/dispenser: Pipet 75 (*)l of specimen with 75 (*)l Dilsim into the designated microelisa well.

   B. Direct manual Method: Pipet 75 (*)l of Dilsim into the designated microelisa well followed by 75 (*)l of OraSure HIV-1 specimen. Mix well by repeatedly aspirating and dispensing contents.

3. Cover the Strips with the adhesive plate sealer. Incubate at 37 + 2(degree) C for 90 to 100 minutes.

4. Wash each well four times with diluted Wash Solution. Refer to "Wash procedure."

(*) denote umalut

5. Pipet 150 (*)l of reconstituted EnzAbody-O solution into each well. Caution: Do not allow EnzAbody-O to contaminate Substrate. If the same equipment is used to add both reagents, new dispoable tips must be used.

6. Cover the strips with a new plate sealer. Incubate at 37 +/- 2(degree)C for 30 to 35 minutes.

7. Wash each well four times with diluted Wash Solution. Refer to "Wash proecdure."

8. Pipet 150 (*)l of prepared ABTS Substrate into each well. Do not mix or agitate. Strips should not be covered with a plate sealer.

9. Incubate at room temperature(15-30(degrees)C) for 10 to 12 minutes.

10. Stop reaction by adding 150 (*)l of Stop Solution to each well (maintain the same sequence and time intervals used for Substrate solution addition) and gently tap to mix. Plates should be read within 2 hours.

11. Blank the microelisa reader on air (without stripholder and Strips) and read the absorbance of the solution in each well at 405 nm.

Quality control
Qualification of Negative Control (NC) values: Absorbance of each NC replicate must be greater than or equal to 0.100 and less than or equal to 0.400. Eliminate one outlier, if present, and calculate the NC mean (NCX). Absorbance of NC must be less than 1.5 multiplied by NCX and greater than 0.5 multiplied by NCX. If two or more values are outside range, the run is invalid and must be repeated.

Qualification of Positive control (PC) value: Absorbance of PC must be greater than or equal to 0.700. If PC is outside this limit, the run is invalid and must be repeated.

Test validity: A test run is valid if the positive and negative control values are qualified and

PC - NCX ** 0.500

If results do not meet this criterion, technique may be suspect and the run must be repeated.

RESULTS
Calculations
Calculations must be made separately for each stripholder.

Cutoff value: If the test run is valid, calculate the cutoff value as follows:

NCX + 0.270

Determination of test specimen results: Compare the test specimen absorbance value to the cutoff value.

A test specimen is nonreactive if specimen absorbance is less than the cutoff value.

A test specimen is reactive if specimen absorbance is greater than or equal to the cutoff value.

(*) denote umalut
** denote greater than equal to

Specimen calculations
Absorbance at 405 nm
NC = 0.175, 0.195, 0.225
NCX = 0.198
PC = 1.469

Acceptance criteria
Eliminate any control absorbance values not meeting the following criteria:
0.100***NC *** 0.400
NC* 1.5 (NCX) or 0.297
NC ** 0.5 (NCX) or 0.099
PC **** 0.700
None eliminated

Ensure that the following is within the specified acceptance criteria.
PC - NCX ** 0.500
1.469 - 0.198 = 1.271 Pass

Kit controls are within acceptable limits.

Calculate cutoff
Cutoff = NCX + 0.270 = 0.468

Interpretation of results

Note: Results of the test using an OraSure HIV-1 specimen must be reported only to the physician who ordered the test or to a person under the supervision of the ordering physician.

In providing test results to the physician, careful note must be taken of the limitations of the procedure (see following section).

Specimens with absorbance values less than the cutoff value are considered nonreactive by the criteria of Oral Fluid Vironostika HIV-1 Microelisa System and may be considered negative for the antibody. Further testing is not required.

2. Specimens with absorbance values greater than or equal to the cutoff value are considered reactive (initially reactive) by the criteria of Oral Fluid Vironostika HIV-1 Microelisa System, but before interpretation, the original specimen source should be retested in duplicate. If either duplicate retest is reactive, the specimen is considered repeatedly reactive and the OraSure HIV-1 specimen is considered positive in a licensed screening test for HIV-1 antibodies.

3. Initially reactive specimens which do not react in either of the duplicate repeat tests are considered negative for antibodies to HIV-1.

* Less than
** Greater than
*** Less than or equal to
**** Greater than or equal to

LIMITATIONS OF THE PROCEDURE

1. False negative results occur more frequently when testing OraSure HIV-1 specimens compared with testing blood specimens. See Performance characteristics section for details.

2. False positive results occur more frequently when testing with OraSure HIV-1 specimens compared with blood specimens. See Performance characteristics section for details. At this time, there is no FDA licensed additional, more specific test for HIV-1 antibodies in an OraSure HIV-1 specimen. The physician should be advised to arrange for follow-up testing of a blood specimen from subjects whose OraSure HIV-1 specimen tests repeatedly reactive.

3. False negative results (the subject is infected, but the OraSure HIV-1 Specimen tests negative) may be a result of antibody levels in oral fluid which are below the sensitivity (lower limit of detection) of this procedure which may occur, for example, during the early phase of infection, or with inadequate processing of the specimen, or with inadequate collection of the OraSure HIV-1 specimen.

4. False positive results may be obtained, for example, as a result of nonspecific cross reacting antibodies, and not from an HIV-1 infection.

5. False results (either positive or negative) may occur as a result of interfering substances, such as foreign matter in the mouth being collected with the specimen.

The Oral Fluid Vironostika HIV-1 Microelisa System may be useful as an aid in the diagnosis of infection with HIV-1. It is recommended that specimens that are repeatedly reactive in an ELISA test be investigated by an additional, more specific test to verify the presence of HIV-1 antibodies. However, in the case of OraSure HIV-1 specimens, there is no licensed, additional, more specific test currently available to demonstrate the presence of HIV-1 antibodies. Therefore, for OraSure HIV-1 specimens that are repeatedly reactive, the follow up investigation requires that a serum or plasma specimen be obtained from the same person and tested in a licensed ELISA and an additional, more specific test, as appropriate. When individuals are notified that their OraSure HIV-1 specimen is repeatedly reactive in the ELISA test, the ordering physician should offer appropriate counseling and medical evaluation and arrange for follow up testing of a serum or plasma specimen.

ELISA testing alone should not be used to diagnose HIV-1 infection, and cannot be used to diagnose AIDS, even if the recommended testing of reactive specimens suggests a high probability that the antibody to HIV-1 is present. AIDS and AIDS-related conditions are clinical syndromes and their diagnosis can only be established clinically./9/ A negative test result at any point in the investigation of individual patients does not preclude the possibility of exposure to, or infection with, HIV-1. The risk of developing AIDS or AIDS-related conditions in an asymptomatic person with a repeatedly reactive ELISA is not known./10/

Data obtained from testing blood specimens of persons both at increased and at low risk for HIV-1 infection suggest that repeatedly reactive specimens with high absorbance by ELISA are more likely to demonstrate the presence of HIV-1 antibodies by additional testing./11/ Reactivity at, or only slightly above, the cutoff value is more frequently nonspecific for OraSure HIV-1 specimens obtained from persons at low risk for HIV-1 than from persons at risk based on follow up testing of serum specimens.

The test procedure and the "Interpretation of results" must be followed closely when testing for the presence of antibodies to HIV-1. Because the ELISA method was designed to test individual units of blood or plasma, most data regarding its interpretation were derived from testing individual specimens. Performance characteristics for OraSure HIV-1 specimens were derived from individual specimens. Insufficient data are available to interpret tests performed on other body specimens, pooled specimens or products made from such pools, therefore, results of testing such specimens may be inaccurate.

EXPECTED RESULTS

Performance characteristics of the test for OraSure HIV-1 specimens
Note: This assay was licensed for use with serum and plasma specimens at the time of the clinical studies.

Sensitivity and specificity: At present, there is no recognized standard for establishing the presence or absence of HIV-1 antibody in human oral fluid. Therefore, sensitivity testing of OraSure HIV-1 specimens with the Oral Fluid Vironostika HIV-1 Microelisa System was computed based on the clinical diagnosis of AIDS and specificity was computed based on testing in low risk populations. In addition, sensitivity and specificity of OraSure HIV-1 testing were computed based on testing in high risk subjects using matched oral fluid/blood specimens from the same subjects.

1. Sensitivity using OraSure HIV-1 specimens, based on an assumed 100% prevalence of HIV-1 antibody in AIDS patients, is estimated in these studies to be 98.6% (287/291). Sensitivity using OraSure HIV-1 specimens was reduced compared with blood specimens in AIDS patients.

   Sensitivity using OraSure HIV-1 specimens is estimated in these studies to be 99.1% (546/551) in high risk subjects, based on the ability of the test to detect HIV-1 antibody in matched oral fluid/blood specimens. Sensitivity using OraSure HIV-1 specimens was reduced compared with blood specimens for high risk subjects.

2. Specificity using OraSure HIV-1 specimens, based on an assumed zero prevalence of HIV-1 antibody in low risk populations, is estimated in these studies to be 99.6% (3991/4009). Specificity using OraSure HIV-1 specimens was reduced compared with blood specimens for low risk subjects.

   Specificity using OraSure HIV-1 specimens is estimated in these studies to be 97.7% (837/857) for high risk subjects, based on the ability of the test to detect HIV-1 antibody in matched oral fluid/blood specimens. Specificity using OraSure HIV-1 specimens was reduced compared with blood specimens for high risk subjects.

Clinical studies
Clinical studies of matched OraSure HIV-1 and serum specimens from AIDS patients, high risk subjects and low risk subjects 18 years of age and older were conducted at seven sites as shown in the following table.

Test Site	AIDS Subjects	High Risk Subjects	Low Risk Subjects
A	11	407	84
B	0	466	0
C	158	299	1,132
D	65	240	104
E	57	0	336
F	0	0	573
G	0	0	1,788
Total	291	1,412	4,017

Clinical sensitivity studies

Reactivity in AIDS patients and high risk populations
The sensitivity of testing OraSure HIV-1 specimens compared with matched serum specimens using the Oral Fluid Vironostika HIV-1 Microelisa System in AIDS patients and high risk subjects (38% intravenous drug users, 23% homosexuals, 17% sexual partners of individuals at risk, 6% prostitutes, 16% others with acknowledged risk factors) is shown in the table that follows.

	No. of Specimens	Nonreactive/a/ No.	Reactive No.	Number Confirmed Positive with Serum
AIDS Patients				
OraSure HIV-1	291	4/b/	287	
Serum	291	1	290	291
High Risk Subjects				
OraSure HIV-1	1,412	843/c/	569/d/	
Serum	1,412	858	554/e/	551

/a/ Includes specimens that were nonreactive on the initial screening test and specimens that were initially reactive, but not repeatedly reactive.

/b/ 4 matched serum specimens were positive (OraSure HIV-1 False Negative). Screening tests for 2 patients were valid by ELISA kit criteria and the matched serum specimens were positive with S/CO of 7.26 and 6.90, but laboratory control reagents failed. Retests of these OraSure HIV-1 specimens at the clinical site were positive for both specimens with S/CO values of 1.69 and 1.15.

/c/ 5 matched serum specimens were positive (OraSure HIV-1 False Negative).

/d/ 20 matched serum specimens were negative (OraSure HIV-1 False Positive); 3 OraSure HIV-1 specimens were IR and not retested and matched serum specimens were negative (OraSure HIV-1 Unresolved).

/e/ 2 subjects were WB/neg/ (Blood False Positive); 1 subject was IR, not retested and WB/ind/ (Unresolved).

ELISA = Oral Fluid Vironostika HIV-1 Microelisa System assay; IR = initially reactive; RR = repeatedly reactive; WB = blood Western blot; pos = positive; ind = indeterminate; neg = negative; RIPA = radioimmunoprecipitation assay; S/CO = signal to cutoff

287 OraSure HIV-1 specimens (98.6%) and 290 matched serum specimens (99.7%) were reactive in the Oral Fluid Vironostika HIV-1 Microelisa System screening test out of the 291 AIDS patients studied. Of the four OraSure HIV-1 specimens that were initially nonreactive, one was nonreactive when retested and three were reactive when retested. One serum specimen that was initially nonreactive was reactive when retested.

546 OraSure HIV-1 specimens (99.1%) and 551 matched serum specimens (100%) were reactive in the Oral Fluid Vironostika HIV-1 Microelisa System screening test out of the 551 high risk subject whose serum tested positive in additional, more specific tests for HIV-1 antibodies (Western Blot, RIPA). Of the five OraSure HIV-1 specimens that were initially nonreactive, two were repeatedly nonreactive on ELISA retest, two were not retested and one was repeatedly reactive on retest.

The sensitivity of testing OraSure HIV-1 specimens with the Oral Fluid Vironostika HIV-1 Microelisa System compared with matched serum specimens was reduced based on the reactivity in AIDS patients and high risk subjects.

Analytical sensitivity
The analytical sensitivity of testing OraSure HIV-1 specimens with the Oral Fluid Vironostika HIV-1 Microelisa System was 1/1000th that of testing serum specimens based on serial dilution of matched specimens from 13 HIV-1 antibody positive subjects. At the dilutions recommended for testing, 1:2 for OraSure HIV-1 specimens and 1:75 for serum specimens, the average sensitivity of testing with OraSure HIV-1 specimens was 1/35th (range 1/7 to 1/107) that of testing with serum specimens based on the highest dilution producing positive results as shown in the following table.

Specimen Number/a/	OraSure HIV-1 Titer/c/	Serum Titer/c/	OraSure HIV-1 Hemoglobin/b/ (mg/dl)
1	128	4,096	
2	128	4,096	
3	64	4,096	
4	64	1,024	
5	128	4,096	
6	128	4,096	
7	128	4,096	
8	512	4,096	
9	128	4,096	
10	512	4,096	
11	160	17,067	11.0
12	1,280	8,533	7.6
13	160	8,533	5.3

/a/ Matched specimens 1-10 were collected from analytical study. Matched specimens 11-13 were collected as part of the clinical field trial.

/b/ Three OraSure HIV-1 specimens (#11-13) of 112 studies contained hemoglobin (**** 5 mg/dl).

/c/ End-point titer indicates the maximum dilution of a specimen (prior to dilution for ELISA testing) which produced positive Oral Fluid Vironostika HIV-1 Microelisa System test results.

The analytical sensitivity of Oral Fluid Vironostika HIV-1 Microelisa System for HIV-1 antibodies in three OraSure HIV-1 specimens studied was not enhanced by the presence of blood in OraSure HIV-1 specimens.

**** Greater than or equal to

Reactivity in seroconversion
OraSure HIV-1 and serum specimens were obtained prospectively from one subject undergoing seroconversion. Results of ELISA testing show that in this case antibodies to HIV-1 were detected in serum specimens on day 8 and OraSure HIV-1 specimens on day 11 based on two consecutive positive determinations. Reactivity of ELISA using serum and OraSure HIV-1 specimens and WB and HIV-1 antigen test using serum is summarized in the following table.

Date	(Day)	OraSure HIV-1 S/CO	Blood S/CO	Blood p24 Ag (ng/ml)	Blood Western blot band reactivity
5/14	(1)	0.36	0.40	13.64*	none
5/15	(2)	0.57			
5/16	(3)	0.31	0.40	20.36*	none
5/17	(4)	0.52			
5/21	(8)	0.49	2.92*	6.43*	gp 160+/- p24+/*
5/22	(9)	1.07*			
5/23	(10)	0.96	4.71*	1.92*	gp 160+/- p24* gp41+/-*
5/24	(11)	1.75*			
5/28	(15)	1.94*	5.26*	0	gp 160+/ p24+ gp41+/- gp120+/-*
5/29	(16)	2.05*			
5/30	(17)	2.04*	5.27*	0	gp 160+/ p24+ gp41+/- gp120+/-*
5/31	(18)	2.04*			
6/4	(22)	1.91*	5.44*	0	gp 160+/ p24+ gp41+/- gp120+/- p66+/- p55+/-*

*Asterisk indicates a reactive test result; S/CO = signal to cutoff; Ag = HIV-1 antigen; + = positive reactivity; +/- = indeterminate reactivity

Reactivity in seropositive subjects with oral pathology
Oral examinations were carried out at a clinic site D on 65 AIDS subjects, 240 high risks subjects and 18 subjects of unknown risk. Of the 303 subjects found to be seropositive, 29 (10%) had significant oral pathology. For these subjects HIV-1 antibodies were detected in 96.6% (28/29) of the OraSure HIV-1 specimens and 100% (29/29) of the serum specimens when tested using the Oral Fluid Vironostika HIV-1 Microelisa System as shown in the following table.

Oral Pathology	Number Tested	Number OraSure HIV-1 ELISA Positive	Number Confirmed Positive with Serum
Hairy Leukoplakia	10	10	10
Candida	10	9*	10
Gingivitis	5	5	5
Gingival Ulcer	1	1	1
Periodontitis	1	1	1
Hairy leukoplakia and candida	1	1	1
Hairy leukoplakia and gingivitis	1	1	1
Total	29	28	29

*Includes one OraSure HIV-1 false negative which was previously noted in high risk population.

This study does not detect an increase in the frequency of false negative results for OraSure HIV-1 specimens from subjects with the above oral pathologies.

Clinical specificity studies

Specificity in low risk and high risk populations

The specificity of testing OraSure HIV-1 specimens with the Oral Fluid Vironostika HIV-1 Microelisa System compared to testing serum specimens was studied in 4017 low risk subjects (55% military inductees, 16% blood donors, 14% insurance applicants, 11% students/hospital staff) and 1412 high risk subjects. The results are shown in the table that follows:

	No. of Specimens	Nonreactive/a/ No.	Reactive No.	Number Confirmed Positive with Serum
Low Risk Subjects				
OraSure HIV-1	4,017	3,992	25/b/	
Serum	4,017	4,008	9/c/	4
High Risk Subjects				
OraSure HIV-1	1,412	843	569/d/	
Serum	1,412	858	554/e/	551

/a/ Includes specimens that were nonreactive on the initial screen test and specimens that were initially reactive, but not repeatedly reactive.

/b/ 18 matched serum specimens were negative (OraSure HIV-1 False Positive); 3 OraSure HIV-1 specimens were IR and not retested and matched serum specimens were ELISA/neg/ and WB/ind/ (Unresolved).

/c/ 4 specimens were confirmed negative (Blood False Positive); 1 specimen was RR, but not tested further (Unresolved).

/d/ 20 matched serum specimens were negative (OraSure HIV-1 False Positive); 3 matched serum specimens were negative and OraSure HIV-1 was IR and not retested. 19/20 subjects with false positive OraSure HIV-1 results were smokers.

/e/ 2 specimens were WB/neg/ (Blood False Positive); 1 specimen was ELISA IR and WB/ind/ (Unresolved).

ELISA = Oral Fluid Vironostika HIV-1 Microelisa System assay; IR = initially reactive; RR = repeatedly reactive; WB = blood Western blot; pos = positive; ind = indeterminate; neg = negative; RIPA = radioimmunoprecipitation assay; S/CO = signal to cutoff

There were 18 repeatedly reactive OraSure HIV-1 specimens (18/4009, 0.45%) compared with 4 repeatedly reactive serum specimens (4/4009, 0.10%) in the low risk subjects whose HIV antibody status was resolved to be negative by additional testing. There were 20 repeatedly reactive OraSure HIV-1 specimens (20/857, 2.3%) compared with 2 repeatedly reactive serum specimens (2/860, 0.23%) in the high risk subjects whose antibody status was resolved to be negative by additional testing.

These results suggest that, compared with testing serum specimens, the incidence of false positive test results using OraSure HIV-1 specimens is increased 4.5-fold in low risk populations and 10-fold in high risk populations.

Reactivity in seronegative subjects with oral pathology
Matched OraSure HIV-1 and serum specimens were obtained prospectively from 47 subjects with various forms of oral pathology. Results of testing OraSure HIV-1 and serum specimens with Oral Fluid Vironostika HIV-1 Microelisa System were negative in all cases as shown in the following table.

Oral Pathology	Number Tested	Number Positive	Number Negative
Periodontitis	21	0	21
Gingivitis	5	0	5
Multiple caries	5	0	5
Multiple caries and periodontitis	8	0	8
Multiple caries and gingivitis	6	0	6
Periodontitis and gingivitis	2	0	2
Total	47	0	47

This study did not detect differences in specificity among the OraSure HIV-1 specimens obtained from subjects with the oral pathology noted above when tested in the Oral Fluid Vironostika HIV-1 Microelisa System.

Reactivity in other disease conditions
38 repository and 53 fresh matched OraSure HIV-1 and serum specimens from patients with medical conditions other than HIV-1 infection were studied. ELISA testing of OraSure HIV-1 and serum specimens were negative in all cases as shown in the following table.

Disease	Number Tested	Number Positive	Number Negative
Hepatitis A	12	0	12
Hepatitis B	5	0	5
Hepatitis C	18	0	18
Autoimmune	13	0	13
H. pylori	3	0	3
Lymphoid malignancy	16	0	16
Other neoplasia	24	0	24
Total	91	0	91

Additional performance studies
The testing of OraSure HIV-1 specimens collected by trained medical professionals and trained non-medical individuals compared with testing of the corresponding serum specimens were evaluated using the Oral Fluid Vironostika HIV-1 Microelisa System. Matched OraSure HIV-1 and serum specimens were obtained from 129 subjects prospectively and the results of testing are presented in the table that follows.

Trained Collector	Specimen	Number Negative	Number Negative
Medical professional	OraSure HIV-1	94	35/a/
Non-medical	OraSure HIV-1	95	34/b/
Medical professional	Serum	96	35/c/

/a/ 3 matched sera were negative (OraSure HIV-1 False Positive)

/b/ 2 matched sera were negative (OraSure HIV-1 False Positive) and coincided with those identified in footnote a above.

/c/ One serum was ELISA/RR/ and WB/ind/ with p65 reactivity (Unresolved).

Positive ELISA results for OraSure HIV-1 specimens collected by trained medical professionals and non-medical individuals from 32 subjects were concordant with serum results. Discordant results were obtained for one subject whose OraSure HIV-1 specimen was ELISA repeatedly negative and serum specimen was ELISA repeatedly reactive and Western blot indeterminate with p65 reactivity. There was no follow up testing to resolve the true serostatus of this subject.

Three OraSure HIV-1 specimens collected by medical professionals and two OraSure HIV-1 specimens collected by non-medical individuals were repeatedly reactive on the ELISA test which matched serum specimens were negative on ELISA and WB tests (OraSure HIV-1 false positive).

In this study, the performance of ELISA testing of OraSure HIV-1 specimens collected by trained non-medical individuals was comparable to OraSure HIV-1 specimens collected by medical professionals.

Reproducibility
The reproducibility of testing, OraSure HIV-1 specimens in the Oral Fluid Vironostika HIV-1 Microelisa System was studied and is summarized in the following table.

Specimen	Mean S/CO	% CV	Test n	Test Days	Location A	Location B	Epitope
	6.046	2.3	36				
	6.018	2.4	36				
	5.933	5.9	33				
	6.142	2.6	5				
	2.852	10.6	24	3		X	X
	1.639	29.6	10	3	X	X	
7	0.422	23.7	82	3	X	X	
8	0.299	14.4	88	3	X	X	

OraSure HIV-1 specimens from four seropositive subjects (specimens 1-4) and two seronegative subjects (specimens 7 and 8) were collected at two test sites. Specimens collected at one clinical site were tested on-site and exchanged with the other site for testing, where indicated. OraSure HIV-1 specimens from two seropositive subjects were collected and diluted at Epitope to provide on intermediate (specimen 5) and one low positive specimen (specimen 6) for testing. Specimens prepared at Epitope were sent to clinical sites for testing and/or tested at Epitope as indicated.

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AVAILABILITY

bioMerieux

Oral Fluid Vironostika(R) HIV-I Microelisa System

192 Test Kit	Product number 259750
9600 Test Kit	Product number 259748

For technical assistance, contact Customer Service at 1-800-682-2666.

[LOGO] BIOMERIEUX

Manufacturer: bioMerieux, Inc.
Box 15969
Durham, North Carolina 27704-0969

bioMerieux, S.A.
69280 Marcy-l'Etoile France
www.biomerieux.com

February 2002

Printed in USA U.S. License No. 1624

EXHIBIT 1.8

TRANSFER PRICE

PRODUCT	Transfer Price
ORASURE ORAL FLUID WESTERN BLOT KIT	**********

EXHIBIT 2.6.3

$500,00.00 Durham, North Carolina

October _____, 2002

Promissory Note

For $1.00 and other valuable consideration, the receipt and sufficiency of which is acknowledged, OraSure Technologies, Inc., a Delaware Corporation ("the undersigned"), promises to pay bioMerieux, Inc., with offices at 100 Rodolphe Street, Durham, NC ("BMX"), the principal sum of Five Hundred Thousand Dollars ($500,000.00) pursuant to Section 2.6 of that certain Distribution Agreement of even date herewith between the undersigned and BMX.

This note shall be due and payable as follows:

a) $250,000 on or before December 31, 2002
b) $250,000 on or before March 31, 2003

This note shall bear no interest if payments are made by the due date. If the principal sum or any portion thereof is not paid on or before the due date thereof, it shall thereafter accrue simple interest at the rate of nine percent (9%) per annum.

It is agreed that if the undersigned shall fail to pay an installment of this note, or any part thereof, promptly as the same shall become due, then upon default in any one or more of the above respects and at any time before such default is made good, the holder may declare this Promissory Note, together with interest thereon, immediately due and payable. The undersigned agrees, in the event of any default hereunder, to pay all collection and attorney fees incurred by the holder hereof.

The makers and endorsers of this Promissory Note severally waive presentment for payment, protest and notice of protest, and non-payment of this note, and all defenses on the grounds of any extension of time for the payment thereof which may be hereafter given by the holders hereof to the undersigned.

IN TESTIMONY WHEREOF, the undersigned has caused its authorized representative to execute and deliver this Promissory Note, and to apply its corporate seal hereto as of the date stated above.

Attest:_____ OraSure Technologies, Inc.
Corporate Secretary

By:
(Corporate Seal) Name:_____

Title:_____

EXHIBIT 6.2

DISTRIBUTION AGREEMENT

[LOGO]
BIOMERIEUX CONTROLLED COPY

RELEASE A

Part Description: OraSure(R) HIV-1 Western Blot Kit Page: 1 of 5

Rev: RA-0 Effective Date: May 21, 2002 P/N: 259766

Part II

REFERENCE	TITLE
P-17	Description
QA-IN.0004	Quality Assurance Inspection of Incoming Material

A. ACCEPTANCE REQUIREMENTS

1. Safety Considerations

a. Biohazards: Contains inactivated HIV-1 reactive human serum and animal anti-serum (goat), handle as if potentially infectious using NCCLS Universal precautions.

b. Chemical Hazards: Sodium Azide: Use of rubber gloves and eye protection is required during the course of all handling operations.

2. Storage Requirements:

a. Upon receipt, store at 2 - 8(degrees)C

b. Kits may be inspected at room temperature.

3. Sampling Requirements

a. Refer to QA-IN.0004.

4. Visual Examination

a. Description:

1. Visually examine shipment for product identity.

b. Approved Supplier:

1. Orasure Technologies, Inc.
8505 SW Creekside Place
Beaverton, OR 97008
Catalog No. 501-0000

A. ACCEPTANCE REQUIREMENTS (CONTINUED)

5. Labeling

a. Verify that carton label lists the following information: (Refer to Appendix I)

Product Name

Part Number of kit label (located in the lower left margin)

Lot Number

6. Certificate of Conformance/Analysis

a. Certificate of Conformance/Analysis must be provided for the specific lot received and must include a minimum of the following information:

OraSure Technologies, Inc. (company letterhead)

OraSure(R) HIV-1 Western Blot Kit

Epitope P/N 501-0000

BioMerieux P/N 259766

Lot Number (Specific to Lot)

Expiration Date: (Specific to Lot)

Number Shipped

BioMerieux Purchase Order Number

Summary of QA Results Statement

State of Human Testing

List of Component Information

Shipping date and statement that shipping time was met

Signature of person attesting to quality statement

7. Expiration Date

a. Minimum shelf life remaining at time of receipt must be 8 months.

b. Assign date according to the expiration date indicated on the Certificate of Conformance.

8. Reassay: Inteval and Test

a. Not applicable.

B. ANALYTICAL PROCEDURES

1. Not applicable.

C. INTERPRETATION OF RESULTS

1. Test results must meet the requirements stated.

APPENDIX I

CARTON LABEL

Part Description: OraSure(R) HIV-I Western Blot Kit	P/N: 269766	Page: 5 of 5
Rev: RA-0	Effective Date: May 21, 2002	Lot No.:

Part II

RESULTS REPORT FORM

TEST	SPECIFICATION	RESULTS CONFORM
Description	OraSure(R) HIV-I Western Blot Kit, 20 test.	Yes [_] or No [_]
Approved Supplier	Material received must be from the following supplier. OraSure Technologies, Inc.	Yes [_] or No [_]
Labeling	Verify that carton label lists the following Information: (Refer to Appendix I)	
	Product Name	Yes [_] or No [_]
	Part Number of kit label (located in the lower left margin)	Yes [_] or No [_]
	Lot Number	Yes [_] or No [_]
Certificate of Conformance/Analysis	Required for release.	Yes [_] or No [_]
Inspection Conditions	Inspected at room temperature	Yes [_] or No [_]
	Out of refrigerator:	(am/pm)Time [_]NA
	In refrigerator (Maximum 2 hours):	(am/pm)Time [_]NA
	Inspected at refrigerator temperature:	Yes [_] or No [_]
Expiration Date	Minimum shelf life remaining at time of receipt must be 8 months.	Yes [_] or No [_]

DOCUMENT	SIGNATURE	DATE
Document and Data Results for this Part Number comply with Device Master Record.	Inspector:	
These Q.C./Q.A. test results were verified by:	Authorization:	
Final Disposition:	[_] Approved	[_] Rejected MDN#

EXHIBIT 10.1

PRODUCT LABELING

Label PN 201-3079-4

Exp.

Lot.

Powdered Milk 30 g

Store at 2-28(degree)C.
For in vitro diagnostic use.

Mfd. by:
OraSure Technologies, Inc.
Beaverton, OR 97008

Label PN 201-3080-4

Exp.

Lot.

Sample Diluent Concentrate 100 mL

Contains 0.01% thimerosal.
Dissolve crystals prior to use.
Store at 2-8(degree)C. For in vitro diagnostic use.

Mfd. by:
OraSure Technologies, Inc.
Beaverton, OR 97008

201-3251-2

Lot

Exp.

Label PN 201-3251-3

Human Immunodeficiency Virus Type 1
OraSure(R)HIV-1 Western Blot Strips

20 strips

HIV-1 preblotted nitrocellulose strips.
For use in the OraSure(R) HIV-1 Western Blot
Assay to detect antibody to HIV-1 in oral
specimens collected with OraSure(R) HIV-1
Oral Specimen Collection Device.

For in vitro diagnostic use.
Store at 2-8(degrees)C. Keep bag tightly sealed.
Caution: Handle as if capable of transmitting
Infectious agents.
Contains 0.1% sodium azide as preservative.

Mfd. by OraSure Technologies, Inc.
Beaverton, OR 97008

201-3259-3

Lot

Exp.

Label PN 201-3259-3

Substrate

22 mL

Store at 2-8(degrees)C.
Protect from light.
For in vitro diagnostic use.

Mfd. by:
OraSure Technologies, Inc.
Beaverton, OR 97008

201-3261-3

Lot

Exp.

Label PN 201-3261-3

OraSure(R) HIV-1 WB
Negative Control

0.65 mL

Store at 2-8(degrees)C.
Caution: Handle as if capable of transmitting infectious agents.
For in vitro diagnostic use.

Mfd. by OraSure Technologies, Inc. Beaverton, OR 97008

201-3262-3

Lot

Exp.

Label PN 201-3262-3

OraSure(R) HIV-1 WB
Low Positive Control

0.65 mL

Store at 2-8(degrees)C.
HIV-1 inactivated.
Caution: Handle as if capable of transmitting infectious agents.
For in vitro diagnostic use.

Mfd. by OraSure Technologies, Inc. Beaverton, OR 97008

201-3263-3

Lot

Exp.

Label PN 201-3263-3

OraSure(R) HIV-1 WB
High Positive Control

0.65 mL

Store at 2-8(degrees)C.
HIV-1 inactivated.
Caution: Handle as if capable of transmitting infectious agents.
For in vitro diagnostic use.

Mfd. by OraSure Technologies, Inc. Beaverton, OR 97008

201-3264-3

Lot

Exp.

Label PN 201-3264-3

Conjugate
Concentrate

0.25 mL

Store at 2-8(degrees)C.
Goat antiserum to Human lgG (H&L)
F(ab')\\2\\ fragment phosphatase conjugate.
Contains 0.1% sodium azide
as preservative.
For in vitro diagnostic use.

Mfd. by OraSure Technologies, Inc. Beaverton, OR 97008

201-3265-3

Lot

Exp.

Label PN 201-3265-3

Human Immunodeficiency Virus Type 1 (HIV-1) 20 tests
OraSure(R) HIV-1 Western Blot Kit

Western Blot Assay for the detection of the antibody to Human Immunodeficiency Virus Type 1 (HIV-1) in oral specimens collected with OraSure(R) HIV-1 Oral Specimen Collection Devices.

Store at 2-8(degrees)C.
For in vitro diagnostic use.

Contains:

OraSure HIV-1 Western Blot Strips**	1 pkg., containing 20 HIV-1 preblotted nitrocellulose strips
Sample Diluent Concentrate*	1 bottle, 100 mL
Powdered Milk	1 bottle, 30 g
Conjugate Concentrate**	1 vial, 0.25 mL, goat antiserum to Human lgG (H&L) F(ab')\\2\\ fragment phosphatase conjugate
Substrate	1 bottle, 22 mL
OraSure HIV-1 WB Negative Control	1 vial, 0.65 mL, human serum in OraSure matrix, negative for HIV-1 Ab
OraSure HIV-1 WB Low Positive Control	1 vial, 0.65 mL, human serum in OraSure matrix, positive for HIV-1Ab
OraSure HIV-1 WB High Positive Control	1 vial, 0.65 mL, human serum in OraSure matrix, positive for HIV-1 Ab
Disposable reaction trays with lids	Five each

Read accompanying package insert for instructions. **Contains 0.1% sodium azide
Caution: Handle as if capable of transmitting infectious agents. *Contains 0.01% thimerosal

Warning: FDA has approved this test kit for use with OraSure oral specimens only. Use of this test kit with specimens other than those specifically approved for use with this kit may result in inaccurate test results.

Note: This test kit should be used to test OraSure specimens only.
OraSure specimens are not to be used to screen the blood supply.

[LOGO]
B I O M E R I E U X

Manufactured by:
OraSure Technologies, Inc.
Beaverton, OR 97008
Made in USA

Distributed by:
bioMerieux, Inc.
Box 15969
Durham, NC 27704-0969

EXHIBIT 11

COMPLAINTS AND RECALLS

Customer communications and complaints and Product recalls shall be managed in accordance with this EXHIBIT 11. BMX will have primary contact with customers in North America.

11.1. If OSUR receives any communications from a customer that may fit the definition of a complaint, it shall direct the person making the complaint to BMX Customer Service.

11.1.1. All customer contacts to BMX involving Product issues which require documentation, pursuant to pertinent laws or FDA regulations or requirements, will be entered by BMX into BMX's automated complaint tracking system. Each contact will be assigned a contact code. Contacts that are considered complaints will be investigated by BMX Customer Service, and to the extent possible, resolved through troubleshooting between BMX Customer Service and the complainant.

11.1.2. Any complaint that requires an investigation and response from OSUR will be communicated by BMX to OSUR, in writing within five (5) business days after receipt of the complaint, on a BMX Supplier Corrective Action Request ("SCAR") form. In such case, BMX will arrange for contact between OSUR and the customer if needed. BMX may elect to participate in any communications between OSUR and the customer.

11.1.3 OSUR will investigate each such complaint and respond, in writing, to BMX on the SCAR form, or attachments thereto. Such response shall include reasonable details relating to the scope of the investigation and OSUR's findings and conclusions regarding the complaint. OSUR will provide a completed complaint response or, if it is not possible to provide a response, a progress update within 20 business days after receipt of the SCAR from BMX. Complaints which are Medical Device Reportable incidents will be expedited via phone and fax.

11.1.4. BMX Quality Assurance will enter the complaint response into the complaint system, and forward the complaint to BMX Customer Service, who will evaluate the adequacy of the complaint response.

11.1.5. BMX shall, using the information developed through the foregoing procedures, communicate to the customer concerning the complaint resolution within 10 business days of its receipt of a completed SCAR.

11.1.6. Upon completion of all investigation activities, technical evaluation of the complaint, and completion of a letter or documented telephone call to the complainant, BMX shall close the complaint in the complaint system.

BMX shall provide OSUR copies of all communications to the complainant within 30 days of closing the complaint investigation.

11.1.7. BMX will provide OSUR with a regular weekly report of all complaints received.

11.1.8 As needed, OSUR and BMX representatives will hold teleconferences for the purpose of discussing complaint status and to expedite the investigation of and closure of complaints.

11.1.9 OSUR and BMX shall maintain complaint files containing the information required by 21 CFR 820.198.

11.1.10 All reports and other information required to be provided to OSUR hereunder shall be provided to OSUR's Vice President, Regulatory Affairs, or such other person designated by OSUR.

11.2 If any regulatory authority issues or requests a recall or takes similar action in connection with the Product, or if either party determines an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal, the party notified of or determining the need for such recall or similar action shall, within 24 hours, advise the other party thereof by telephone or facsimile. Following notification of a recall, within 48 hours, the parties shall discuss whether or not to conduct a recall, and if so, the timing of the recall, the breadth, extent and level of customer to which the recall shall reach, the strategies and notifications to be used, and other related issues. Upon reaching agreement as to the matters set forth above, BMX shall prepare the customer distribution list and notify customers. The notification letter will contain text agreed upon by BMX and OSUR, and shall be distributed on OSUR letterhead. With OSUR's consent, BMX may include a cover letter on BMX letterhead making reference to the communication contained in the OSUR letter. Each party shall bear the expenses of any recall resulting from a breach of its respective obligations hereunder.

EXHIBIT 10.4

SUPPLY AGREEMENT

This Supply Agreement ("Agreement") is entered into as of October 11, 2002 between bioMerieux, Inc., a Missouri corporation ("BMX"), and OraSure Technologies, Inc., a Delaware corporation ("OSUR").

BACKGROUND

BMX, through its predecessor, Organon Teknika Corporation, a Delaware corporation, and OSUR, through its predecessor, Epitope, Inc., an Oregon corporation, previously entered into a Supply Agreement (the "Original Supply Agreement") and Distribution Agreement (the "Original Distribution Agreement"), each dated as of April 1, 1994. Pursuant to the Original Supply Agreement, BMX agreed to supply all of OSUR's requirements of Antigen (as defined below) in connection with the research and development, manufacture, use and sale of Products (as defined below) to BMX under the Original Distribution Agreement. Pursuant to the Original Distribution Agreement, OSUR appointed BMX and its Affiliates (as defined below) as exclusive distributor of the Products. BMX and OSUR desire to enter into this Agreement in order to amend and restate the terms of the Original Supply Agreement.

AGREEMENT

In consideration of the mutual covenants contained herein, and the premises set forth above, the parties hereby amend and restate the Original Supply Agreement in its entirety, and agree as follows:

1. Definitions.

1.1 "Affiliate" shall mean any individual or entity that controls, is controlled by, or is under common control with, the specified party. For purposes of this definition, "Control" shall mean direct or indirect beneficial ownership of more than 50% of the voting stock, ownership interest or income interest in an entity.

1.2 "Antigen" shall mean purified disrupted Human Immunodeficiency Virus Type 1, H-9 (HIV-1) strain produced by BMX's Affiliate(s) and supplied hereunder by BMX as described in the Specifications. The Antigen may be produced via either BMX's Prostak process (referred to as "Prostak Antigen") or, if made available by BMX and included in the Product specifications, the Prostak Plus process (referred to as "Prostak Plus Antigen").

1.3 "Products" shall mean oral fluid confirmatory tests for HIV-I manufactured from time to time during the Term hereof by OSUR using the Antigen. A list of the current Products is contained in Exhibit 1.3 hereto.

1.4 "Specifications" shall mean the specifications set forth on Exhibit 1.4 attached hereto with respect to the Antigen and Vironostika Assays (as defined below), or such other specifications as may be established pursuant to Article 6 hereof.

1.5 "Distribution Agreement" shall mean that certain Distribution Agreement entered into by BMX and OSUR as of the date hereof, which amends and restates the Original Distribution Agreement.

1.6 "Term" shall have the meaning described in Section 9.1.

1.7 "Transfer Price" for the types of Antigen and Vironostika Assays shall be as set forth in Exhibit 1.7 attached hereto and shall be subject to adjustment as provided in Section 3.1 hereto.

1.8 "FDA" shall mean the U. S. Food and Drug Administration, or any successor agency thereto.

1.9 "Vironostika Assay" means the BMX Vironostika HIV-1 microplate assay which is approved by the FDA for detecting HIV-1 in an oral fluid specimen for use solely for QA and other internal testing by OSUR for the Products.

2. Supply.

2.1 BMX shall sell to OSUR all of OSUR's requirements for Antigen and Vironostika Assays in connection with OSUR's research and development, manufacture, use and sale of the Products to BMX under the Distribution Agreement, or for other internal research or development purposes by OSUR. OSUR shall not resell or use the Antigen or Vironostika Assays acquired from BMX for any other purpose nor make for, or sell to, any third party, the Products covered by the Distribution Agreement or any other products made from the Antigen, except as expressly provided under Sections 9.6.3 or 9.7.

2.2 As of the effective date of this Agreement and, upon request of BMX, on the first business day of each calendar quarter thereafter, OSUR shall inform BMX, in writing, of the quantity of Antigen and Products that OSUR has in inventory.

2.3 Notwithstanding anything to the contrary herein, OSUR shall be entitled to purchase additional Antrigen and Vironostika Assays for production of Products sufficient to effect a transfer of Product manufacturing from OSUR's facilities in Beaverton, Oregon to OSUR's facilities in Bethlehem, Pennsylvania and to effect a transfer of manufacturing of the OraSure(R) Oral Specimen Collection Device from a contract manufacturer in Oregon to OSUR's facilities in Bethlehem, Pennsylvania, and to obtain FDA approval of such transfers.

3. Price; Payment.

3.1 OSUR shall pay to BMX an amount equal to the applicable Transfer Price for the Antigen and any Vironostika Assays sold hereunder. Commencing on January 1, 2004 and on each January 1 thereafter during the Term, BMX may increase the Transfer Price for the Antigen and any Vironostika Assays purchased during the calendar year beginning on such January 1, upon 60 days prior notice to OSUR, by an amount equal to the percentage change in the Consumer Price Index published by the United States Bureau of Labor Statistics of the United States Department of Labor during the twelve (12) consecutive calendar months immediately prior to the date of the notice for which data (either preliminary or final) is then available. Comparisons shall be made using the index entitled U.S. City Average - All Items and Major Group Figures for All Urban Consumers (1982-84 = 100), or the nearest comparable data on changes in the cost of living if such index is no longer published. The Transfer Price shall not include sales, use or similar taxes, and OSUR shall be responsible for payment of any such taxes.

3.2 OSUR shall pay BMX within 30 days of the date of BMX's invoice, which shall not be dated earlier than the date of shipment of Antigen and/or Vironostika Assays. Amounts not paid when due shall bear interest from the invoice date at 1 percent per month or, if less, the highest rate of interest permitted under applicable law.

4. Purchase Orders; Forecasts.

4.1 All purchases of Antigen and/or Vironostika Assays pursuant to this Agreement shall be effected by OSUR's issuance of its purchase order forms. Each purchase order shall identify the Antigen and/or Vironostika Assays purchased, quantity purchased, delivery date(s) (in accordance with applicable forecasts, unless otherwise agreed), dating, routing instructions, destination and confirmation of price. For accounting convenience, each purchase order may bear a separate number having no numerical relationship to this Agreement. No term or condition contained in any such purchase order shall alter, amend, modify or supplement BMX's obligations hereunder unless specifically agreed to in writing by BMX. BMX shall accept facsimile orders. OSUR shall submit orders at least 45 days in advance of the requested delivery date. BMX may, but shall not be required to, accept orders placed less than 45 days before the requested delivery date.

4.2 Provided BMX delivers forecasts of Product purchases in accordance with Section 4.2 of the Distribution Agreement, by the 46th day of each calendar quarter, OSUR shall provide BMX with a forecast of the amount of Antigen and Vironostika Assays that OSUR expects to order for shipment during the next four calendar quarters. The forecast shall constitute a binding commitment by OSUR to purchase not less than the quantity of Antigen and Vironostika Assays stated for each of the first three months of the forecast; provided that OSUR shall be permitted to change any forecast, including the first three months of a forecast if necessary, in order to reflect any changes in actual yields from the Antigen in manufacturing Products or any changes in Product forecasts provided by BMX under the Distribution Agreement. BMX shall use its best efforts to meet all delivery dates for Antigen and Vironostika Assays up to the amounts specified in the applicable forecast and shall use commercially reasonable efforts to meet requested delivery dates for Antigen and Vironostika Assays ordered by OSUR in excess of such quantities. Notwithstanding the foregoing, and subject to Article 2 of this Agreement, BMX may at its option and without being in breach of this Agreement decline to accept an order, or if accepted, revoke the acceptance of an order, in total or in part, which exceeds the amount of Antigen which is reasonably required by OSUR to produce the amount of Products which BMX has made a firm commitment to purchase under the Distribution Agreement. Upon request, OSUR will provide reasonable documentation to show the amount of Antigen required to produce such Products.

5. Delivery; Acceptance; Returns.

5.1 All Antigen and Vironostika Assays shall be delivered EX WORKS (Incoterms 2000) BMX's facility. Antigen shall be shipped on dry ice by overnight air express, the cost of which shall be borne by OSUR. BMX shall obtain all necessary regulatory approvals prior to the shipment of Antigen. BMX shall not deliver any Antigen more than 15 days in advance of OSUR's requested delivery date, and OSUR may return any Antigen delivered prior to such time at BMX's expense.

5.2 BMX shall be responsible for boxing, crating, handling, storage and other packing requirements prior to shipment. All Antigen and Vironostika Assays shall be packaged, marked and otherwise prepared for shipment in a manner which is (i) in accordance with good commercial practice, (ii) acceptable to common carriers for shipment and (iii) adequate to ensure safe arrival of the Antigen and Vironostika Assays. All such costs shall be paid by BMX.

5.3 BMX shall supply to OSUR for evaluation purposes only and at no charge to OSUR except for shipping expenses, a 250-microgram sample taken from Prostak Antigen lots

and Prostak Plus Antigen lots. Such samples shall be sent to OSUR prior to BMX's shipping of the applicable type of Antigen to fill an order. OSUR will evaluate the sample for compliance by the lot with the Specifications, and shall notify BMX of its approval or rejection of the Antigen represented by the sample within 37 days of receipt. In the absence of such notice, OSUR will be deemed to have accepted and approved the sample. Evaluation by and acceptance of, or any failure to evaluate or accept, any Antigen by OSUR shall in no way relieve BMX of its obligation to deliver Antigen in accordance with the warranties set forth in Section 7.1 or otherwise comply with this Agreement. Upon written approval of each lot by OSUR, BMX may include (but may not mix) more than one lot in a shipment and shall ship in volumes of approximately 130 milligrams or such smaller amounts as OSUR may reasonably request. With respect to any unused portion of a sample remaining after OSUR's evaluation (or in the event no evaluation is made), OSUR may use the remaining sample for manufacturing Products, but shall not use such sample for any other purpose whatsoever without BMX's prior written consent. OSUR, at its option, may destroy or otherwise dispose of such remaining Antigen sample, and upon termination of this Agreement, any remaining sample material shall be destroyed by OSUR. Notwithstanding the foregoing, OSUR may permanently retain a portion of each sample for lot control or other quality control purpose.

5.4 OSUR is authorized upon reasonable notice and during normal business hours to inspect BMX's or its Affiliates' manufacturing facilities, operations and quality control records to review compliance with Specifications, FDA Quality Systems Regulations and this Agreement. Any such inspection and review shall be subject to the obligations of confidentiality set forth in Article 8 hereof. Any such inspection or right to inspect by OSUR shall in no way relieve BMX of its obligation to deliver Antigen or Vironostika Assays conforming to the applicable Specifications and shall in no way waive OSUR's rights to inspect and accept or reject Antigen or Vironostika Assays.

5.5 BMX shall advise OSUR in writing (including a description of any and all observations or notices made or given relating to this part of BMX's business) of any inspection of its facilities by any governmental or regulatory agency or authority and of any other governmental or regulatory action, which BMX's management reasonably believes, or should reasonably believe, may substantially and adversely affect the Antigen, the Vironostika Assays or BMX's performance of its obligations under this Agreement (including, without limitation, BMX's obligation to comply with applicable laws and regulations). In addition, at OSUR's request, BMX shall make available for review by the FDA the manufacturing and control documentation required in connection with any FDA approvals, which may be accomplished in any manner acceptable to the FDA, including the review of a suitable master file.

6. Specifications.

BMX shall notify OSUR at least 90 days prior to any changes in the Specifications proposed by BMX and shall not make any change that would affect Product performance or regulatory approval without OSUR's prior approval, except as may be required by FDA. BMX will notify OSUR of changes required by FDA within 10 days of receipt of notice thereof. Any change in Specifications made in accordance with the provisions of this Article 6 shall be subject to the warranties given by BMX in Section 7.1. If BMX shall effect the change in Specifications in accordance with this Article 6, (i) either party shall be entitled to terminate this Agreement and the Distribution Agreement if its ability to make and/or sell the Products will be materially adversely affected by its inability to use Antigen with such modified Specifications in connection therewith; provided, however, BMX shall be entitled to make such termination only if such change is required by FDA; and (ii) the parties shall cooperate with each other in seeking

to obtain any FDA approvals required with respect to the Products as a result of any change in Specifications.

7. Warranties and Indemnities.

7.1 BMX warrants that it has full right, title and authority to sell the Antigen and Vironostika Assays to OSUR in accordance with the terms hereof. BMX further warrants that the Antigen will conform to the Specifications through 18 months from the date of delivery to OSUR and the Vironostika Assays will conform to the Specifications through the expiration date stated on the package; that in the production of the Antigen and Vironostika Assays, by BMX, or any Affiliate producing the Antigen or Vironostika Assays, as applicable, will comply with the FDA Quality Systems Regulations as well as the then current good manufacturing practices, good laboratory practices and all other applicable requirements of the FDA, and with all other applicable Federal, state and local laws; and that the Antigen and Vironostika Assays will be free from defects in materials and workmanship through their respective warranty periods stated above. THE FOREGOING WARRANTIES ARE THE SOLE AND EXCLUSIVE WARRANTIES CONCERNING THE ANTIGEN AND VIRONOSTIKA ASSAYS, AND ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ALL WARRANTIES OF MERCHANTIBILITY AND FITNESS FOR PARTICULAR PURPOSE, ARE EXPRESSLY DISCLAIMED.

7.2 BMX shall indemnify, defend and hold harmless OSUR from all claims, suits, liabilities, damages and expenses (including reasonable attorney fees) incurred on account of any third party product liability claim, including recall claims, resulting from, arising out of or connected with BMX's breach of any of the foregoing warranties or its other obligations under this Agreement; provided, however, that the foregoing indemnity shall not extend to any claim, suit, liability, damage or expense of any kind attributable to the negligent conduct of OSUR or a defect in Products not resulting from defective Antigen or Vironostika Assays.

7.3 It shall be a condition to BMX's indemnification obligation that OSUR follow the procedures set forth below:

7.3.1 OSUR shall promptly notify BMX upon learning of any claim as to which indemnification may be sought; provided, however, that failure to give such prompt notice shall only relieve BMX of its obligation to provide indemnification to the extent such failure has a material adverse effect which limits BMX from making a proper defense of such claim.

7.3.2 OSUR shall permit BMX to control the response to and any settlement or defense of any claim for which indemnification may be sought, but may require that any settlement agreement impose no obligation on OSUR other than the payment of monetary damages for which BMX indemnifies OSUR. OSUR's written consent, not to be unreasonably withheld, shall be required on any term other than the payment of such damages. OSUR shall have the right to participate in the response to and any settlement or defense of the claim using its own counsel at its own expense. If BMX fails within a reasonable time to respond to or undertake a settlement or defense of the claim, OSUR shall have the right, but not the obligation, to undertake such response, settlement, and defense at BMX's expense and risk.

7.3.3 OSUR shall cooperate fully with BMX with respect to any claim as to which indemnification may be sought, making available all information and assistance that BMX may reasonably request and that is under OSUR's control.

7.4 Each party shall immediately notify the other in writing should it become aware of any defect or condition that may constitute a deviation from the Specifications or warranties for Antigen or Vironostika Assays. BMX shall reimburse OSUR in full for all reasonable costs of retrieval and recall, replacement, or repair of Products incorporating defective Antigen, and for the purchase price paid by OSUR for the defective Antigen or Vironostika Assays, but only if the recall or replacement does not result from a defect in the manufacture, packaging, labeling or handling of Products by OSUR, in which case OSUR shall likewise be responsible.

8. Confidentiality.

8.1 Each party shall take such steps, and when necessary to protect the rights of the other shall cause its Affiliates to take such steps, as are reasonably required to protect and keep confidential, and shall not use, publicize or otherwise disclose to third parties other than Affiliates, Confidential Information (as defined below) of the other party (or its Affiliates), which Confidential Information was acquired from the other party (or its Affiliates) pursuant to this Agreement, including, without limitation, following procedures designed to limit access to such Confidential Information to those persons having the need to know it. The parties shall not disclose or use such Confidential Information except as they may be entitled to do so under this Agreement or if necessary pursuant to or in the performance of this Agreement.

8.2 The obligation of confidentiality and restriction on use imposed by the foregoing Section 8.1 shall not apply to any particular item of Confidential Information that:

8.2.1 is known or generally available, or subsequently becomes known or generally available, to the public, or is otherwise at the time of disclosure or subsequently becomes part of the public domain, whether by printed publication or otherwise, through no fault of the receiving party;

8.2.2 the receiving party can demonstrate by competent evidence, based in substance upon writings and/or physical evidence, (i) was known to the receiving party at the time of receipt or (ii) is furnished to the receiving party without obligation of confidentiality or nonuse by a third party, either before or after the time of its disclosure by the disclosing party, which third party is not restricted by a confidential undertaking to the disclosing party at the time of the disclosure;

8.2.3 the receiving party can demonstrate by competent evidence, based in substance upon writings and/or physical evidence, has been developed independently by the receiving party by persons not having access to the Confidential Information; or

8.2.4 is the Confidential Information of the disclosing party that the disclosing party discloses to a non-Affiliate without restriction.

8.3 The obligations of confidentiality and restriction on use under this Article 8 shall continue to be binding upon the parties, for a period of five years following termination or expiration of this Agreement.

8.4 Either party may also disclose Confidential Information disclosed to it by the other party to the extent, and only to the extent, such disclosure is necessary for such party to comply with applicable governmental laws or regulations, including disclosures in any

regulatory filings required in connection with the Products. The party that desires to so disclose Confidential Information shall give the other party reasonable advance notice of any such proposed disclosure pursuant to such compliance with law or regulation, shall use its best efforts to secure confidential treatment of the Confidential Information thus disclosed, and shall advise the other party in writing of the manner in which that was done.

8.5 For purposes of this Agreement, Confidential Information shall mean: (a) data, inventions, information, processes, know-how, patent applications, trade secrets and similar intellectual property rights of a party, including, without limitation, the original and copies of all documents, inventions, laboratory notebooks, drawings, specifications, devices, equipment, prototype models and tangible manifestations embodying any technology disclosed hereunder, (b) a party's customer lists and marketing, sales, costs, royalty and similar information related to the manufacture or sale of Antigen, Vironostika Assays or Products, and (c) any other information disclosed in writing and marked as "Confidential Information" or, if disclosed orally, reduced to writing and marked as "Confidential Information" and submitted within thirty (30) days of the original oral disclosure.

9. Term; Termination.

9.1 The initial term of this Agreement shall commence on the date first written above and shall continue until December 31, 2005 (the "Initial Term"), unless terminated earlier as provided below; provided, however, that this Agreement shall automatically renew for successive additional periods of one year each (each a "Renewal Term" and together with the Initial Term, the "Term") unless either party gives written notice of its election not to have this Agreement renewed, which notice must be given not less than 180 days prior to the expiration of the Initial Term or applicable Renewal Term. In the event FDA approval for the use of BMX's HIV-0-TEK HIV-1 assay for detection of HIV-1 in an oral fluid sample collected with an OraSure(R) Oral Specimen Collection Device is received on or before December 31, 2004, the Initial Term shall automatically be extended to December 31, 2007 (notwithstanding either party providing notice of their election not to renew).

9.2 Without waiving any other rights OSUR may have, OSUR shall have the right to terminate this Agreement at any time within 90 days following the occurrence of any of the following events:

9.2.1 BMX shall fail, on more than one occasion in any calendar year, to deliver Antigen or Vironostika Assays (for reasons other than as specified in 9.2.2) within 20 working days after the delivery dates established thereof pursuant to the terms of this Agreement and any applicable purchase order; or

9.2.2 the Antigen or Vironostika Assays delivered shall not conform to the applicable warranties contained in this Agreement and such failure to conform is not remedied within 10 days after notice thereof (either written, or oral with written confirmation) to BMX; or

9.2.3 BMX shall be in material breach of any of the other provisions of this Agreement or of any purchase order issued pursuant to this Agreement (not covered by Subsections 9.2.1, 9.2.2 or 9.3) and such breach is not cured within 30 days of written notice thereof to BMX; or

9.2.4 BMX shall become insolvent or file a voluntary petition in bankruptcy; BMX shall make an assignment for the benefit of creditors; a receiver, trustee

in bankruptcy or similar officer shall be appointed to take charge of all or part of BMX's assets or property; or an involuntary petition of bankruptcy shall be filed against BMX and, in the case of any of the foregoing, the same shall not have been dismissed or otherwise resolved within 30 days.

9.2.5 The Distribution Agreement expires without being renewed or is terminated other than for default of OSUR.

9.3 OSUR acknowledges that the production of Antigen involves a biological process and is therefore subject to many variable factors which may make it impossible to furnish Antigen which conforms to the applicable Specifications contained herein despite best efforts to do so. In the event BMX is unable to furnish Antigen conforming to the Specifications or is otherwise unable to supply all of OSUR's requirements of Antigen, despite best efforts to do so, then OSUR shall, as its sole remedy, be entitled either to (i) terminate this Agreement if such failure is not remedied within 30 days after written notice from OSUR; (ii) and/or to purchase Antigen meeting the Specifications hereunder from an alternative source in such quantities as OSUR shall determine until such time as BMX is able to fully resume production and delivery of Antigen under this Agreement, provided that OSUR shall have the right to purchase such quantities of Antigen from BMX as OSUR shall determine and BMX shall be able to supply. If OSUR makes the election set forth in clause (ii), above, BMX shall use its best efforts to assist OSUR in finding an alternative source of Antigen.

9.4 Without waiving any other rights BMX may have, BMX shall have the right to terminate this Agreement at any time within 90 days following the occurrence of any of the following events:

9.4.1 OSUR shall be in material breach of any of the provisions of this Agreement and such breach is not cured within 30 days of written notice thereof to OSUR (15 days for breach of payment terms); or

9.4.2 OSUR shall become insolvent or file a voluntary petition in bankruptcy; OSUR shall make an assignment for the benefit of creditors; a receiver, trustee in bankruptcy or similar officer shall be appointed to take charge of all or part of OSUR's assets or property; or an involuntary petition of bankruptcy shall be filed against OSUR, and in the case of any of the foregoing, the same shall not have been dismissed or otherwise resolved within 30 days.

9.4.3 The Distribution Agreement expires without being renewed or is terminated other than for default of BMX.

9.5 Termination or expiration of this Agreement shall not relieve any party from performance of any obligation due nor affect any rights accrued prior to the effective date of such termination or expiration.

9.6 Antigen purchased by OSUR under this Agreement which remains unused by OSUR at the time of expiration or termination of this Agreement shall be handled as follows:

9.6.1 If this Agreement is terminated as a result of a default by BMX under this Agreement or the Distribution Agreement, BMX shall, at OSUR's request, be required to repurchase any remaining Antigen held by OSUR, not to exceed the quantity of Antigen needed to produce OSUR's forecasted requirements for the following six (6)

months, provided such Antigen meets the Specifications and has not been in OSUR's possession for more than twelve (12) months. BMX shall pay OSUR the amount paid by OSUR for such Antigen. OSUR shall package and ship such Antigen to BMX, with the cost of freight to be paid by BMX. Payment shall be made within 30 days of receipt of such Antigen.

9.6.2 If this Agreement expires or is terminated as a result of a default by OSUR under this Agreement or the Distribution Agreement, BMX shall have the option, upon written notice to OSUR within 60 days after such event, to repurchase any or all Antigen held by OSUR which is not needed to fulfill OSUR's requirements to complete the production of Products for BMX under the Distribution Agreement. BMX shall pay OSUR or provide a credit to OSUR's account, at BMX's option for the amount paid by OSUR for such repurchased Antigen. OSUR shall package and ship such Antigen to BMX with the cost of freight to be paid by BMX. BMX shall pay OSUR or credit OSUR's account within 30 days of receipt of such returned Antigen.

9.6.3 With respect to any Antigen not repurchased by BMX under Section 9.6.1 or 9.6.2, OSUR may make Products therefrom and sell such Products provided OSUR has first obtained a license to do so from the National Institutes of Health ("NIH") (the holder of certain applicable U.S. patents covering the Antigen and the Products) or a sublicense from a holder of such license, if deemed necessary by the NIH. OSUR shall not resell Antigen to any third party and shall not sell Products unless it has obtained the aforesaid license or sublicense, if deemed necessary by the NIH. OSUR shall indemnify, defend and hold harmless BMX from any claim by NIH and any liability, cost or expense arising from such claim due to OSUR's failure to obtain such license.

9.7 In the event this Agreement expires, or terminates other than as a result of a default by OSUR, BMX shall negotiate in good faith with OSUR for production and sale to OSUR of a two (2) year supply of Antigen and OSUR shall be permitted to make Products from such Antigen and sell such Products (provided OSUR has secured, if necessary, the appropriate license(s) or sublicense(s) to make, use and sell the Products). The two (2) year supply shall be not greater than the quantity of Antigen sold to OSUR during the previous two (2) years of the Agreement, plus an amount equal to ten percent (10%) of that two (2) year supply. The Transfer Price payable by OSUR for the two (2) year supply shall not exceed the Transfer Price for the Antigen in effect on the date the Agreement expires or terminates, and OSUR shall pay BMX a royalty equal to *** percent (**%) of the gross revenues, less only the costs of freight, insurance, taxes, duties, returns and rebates paid or allowed by OSUR, from sales of Products manufactured with such two (2) year supply of Antigen.

9.8 Royalty. Royalties due under Section 9.7 will be payable on a quarterly basis and will be due within 45 days after the end of each calendar qarter. OSUR shall, as of the same date, provide BMX a written report, specifying in such detail as BMX may reasonably request, the total revenue received during such quarter from such Products, the total number of units of each Product involved, and the allowable deductions taken. OSUR shall, for a period of three years after the end of each calendar quarter for which reports are due, keep and maintain full and complete records to document all revenue received and all allowable deductions with respect to such Products. BMX shall be entitled to audit OSUR's records, not more than once annually, to verify the accuracy of OSUR's quarterly reports and royalty payments; provided, however any audit(s) shall commence no later than three years from the date of the royalty report to which it pertains. All information received by BMX from OSUR in connection with such

audits and all royalty calculations shall be subject to the confidentiality provisions of Article 8. Any amounts determined to be due as a result of such audits shall be paid within thirty days after OSUR's receipt of BMX's request, except that any disputed amounts will be settled pursuant to Section 10.12 hereof (Dispute Resolution).

10. Miscellaneous.

10.1 Notices. Notices required or permitted hereunder shall be in writing and shall be personally delivered or sent by registered or certified mail or facsimile to the addresses set forth below or to such other address in the United States that the parties may hereafter specify, and shall be effective upon receipt:

10.1.1 If to BMX:

bioMerieux, Inc.
100 Rodolphe Street
Durham, N.C. 27712
Attn: President
Copy: General Counsel
Fax: (919) 620-2519

10.1.2 If to OSUR:

OraSure Technologies, Inc.
150 Webster Street
Bethlehem, PA 18015
Attn: President
Copy: General Counsel
Fax: (610) 882-2275

10.2 Governing Law. This Agreement shall be governed by and interpreted in accordance with the laws of the State of North Carolina, without regard to the choice of law rules thereof.

10.3 Assignment. Neither this Agreement nor any right or obligation arising hereunder may be assigned, in whole or in part, by either party without the prior written consent of the other, which consent shall not be unreasonably withheld. Notwithstanding the above, this Agreement may be assigned by either BMX or OSUR to a third party which succeeds to all or substantially all of the assigning party's business, whether by merger, consolidation, sale or otherwise, without the consent of the non-assigning party, except that, in the event of an assignment by OSUR to any party reasonably deemed a competitor of BMX, as defined below, by BMX, BMX retains the right to refuse such assignment. A competitor of BMX shall mean an entity that competes with BMX in the manufacture, distribution or sale of diagnostic products. Subject to the foregoing restrictions on assignment, this Agreement shall inure to the benefit of and be binding upon the successors and permitted assigns of each of the parties.

10.4 Entire Agreement. From and after the effective date hereof, this Agreement (together with all Exhibits), the Distribution Agreement and that certain Release and Settlement Agreement between OSUR and BMX of even date herewith, set forth and constitute the entire agreement between the parties with respect to the subject matter hereof, and supersede any and all other prior agreements, understandings, promises and representations

made by either party to the other concerning the subject matter hereof; provided, however that any sales of Antigen which occurred under the Original Supply Agreement or which are pending as of the date of this Agreement, and the parties' rights and obligations with respect thereto, shall continue to be governed by the terms of the Original Supply Agreement. This Agreement may not be released, discharged, amended or modified in any manner except by an instrument in writing, making specific reference to this Agreement, and signed by duly authorized representatives of both parties.

10.5 Waiver. No waiver of any right under this Agreement shall be deemed effective unless contained in writing and signed by the party charged with such waiver, and no waiver of any right arising from any breach or failure to perform shall be deemed to be a waiver of any future right or any other right arising under this Agreement.

10.6 Survival. Articles 7, 8, and 10 and Sections 9.6, 9.7 and 9.8 shall survive expiration or termination of this Agreement, notwithstanding the delivery or acceptance of or payment for Antigen.

10.7 Severability. If any provision of this Agreement is held invalid by any law, rule, order or regulation of any government or by the final determination of any state or federal court, such invalidity shall not affect the enforceability of all other provisions of this Agreement not held to be invalid.

10.8 Compliance with Law. Each party shall comply with all applicable laws, rules and regulations, including FDA regulations, in the performance of its obligations under this Agreement.

10.9 Captions. Captions and section headings of this Agreement are for convenience of reference only and shall not affect the interpretation or meaning of this Agreement.

10.10 Attorney Fees. In the event suit or action or arbitration is instituted to enforce or interpret the terms of this Agreement, the prevailing party shall be entitled to recover from the other party such sum as the court or arbitrator may adjudge reasonable as attorney fees at trial or arbitration, on appeal, and on any petition for review, in addition to all other sums provided by law; provided, however, such sums shall not exceed the damages awarded to the prevailing party.

10.11 Press Releases. Neither party shall make any public disclosure (including press releases) of the terms of this Agreement without the prior written consent of the other party, except to the extent required by securities or other laws in the reasonable opinion of such party or its counsel. If a party intends to issue a press release regarding this Agreement as permitted under this Section 10.11, it shall provide the proposed release by facsimile or otherwise to the other party at least twenty-four (24) hours before the release is issued and shall make any changes reasonably requested by the other party before the release is issued.

10.12 Alternate Dispute Resolution. The parties shall attempt in good faith to resolve promptly any dispute arising out of or relating to this Agreement by negotiation. If the matter cannot be resolved in the normal course of business, either party shall give the other party written notice of any such dispute not resolved, after which the dispute shall be referred to senior executives of both parties, who shall likewise attempt to resolve the dispute. If the dispute has not been resolved by negotiation within forty-five (45) days of the disputing party's written notice or if the parties fail to meet within twenty (20) days from such

notice, the parties shall endeavor to settle the dispute by mediation under the supervision of and in accordance with the Center for Public Resources ("CPR") Model Mediation Procedure for Business Disputes. Unless otherwise agreed, both parties and either individual party may request the CPR to appoint an independent mediator. The location of the mediation shall be agreed upon by both parties and, in the event parties do not timely agree, the location will be determined by the mediator. Any dispute not settled by the mediation referenced above within sixty (60) days after appointment of a mediator may, upon the request of either party, be submitted to arbitration in accordance with the CPR Arbitration Rules and Commentary. A single, impartial arbitrator mutually acceptable to the parties shall conduct the arbitration. In the event the parties cannot agree on an arbitrator within twenty-one (21) days after the end of the aforesaid sixty (60) days, either party may have an arbitrator appointed by the CPR. The location of the arbitration shall be agreed upon by both parties. As a condition of appointment of the arbitrator, said arbitrator shall agree to use her/his best efforts to conclude the proceeding within sixty (60) days. Said arbitrator shall further have the authority to limit the volume of evidence and documents to be submitted by the parties. Any court having jurisdiction thereof may enter judgment upon the award rendered by the arbitrator. This Section 10.12 shall, however, not be construed to limit or to preclude either party from bringing any action in any court of competent jurisdiction for injunctive or other provisional relief as necessary or appropriate.

10.13 Counterparts. This Agreement may be executed in more than one counterpart, each of which shall be an original and together all such counterparts shall constitute a single instrument. A facsimile transmission of a signed counterpart shall be the same as delivery of an original.

IN WITNESS WHEREOF, the parties have executed this Supply Agreement as of the date and year first written above.

BioMerieux, Inc.	OraSure Technologies,Inc.
By: /s/ Brian W. Arnstrong	By: /s/ Mike Gausling
Its: CFO	Its: CEO

EXHIBIT 1.3

PRODUCTS

PRODUCT	OSUR Part Number
ORASURE ORAL FLUID WESTERN BLOT KIT	501-0000

EXHIBIT 1.4

SPECIFICATIONS

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EXHIBIT 1.7

TRANSFER PRICE

PRODUCT	PART NUMBER	TRANSFER PRICE
HIV-1 PROSTAK ANTIGEN	259109	**********
HIV-1 PROSTAK PLUS ANTIGEN	259677	**********
VIRONOSTIKA HIV-1 MICROPLATE ASSAY KITS (192 Tests per Kit and ******* per Test)	259750	**********

Exhibit 99.1

CERTIFICATION PURSUANT TO
18 U.S.C. (S)1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Michael J. Gausling, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. (S)1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Michael J. Gausling

Michael J. Gausling
President and Chief Executive Officer

November 13, 2002

Exhibit 99.2

CERTIFICATION PURSUANT TO
18 U.S.C. (S)1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of OraSure Technologies, Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2002 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Ronald H. Spair, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. (S)1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Ronald H. Spair

Ronald H. Spair
Executive Vice President and
Chief Financial Officer

November 13, 2002

* Portions of this Exhibit were omitted and filed separately with the Securities and Exchange Commission pursuant to an application for confidential treatment.