



OraSure Technologies, Inc. Announces FDA Clearance that Expands Patient-Friendly Access to Testing for Sexually Transmitted Infections

June 11, 2026

The clearance combines OraSure's Colli-Pee™•Dx Urine Collection Kit for at-home sample collection with Roche's cobas® molecular lab testing equipment

BETHLEHEM, Pa., June 11, 2026 (GLOBE NEWSWIRE) -- OraSure Technologies, Inc. ("OraSure") (NASDAQ: OSUR), a leader in point-of-need and home diagnostic tests and sample management solutions today announced U.S. Food and Drug Administration (FDA) clearance of its Colli-Pee™•Dx Urine Collection Kit from its subsidiary DNA Genotek Inc., for use with Roche's tests for *Chlamydia trachomatis* (CT), *Neisseria gonorrhoeae* (NG), *Trichomonas vaginalis* (TV), and *Mycoplasma genitalium* (MG) and run on Roche's cobas® 5800, 6800, and 8800 molecular diagnostic systems. The FDA-cleared collection kit supports at-home self-collection of first-void urine, enabling convenient sample collection at-home or in any private setting for both male and female patients.

This clearance marks a significant advancement in patient-centric diagnostics, combining OraSure's Colli-Pee™•Dx Urine Collection Kit, which includes NucleoPrecision™ Technology, a proprietary chemistry for DNA and RNA stabilization, with Roche's cobas® high-throughput molecular testing capabilities. The Colli-Pee™•Dx Urine Collection Kit uses innovative stabilization technology to make STI laboratory testing easier by allowing reliable, private at-home urine collection and maintaining urine sample integrity at ambient temperatures. It expands access for individuals constrained by mobility, geography, or other barriers; improves patient convenience; and makes population-level screening programs feasible for broader, previously underserved populations. Healthcare providers can now prescribe, and laboratories can now receive, self-collected urine specimens directly from patients' homes and process them seamlessly and at scale using Roche's cobas® automated laboratory platforms.

The Colli-Pee™•Dx Urine Collection Kit is designed to collect volumetric, first-void urine, ensuring optimal sample-to-preserved-ratio, a critical factor for STI detection, while offering a simple, non-invasive experience that prioritizes patient convenience and privacy.

"This clearance connects people to care that is more accessible, convenient, private, and personalized. It showcases what's possible when you design solutions around real-life patient behavior," said Carrie Eglinton Manner, President and Chief Executive Officer of OraSure. "We are committed to delivering user-friendly tests and collection devices that can be conveniently used in decentralized settings, and this clearance reflects meaningful progress on our innovation roadmap."

Enabling Scalable, Decentralized Testing

With FDA clearance, laboratories and health systems can now deploy a fully validated mail-in workflow that supports high-volume molecular STI testing without invasive sample collection methods. The collaboration enables the convenience of at-home urine collection, improves reach to populations in need, and supports public health initiatives focused on early detection and treatment of STIs.

The Colli-Pee™•Dx Urine Collection Kit will be sold by OraSure subsidiary DNA Genotek.

About OraSure Technologies

OraSure Technologies, Inc. ("OraSure" and "OTI") transforms health through actionable insight and decentralizes diagnostics to connect people to healthcare wherever they are. OTI improves access, quality, and value of healthcare with innovation in effortless tests and sample management solutions. Together with its wholly-owned subsidiaries, DNA Genotek Inc., Sherlock Biosciences, Inc., and BioMedomics, Inc., OTI is a leader in the development, manufacture, and distribution of rapid diagnostic tests and sample collection and stabilization devices designed to discover and detect critical medical conditions. OTI's portfolio of products is sold globally to clinical laboratories, hospitals, physicians' offices, clinics, public health and community-based organizations, research institutions, government agencies, pharmaceutical companies, and direct to consumers. For more information, please visit www.orasure.com.

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Forward Looking Statement

This press release contains certain "forward-looking statements." Forward-looking statements are based on current expectations of future events and are not guarantees of future performance or results. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from expectations and projections. Known and unknown factors that could cause actual performance or results to be materially different from those expressed or implied in these statements include, but are not limited to: uncertainty of commercial success; ability to manufacture or have manufactured products in accordance with applicable specifications, performance standards and quality requirements; unexpected safety, quality or manufacturing issues; government regulation and unexpected regulatory actions or delays; ability to comply with applicable regulatory requirements; uncertainty relating to patent protection and potential patent infringement claims; impact of competitors, competing products and technology changes and patents obtained by competitors; reduction or deferral of public funding available to customers; competition from new or better technology or lower cost products; impact of negative economic conditions; changes in behavior and spending patterns of purchasers; product efficacy or safety concerns resulting in product recalls or regulatory action; and changes to applicable laws and regulations. These and other factors that could affect our results are discussed more fully in our SEC filings, including our registration statements,

Annual Report on Form 10-K for the year ended December 31, 2025, Quarterly Reports on Form 10-Q, and other filings with the SEC. Although forward-looking statements help to provide information about future prospects, readers should keep in mind that forward-looking statements may not be reliable. Readers are cautioned not to place undue reliance on the forward-looking statements. The forward-looking statements are made as of the date of this press release and OraSure undertakes no duty to update these statements.