



NEWS RELEASE

Waters Corporation and Quest Diagnostics Help Close Cervical Cancer Screening Gap Bringing Nationwide Access to the Most Comprehensive FDA-Cleared At-Home HPV Screening Option

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- Expands access to most comprehensive FDA-approved HPV test and at-home self-collection option across Quest's national clinician, health plan, and consumer channels starting in 2027
- First and only FDA-approved HPV test that supports all ASCCP Enduring Risk-Based Management Guidelines by providing comprehensive extended genotyping
- Quest Diagnostics serves half of U.S. physicians and hospitals and one in three American adults each year

MILFORD, Mass. and SECAUCUS, N.J., Oct. 20, 2026 /PRNewswire/ -- Quest Diagnostics (NYSE: DGX), a leader in diagnostic information services, and Waters Corporation (NYSE: WAT), a global life sciences and diagnostics leader, today announced a collaboration intended to broaden access to clinically appropriate at-home cervical cancer screening through the FDA-cleared Onclarity™ Self-Collection Kit.^{1,2,13}

This collaboration is the first formed by Waters that will provide access to the Onclarity Self-Collection Kit through clinical, health plan, and consumer health channels, along with patient service centers, in the United States. Quest serves one in three American adults and one in two physicians and hospitals each year, and has a nationwide network of over 2,000 patient service centers. This marks a significant step forward in the fight against cervical cancer, positioning both companies at the forefront of closing the U.S. screening gap.

Cervical cancer is largely preventable with regular screening and early detection of human papillomavirus (HPV), the leading cause of cervical cancer, yet screening gaps persist, in part because of the sample collection process of traditional tests, which is often inaccessible and uncomfortable for patients.²⁻⁶ The Onclarity Self-Collection Kit used

with the BD Onclarity™ HPV Assay delivers breakthrough innovation by offering at-home patient self-collection while simultaneously reporting an extended number of individual HPV genotypes to provide more comprehensive results.^{7,14}

"In the U.S., there are over 24 million un- and under-screened individuals and approximately 14,000 new cases of cervical cancer each year,"⁸ said Jeff Andrews, M.D., FRCSC, Vice President of Medical Affairs, Waters Advanced Diagnostics, Waters Corporation. "By bringing together Waters' diagnostic innovation with Quest's national reach and capabilities, we have an opportunity to make a meaningful impact for these millions of individuals who remain at risk, advancing our shared goal of eliminating this highly preventable disease."

Beginning in 2027, Quest will drive expanded patient access to Waters' innovation through their broad clinician channel, their Gaps in Care channel serving health insurance plans, and their consumer-initiated testing channel, **questhealth.com**, all combined with access to their patient service center network.

"Many women struggle to participate in traditional cervical cancer screening methods, primarily due to geographic, socioeconomic, and logistical barriers," said board-certified OB/GYN Damian ("Pat") Alagia, M.D., Senior Medical Director, Women's & Reproductive Health, Quest Diagnostics. "We believe in making healthcare more proactive, personal, and connected for all patients, including through transformational options like at-home self-collection to help fill critical gaps in access to care."

With the new self-collection option, more patients will be able to collect their own sample in the comfort of their home using the Onclarity Self-Collection Kit, enabled by the BD Onclarity HPV Assay.⁷ Patients will then mail the sample back to Quest or drop it off at one of the approximately 2,000 Quest patient service centers nationwide. Quest's full-service laboratory will process samples, powered by the fully automated BD COR™ System, which uses advanced robotics to prepare, analyze, and report results while preserving specimen integrity and ensuring reliable, high-quality outcomes.⁹

Certain HPV genotypes, including types 16, 18, and 45, are associated with an increased risk of cervical cancer, making genotype-specific information important for patient management.¹⁰ As HPV vaccination has reduced infections from HPV types 16 and 18, other high-risk HPV strains now account for a growing share of cervical disease, particularly among younger, vaccinated populations.¹¹ The Onclarity Self-Collection Kit is enabled by the BD Onclarity HPV Assay, the first and only FDA-approved HPV test that supports all of the American Society for Colposcopy and Cervical Pathology (ASCCP) Enduring Risk-Based Management Guidelines.^{7,10} Updated Health Resources and Services Administration (HRSA) guidelines identify high-risk HPV testing, whether clinician- or self-collected, as the preferred screening method for average-risk individuals ages 30 to 65.¹² The BD Onclarity HPV Assay offers extended genotyping beyond HPV 16, 18, and 45 and individually identifies HPV types 16, 18, 31, 45, 51,

and 52 along with three sets of strategically pooled results, regardless of collection method.⁷

Quest Diagnostics is a leader in women's and reproductive health and offers a complete menu of solutions for screening and diagnosing cervical cancer. For more information, visit www.QuestWomensHealth.com.

Waters Corporation is an advanced diagnostics leader, offering the **FDA-cleared Onclarity HPV Self-Collection Kit for at-home use, used with the BD Onclarity HPV Assay with extended genotyping**, marking a significant milestone in expanding access to cervical cancer screening and removing barriers that currently prevent many individuals from receiving routine screening.

About Quest Diagnostics:

Quest Diagnostics works across healthcare to create a healthier world, one life at a time. We connect people, from clinicians to consumers, with laboratory insights that illuminate a path to better health. With a focus on delivering smarter, simpler testing, we help reveal new avenues to identify and treat disease, empower healthy behaviors, and improve healthcare management. Quest Diagnostics serves half the physicians and hospitals in the United States and one in three American adults each year, and our nearly 60,000 employees work together to deliver diagnostic insights that inspire actions to transform lives. www.QuestDiagnostics.com

About Waters Corporation:

Waters Corporation (NYSE: WAT) is a global leader in life sciences and diagnostics, dedicated to accelerating the benefits of pioneering science through analytical technologies, informatics, and service. With a focus on regulated, high-volume testing environments, our innovative portfolio harnesses deep scientific expertise across chemistry, physics, and biology. We collaborate with customers around the world to advance the release of effective, high-quality medicines, ensure the safety of food and water, and drive better patient outcomes by detecting diseases earlier, managing routine infections, and combating antibiotic resistance. Through a shared culture of relentless innovation, our passionate team of ~15,000 colleagues turn scientific challenges into breakthroughs that improve lives worldwide. For more information, please visit www.waters.com/about.

The BD Biosciences and BD Diagnostic Solutions businesses have been acquired by Waters Corporation ("Waters"). Becton, Dickinson and Company or one of its affiliates or subsidiaries ("BD") remains the legal manufacturer of Biosciences and Diagnostic Solutions products until all required regulatory transfers are completed. During this interim period, BD maintains full responsibility for all regulatory obligations of the legal manufacturer. Product information provided here is supplied under BD's regulatory authority. To learn more about the relationship between Waters and BD during this transition period, please see our detailed summary:

www.waters.com/bdtransaction.

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Self-collected vaginal specimens can be tested as an alternative specimen type when cervical sampling is either contraindicated or cervical samples otherwise cannot be obtained.

There are currently two FDA-approved HPV tests with extended genotyping with different configurations. The BD Onclarity™ HPV Assay individually identifies 6 high-risk HPV genotypes and strategically groups 3 results for 8 moderate risk HPV genotypes.

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SOURCE Waters Corporation; Quest Diagnostics