

## Waters Announces FDA Clearance of the Most Comprehensive At-Home Cervical Cancer Screening Tool, the Onclarity HPV Self-Collection Kit and FDA-Approved HPV Assay

2026-04-08

- FDA-approved BD Onclarity™ HPV Assay is the most comprehensive screening tool for HPV in the U.S.<sup>1,4</sup> with extended genotyping and end-to-end automated lab workflows.
- At-home self-collection reduces significant barriers for unscreened or under-screened individuals who make up approximately 60% of cervical cancer cases.<sup>3</sup>
- Waters is establishing partnerships to enable broader nationwide access to the Onclarity™ HPV Self-Collection Kit for patients and prescribers to reduce cervical cancer risk.

MILFORD, Mass., April 8, 2026 /PRNewswire/ -- Waters Corporation (NYSE: WAT) today announced that the U.S. Food and Drug Administration (FDA) has cleared the Onclarity HPV Self-Collection Kit and approved the BD Onclarity HPV Assay with extended genotyping for at-home use, marking a significant milestone in expanding access to cervical cancer screening, and removing barriers that currently prevent many individuals from receiving routine screening.

Cervical cancer is largely preventable with regular screening and early detection of human papillomavirus (HPV), the virus responsible for nearly all cervical cancers.<sup>2</sup> Approximately 60% of cervical cancer cases occur in individuals who are unscreened or under-screened.<sup>3</sup> Expanding screening options and access, including at-home self-collection, has been identified by public health experts as an instrumental strategy for improving early detection and reducing cervical cancer deaths.

"Expanding access to screening is one of the most important steps we can take to prevent cervical cancer, and at-

home HPV self-collection is a game changer for making screening easier to complete," said Jeff Andrews, M.D., FRCSC, Vice President of Medical Affairs, Waters Advanced Diagnostics, Waters Corporation. "As a practicing obstetrician-gynecologist who has performed cervical cancer screenings for decades, I have seen firsthand the profound difference early detection makes for patients. When more patients are able to get screened, whether at home or in the clinic, clinicians have better information to identify risks earlier and intervene sooner. That allows us to spend less time trying to reach patients who have fallen behind on screening and more time focusing on prevention, follow-up care, and treatment for those who need it."

The kit is tested with the BD Onclarity HPV Assay, which detects all of the high-risk, carcinogenic genotypes of HPV and is the only FDA-approved HPV assay to identify six individually and three groups of pooled results, making it the most comprehensive HPV screening tool available in the U.S. today.<sup>1</sup> Samples are processed on 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. Waters collaborated with the National Institutes of Health's (NIH) National Cancer Institute (NCI) through the Cervical Cancer 'Last Mile' Initiative SHIP Trial to evaluate the accuracy of self-collection for HPV testing.

"U.S. FDA clearance of the Onclarity Self-Collection Kit for at-home use marks a meaningful step towards removing today's primary barriers to screening, and supporting more personalized care," said Jianqing Bennett, Senior Vice President, Waters Advanced Diagnostics, Waters Corporation. "We're proud to provide this kit to advance earlier detection, achieve greater health equity, and ultimately reduce the burden of cervical cancer for women and persons with a cervix."

Waters is currently establishing partnerships to enable broader nationwide access to the Onclarity HPV Self-Collection Kit, which is expected to be available by prescription in the coming months. Covered by private insurance, Medicaid, and Medicare, the kit can be mailed directly to a patient's home, allowing them to collect a sample at their convenience and mail it to a laboratory for processing. Results are shared with the patient's healthcare provider to guide follow-up and care decisions.

## Additional Resources:

- [Product Page](#)

BD is a trademark of Becton, Dickinson and Company. Waters is a trademark of Waters Corporation or its affiliates. All other marks are the property of their respective owners.

The Onclarity HPV Self-Collection Kit, Onclarity HPV Assay, and BD COR System are manufactured by Becton, Dickinson and Company or one of its affiliates or subsidiaries.

## 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 ~16,000 colleagues turn scientific challenges into breakthroughs that improve lives worldwide. For more information, please visit [www.waters.com/about](http://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](http://www.waters.com/bdtransaction).

## References:

BD Onclarity HPV Assay Package Insert [8089894].

World Health Organization. (2026, March 17). Cervical Cancer. <https://www.who.int/news-room/fact-sheets/detail/cervical-cancer>.

Scarinci IC, Garcia FA, Kobetz E, Partridge EE, Brandt HM et al. (2010) Cervical cancer prevention: new tools and old barriers. *Cancer* 116 (11): 2531-2542.

Wei F, Georges D, Man I, Baussano I, Clifford GM. Causal attribution of human papillomavirus genotypes to invasive cervical cancer worldwide: a systematic analysis of the global literature. *Lancet*. 2024;404(10451):435-444. doi:10.1016/S0140-6736(24)01097-3.

## Contact:

Molly Gluck

Head of External Communications

Waters Corporation

+1.508.498.9732

[molly\\_gluck@waters.com](mailto:molly_gluck@waters.com)

View original content to download multimedia:<https://www.prnewswire.com/news-releases/waters-announces-fda-clearance-of-the-most-comprehensive-at-home-cervical-cancer-screening-tool-the-onclarity-hpv-self-collection-kit-and-fda-approved-hpv-assay-302736967.html>

SOURCE Waters Corporation