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ASIA EDITION

Waters receives US FDA clearance of at-home cervical cancer screening tool

April 9, 2026 | News

Waters is establishing partnerships to enable broader nationwide access to the Onclarityâ?¢ HPV Self-Collection Kit



Waters Corporation has announced that the US 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.

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 US today. 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.

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.