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U.S. Human Papillomavirus Testing Market Size, Share & Trends Analysis Report By Application (Cervical Cancer Screening, Vaginal Cancer Screening), By Product, By Technology, By End Use, And Segment Forecasts, 2025 - 2033

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Abstracts

Market Size & Trends

The U.S. human papillomavirus testing market size was estimated at USD 638.37 million in 2024 and is projected to grow at a CAGR of around 13.56% from 2025 to 2033. The market growth is propelled by evolving clinical guidelines, technological innovation, and growing emphasis on preventive healthcare. The U.S. Preventive Services Task Force (USPSTF) and American Cancer Society (ACS) recommend primary HPV testing or co-testing for women aged 30-65, boosting adoption. FDA approvals, such as Abbott's Alinity m HR HPV assay (November 2023) and Roche's cobas Human Papillomavirus (HPV) Test, have expanded high-sensitivity, genotype-specific options. Increasing self-sampling pilots, led by organizations like Kaiser Permanente, are improving screening access for underserved populations. Rising awareness campaigns from the CDC and American Sexual Health Association further drive demand, aligning with national goals to reduce cervical cancer incidence.

The U.S. HPV testing industry is undergoing rapid transformation, fueled by updated clinical guidelines, landmark regulatory approvals, and a shift toward patient-centered screening models. In July 2020, the American Cancer Society (ACS) updated its recommendations, making primary HPV testing every five years the preferred method for individuals aged 25–65, citing superior accuracy, longer screening intervals, and reduced unnecessary interventions compared with Pap smears. This move reflects growing evidence that HPV testing more reliably detects high-grade precancerous

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lesions while avoiding the overdiagnosis associated with cytology.

In December 2024, the U.S. Preventive Services Task Force (USPSTF) released draft guidelines recommending HPV testing every five years for women aged 30–65, with Pap testing or HPV/Pap co-testing as acceptable alternatives. Critically, the USPSTF included self-collected HPV samples taken in healthcare settings for the first time, acknowledging studies showing comparable accuracy to clinician-collected specimens and significantly higher uptake among historically underscreened groups.

A major regulatory milestone followed in May 2024, when the FDA approved HPV self-collection for cervical cancer screening in clinical environments. ACS CEO stated, “Self-collection can expand access to screening and reduce barriers, giving more people the opportunity to detect, treat, and ultimately survive cancer.” On the same day, Roche secured FDA approval for its cobas HPV self-collection solution, enabling patients to privately collect vaginal samples for laboratory testing. Roche Diagnostics CEO emphasized, “Our HPV self-collection solution helps support the goal of eliminating cervical cancer by 2030 by reducing barriers and providing access to HPV screening.”

With 13,000 new cervical cancer diagnoses and 4,000 related deaths annually in the U.S.-over half in underscreened populations-these combined initiatives are poised to close critical screening gaps. Public–private collaborations, such as the National Cancer Institute’s Cervical Cancer “Last Mile” Initiative, are aligning with WHO’s 2030 elimination strategy to expand reach, modernize screening pathways, and ensure equity in access. As adoption of self-collection and guideline-driven HPV testing accelerates, the U.S. HPV testing market is expected to see robust growth, driven by increased demand for high-sensitivity molecular assays, broader participation, and expanded reimbursement coverage.

U.S. Human Papillomavirus Testing Market Report Segmentation

This report forecasts revenue growth at country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the U.S. HPV testing market report on the basis of application, product, technology, and end use:

Application Outlook (Revenue, USD Million, 2021 - 2033)

Cervical Cancer Screening

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