FDA Approves Self-Collection cobas HPV Test for Early Detection of Cervical Cancer Early

The FDA approved one of the first human papillomavirus (HPV) self-collection solutions available in the US using a cobas molecular instrument. By screening for HPV, health care professionals can identify patients who are at risk of developing cervical cancer and initiate early treatment before the cancer has the chance to develop.[1]

According to the National Institutes of Health, more than half of US patients who are diagnosed with cervical cancer do not participate in routine screening, and have either never been screened or have been screened infrequently. Because many factors may contribute to patients' ability to get screened—access barriers to health care, social and economic barriers, and traumatic experiences, among others—the self-collection solution can help reduce barriers by offering an alternative method to in-office procedures and testing.[1]

The cobas HPV test is an automated qualitative in vitro test for the detection of HPV DNA in patient specimens. In a single analysis, the test utilizes amplification of target DNA through a polymerase chain reaction (PCR) and nucleic acid hybridization to detect 14 high-risk HPV (hrHPV) types. The test simultaneously gives patients pooled results on high-risk genotypes—HPV 16 and HPV 18—at clinically relevant infection levels. According to Roche, cervical cell specimens can be collected in ThinPrep Preserv Solution as well as SurePath Perservative Fluid. Following results from the ATHENA clinical trial (NCT0070989) in 2014, the FDA approved the cobas HPV test for first-line, primary screening in women aged 25 years and older.[2]

The cobas HPV test was evaluated in the ATHENA trial, a large, prospective clinical trial that examined the test's performance in women aged 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology, women aged 30 years and older with normal cervical cytology, and an overall screening population of individuals aged 25 years and older to determine HPV as a first-line test. The trial enrolled more than 47,000 women and it was the first screening trial to evaluate the simultaneous real-time genotyping of 12 pooled hrHPV genotypes plus HPV 16 and HPV 18 individually.[3]

According to the findings, the trial not only validated the HPV test as comparable to the current standard of pooled hrHPV testing among patients with ASC-US, but it also quantified risk of precancer and cervical cancer in HPV 16+ and or/ HPV 18+ women who had either ASC-US or normal cytology. Further, the results demonstrated that 1 in 4 women who were HPV 16 positive will have cervical disease within 3 years, and that approximately 1 in 7 patients who are HPV 16 positive with a normal Pap cytology had high-grade cervical disease that was missed by a cytology.[3]

Not only was cobas validated as comparable to the current standard of pooled hrHPV testing, but the trial also quantified risk of precancer and cervical cancer in HPV 16 positive and/or HPV 18 positive women with ASC-US or a normal cytology. The ATHENA trial also demonstrated that the copas HPV test when using cervical cytology as a follow-up test, providers were able to detect more disease in

women who were HPV 16 or HPV 18 positive, without the need to refer patients for unnecessary follow-up visits.[3]

“With vaccinations, innovative diagnostic tools and screening programs, achieving the WHO’s goal of eliminating cervical cancer by 2030 is within reach,” said Matt Sause, CEO of Roche Diagnostics, in a press release. “Our HPV self-collection solution helps support this goal by reducing barriers and providing access to HPV screening by allowing people to privately collect their own sample for HPV testing.”[1]

References

1. Roche. Roche announces FDA approval of one of the first HPV self-collection solutions in the U.S., expanding access and screening options to help eliminate cervical cancer. News release. May 15, 2024. Accessed May 20, 2024. https://www.roche.com/media/releases/med-cor-2024-05-15
2. Roche Diagnostics. Delivering confidence with every result on cobas® 4800 / 5800 / 6800 / 8800 systems. Accessed May 20, 2024. https://diagnostics.roche.com/us/en/products/lab/cobas-hpv-5800-6800-8800-pid00000297.html
3. Roche. Shaping our Understanding of the Role of High-Risk HPV Testing in Cervical Cancer Screening. News release. Accessed May 20, 2024. https://diagnostics.roche.com/global/en/article-listing/athena-trial.html#:~:text=ATHENA%20Key%20Findings%3A&text=ATHENA%20not%20only%20validated%20the,or%20who%20had%20normal%20cytology.

About the Trial

Trial Name: Evaluation of the Cobas® 4800 HPV Test for the Detection of High-grade Cervical Disease

ClinicalTrials.gov ID: NCT00709891

Sponsor: Hoffmann-La Roche

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