Accurately detect HPV infection. Help prevent cervical cancer.

Xpert® HPV

Reliable detection of high-risk HPV DNA with genotyping of HPV 16 and 18/45

Cepheid®
A better way.

CE IVD In Vitro Diagnostic Medical Device

High-risk human papillomavirus (HPV) testing is a highly effective and reliable method of screening to prevent cervical cancer. An easy-to-use, rapid (~60 minutes to results), and scalable (1 to 80 tests per hour) HPV test with partial genotyping for the most important HPV types (HPV16 and HPV18/45) for risk stratification is transformative.

It now will be possible to deploy centralized or point-of-care HPV testing for cervical cancer screening in all settings throughout the world using a wide range of clinical algorithms, including same-day screen-and-treat strategies."

Philip E. Castle, Ph.D., MPH

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THE NEED

Human papillomavirus (HPV) infection is the most common sexually transmitted infection worldwide. On a global basis, HPV genotypes 16 and 18 are associated with approximately 71% of all cases of cervical cancer, and HPV genotype 45 is associated with approximately 6% of additional cases of cervical cancer.[1]

Cervical cancer screening programs vary, based upon local guidance that consider testing algorithms, resources, skill set and infrastructure.

Most HPV Nucleic Acid Amplification Tests (NAAT) are complicated to use and batch testing can delay results critical for scheduling patient consultations for follow-up testing or colposcopy.

The ideal HPV test can flexibly integrate easily into most environments, and enable physicians to effectively risk stratify patients based on cytology and high-risk HPV status. Further, rapid HPV results that include integrated high risk HPV 16 and HPV 18 genotyping support quality decision making for colposcopy referral.[2]

THE SOLUTION

Now both cytology and molecular laboratories can run a HPV test with confidence. Based on the GeneXpert technology, Xpert® HPV automates the test process including DNA extraction, amplification, and detection in one fully integrated cartridge. ONE test for all screening algorithm options.

On-demand HPV testing — a next generation solution:

- Highest risk HPV 16 and HPV 18/45 call-outs enhances patient stratification
- Optimized detection of 14 hrHPV reported as: HPV16, HPV18/45 or other hrHPV (31, 33, 35, 52, 58; 51, 59; 39, 56, 66, 68)
- E6/E7 oncogenes target eliminates concerns in case of L1 gene deletion[3]
- Sample adequacy control (SAC) confirms patient sample contains human DNA
- Reporting of hrHPV DNA in captured cervical cells for improved performance
- HPV results in 60 minutes for same-visit clinician/patient consult, minimizes need for repeat visits
- Scalable platform automation delivers on-demand results, eliminating delays associated with batch testing

THE IMPACT

Improve your laboratory workflow with simple, on-demand, random-access flexibility. Combine performance with the ability to run other tests (such as CT/NG, TV, HIV, HCV, and GBS) on the GeneXpert® System to achieve a proven increase in overall laboratory level service.

Shift from reactive to proactive

- Improved patient care: risk stratification in less than 60 minutes to support better clinical decisions.
- Full ownership of patient results with same day cytology and HPV testing.
- Optimal assay design for improved accuracy and reproducibility.
- Adaptable: remote, near patient, in a cytology center, or in a molecular laboratory.

CLINICAL PERFORMANCE

Clinical performance characteristics of Xpert® HPV were established in multi-site, prospective investigational studies at US and European institutions. These studies included both a colposcopy referral population and a general cervical cancer screening population. Performance of Xpert HPV was established relative to cervical disease status and/or in comparison to two currently marketed HPV (NAAT) tests.[4]

TABLE 1. CLINICAL PERFORMANCE RELATIVE TO ≥ CIN2* DISEASE STATUS

	Xpert HPV	cobas® Roche	hc2 (Qiagen)
Sensitivity *95%CI*	**90.8%** (84.7-95.0%)	**90.8%** (84.7-95.0%)	**81.6%** (74.2-87.6%)
Specificity *95%CI*	**42.6%** (38.5-46.9%)	**39.6%** (35.5-43.8%)	**47.7%** (43.4-51.9%)

TABLE 2. CLINICAL PERFORMANCE RELATIVE TO ≥ CIN3* DISEASE STATUS

	Xpert HPV	cobas® Roche	hc2 (Qiagen)
Sensitivity *95%CI*	**92.3%** (84.8-96.9%)	**92.3%** (84.8-96.9%)	**80.2%** (70.6-87.8%)
Specificity *95%CI*	**40.0%** (36.1-44.0%)	**37.2%** (33.3-41.2%)	**45.0%** (40.9-49.0%)

* Preinvasive precursor lesions or dysplasia (often referred to as "CIN", for cervical intraepithelial neoplasia), are graded into histological grades of mild (CIN1), moderate (CIN2) or severe (CIN3). Lesions often regress and do not progress to invasive cancer.[5]

CLINICAL VALIDATION

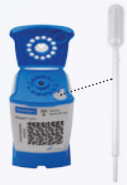
Clinical validation of the Xpert HPV test according to the international guidelines[6] was established in multi-site, investigational studies at European institutions. [7,8] Xpert HPV demonstrated high accuracy for use in cervical cancer screening with a relative clinical sensitivity for ≥CIN2 of 0.98 [0.931-1.040] and a relative clinical specificity for ≤CIN1 of 1.006 [0.997-1.016]. Additionally, Xpert HPV showed excellent overall intra-laboratory reproducibility with an agreement of 96.9% [95% CI, 95.0-98.2%]. The inter-laboratory test also showed an excellent agreement of 97.8% [95% CI, 96.2-98.9%].[9]

WORKFLOW:

2 Easy Steps

Total hands-on time: <1 minute

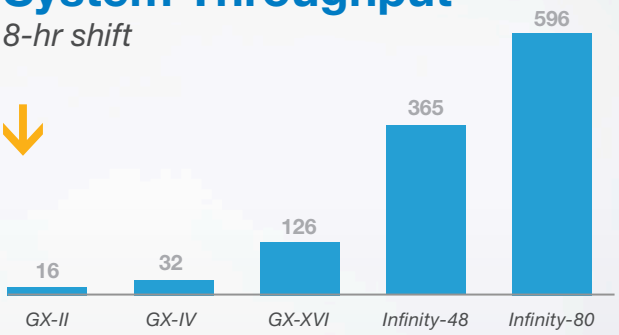
1 Transfer 1 ml of appropriately collected cervical specimen to the cartridge*.



2 Insert cartridge and start test. Results in less than 60 minutes.

System Throughput^

8-hr shift



^ Operational throughput per 8-hr shift based on HPV testing, internal analysis.

Xpert® HPV is a qualitative real-time PCR test for automated and rapid detection of Human Papillomaviruses (HPV).

CATALOG INFORMATION

Xpert HPV (10 tests) GXHPV-CE-10

References:

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9. Cuschieri K, et al. Performance of a cartridge based assay for the detection of clinically significant HPV infection lessons from VALGENT (Validation of HPV Genotyping Tests). J Clin Microbiol. 2016 Jul.

* Refer to Xpert HPV package insert for instruction on collection of ThinPrep (PreservCyt) specimen

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