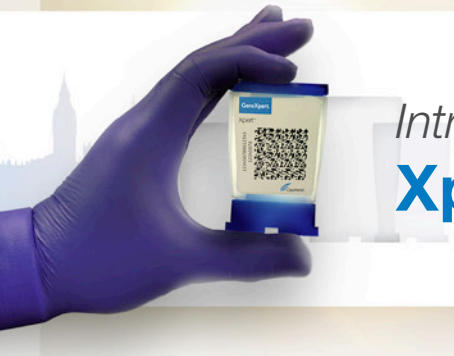

Introducing

Xpert® HPV*

Projected Release (CE-IVD) Q4 2013:

Situation/Introduction

- Human papillomavirus (HPV) infection is the most common sexually transmitted infection worldwide. On a global basis, HPV types 16 and 18 are associated with approximately 71% of all cases of cervical cancer, with the more aggressive type HPV type 45 associated with roughly 6% of cases.[1]
- Of the fourteen high risk types, HPV 18 and HPV 45 together have been observed in significantly more common in cases of adenocarcinoma than in cases of squamous cell carcinoma. Cancers related to HPV 45 and HPV 18 arise at a much younger age (<50 years), and along with HPV 16, are more likely to be incorporated into the human genome to increase E6/E7 expression to promote cellular proliferation and the chance of malignancy.[2]
- Unfortunately, current HPV NAAT tests are complicated to use and batch testing can delay results critical for scheduling Physician/Patient consultations on next steps for retesting or colposcopy. Rapid and comprehensive HPV results can be integral to the implementation of new testing strategies that include integrated HPV 16/18 testing for more efficient referral to colposcopy.[3]

Unmet Need

- Reflex cytology algorithms following detection of high risk HPV or a HPV16/18 result, often require women to return for inconvenient follow-up appointments for colposcopy. The drawn out series of visits are disruptive and may contribute to patient anxiety.
- Molecular testing options for cervical cancer cytology specialists have been difficult and burdensome to adopt, presenting additional demands on cytologists occupied with an already full workload to develop additional skills to utilise these highly complex and contamination prone laboratory tests.
- To address the variety of cervical cancer testing and patient management programs emerging around the world, it is desirable to have a rapid, accurate and easy to use NAAT that delivers thorough actionable information to support appropriate patient treatment on a timely basis.

Preliminary Intended Use

- Xpert HPV is a qualitative in vitro test for the detection of Human papillomavirus (HPV) in patient specimens collected in Cervical specimens in ThinPrep® Pap Test vials containing PreservCyt Solution.[4] The test utilises amplification of target DNA by real-time Polymerase Chain Reaction (PCR) of 14 high-risk HPV types in a single analysis. The test specifically identifies HPV 16, HPV 18/45, and concurrently detects other 11 high risk types (31, 33, 35, 39, 51, 52, 56, 58, 59, 66 and 68).

* Pending CE-IVD approval. Product distribution outside the United States.

Introducing

Xpert® HPV*

Cepheid Molecular Testing Delivers:

- Consistent high quality results for near patient, Physician Office Laboratories (POL) and large laboratory environments.
- HPV results tailored to support decisions for immediate course of treatment in around 1 hour.
- Moderate complexity for ease of HPV technology adoption.

Why GeneXpert®?

- A qualitative diagnostic test for accurate detection of high risk HPV and reporting for the highest risk genotypes.
- On-demand results with throughput and scalability suitable to a variety of testing environments.
- One platform provides flexibility to perform a broad menu of easy to perform assays.

Impact:

- Identify patients with high risk genotypes for cytology referral or triage.
- On-demand results suited to algorithm requirements in cytology primary screening, co-testing primary screening, or HPV screening.
- Address changes in patient pathways and cost of healthcare delivery.

Xpert HPV: When available, Cepheid's on-demand Xpert test for accurate detection of high risk HPV will provide results in approximately one hour.

* Pending CE-IVD approval. Product distribution outside the United States.

References:

1. de SanJose, S. et al. Human papillomavirus genotype attribution in invasive cervical cancer: a retrospective cross-sectional worldwide study. Lancet Oncol 2010; 11: 1048–56.
2. ibid.
3. Cox JT, Castle PE, Behrens CM, et al. Comparison of cervical cancer screening strategies incorporating different combinations of cytology, HPV testing, and genotyping for HPV 16/18: results from the ATHENA HPV study. Am J Obstet Gynecol 2013;208:184.e1-11.
4. PRESERVCYT and THINPREP are trademarks of Hologic, Inc.

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