

ANCILLARY TESTING for LIQUID BASED PAPS

Testing for Low and/or High Risk HPV

HPV is a family of over 100 virus types, of which 30 are associated with anogenital lesions and spread through genital contact (sexual intercourse). The disease spectrum represented ranges from common genital warts to cervical cancer. Approximately 12 types are called “low-risk” and can cause genital warts. There are approximately 15 “high-risk types and current data show that over 90% of high-grade lesions are oncogenic High Risk HPV positive and nononcogenic Low Risk HPV negative. Human Papillomavirus DNA (HPV) by in situ hybridization is extremely useful in providing information about the risk profile of HPV if present.

Data shows that patients with oncogenic HPV and a Pap abnormality of ASCUS have a significantly increased risk of having a concurrent high-grade lesion (CIN 2 or 3, or Carcinoma).

NOTE: The American Society for Colposcopy and Cervical Pathology (ASCCP) has recently released management algorithms that take into account if the patient is pregnant or an adolescent. Please refer to these consensus guidelines for further information:

www.asccp.org/consensus.shtml

We offer HPV testing as a screening or as a reflex test and have validated our in situ hybridization technique using Ventana’s Inform™ HPV Analyte Specific Reagent (ASR) High and Low Risk ISH Probes for both ThinPrep and SurePath liquid based paps.

The in situ system offers several advantages over other methods that involve the obligatory destruction of the target squamous cell, including:

- **Direct correlation with the cytologic findings**
- **Ability to test archival specimens**
- **High sensitivity and specificity**
- **May also be used to test Tissue specimens**

All such advantages are important when dealing with an oncogenic and sexually transmitted virus. Especially important is the ability to differentiate those cases of ASCUS associated with a high risk of SIL from those that are due to benign conditions.

Both the SurePath and ThinPrep specimens are stable for up to 3 weeks at room temperature. The HPV test is run in two panels, one for non-oncogenic strains (Low Risk HPV Types: 6, 11, 42, 43, and 44) and one for oncogenic strains (High Risk HPV Types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68 and 70). Each test panel is billed separately with a CPT code 88365.

Unit Code 9467, HPV High Risk by Liquid Based Pap, CPT 88365

Unit Code 9468, HPV Low Risk by Liquid Based Pap, CPT 88365-91

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Chlamydia and Gonorrhea Testing (C/GC)

Chlamydia trachomatis is a gram-negative, non-motile bacterium that exists as an obligate intracellular parasite. Chlamydia trachomatis infections are now recognized as the leading cause of sexually transmitted diseases (STD) in the United States with approximately 4 million cases occurring annually.

Neisseria gonorrhoeae is a gram-negative, diplococci and is the causive agent of Gonorrhea. Approximately 600,000 new cases are diagnosed in the United States annually.

We offer both as added tests on the Cytology Requisition for either SurePath or ThinPrep liquid based paps.

- ***NOTE: because of the danger of cross contaminating the specimen while processing the liquid based pap smear – no add orders will be taken. Please resubmit the specimen as a genital swab in a ProbeTec tube, urine specimen, or liquid based Pap vial after 5 weeks.***
- ***There is no evidence of degradation of cytology results by Aliquot Removal, however, this cannot be ruled out for all specimens. If negative results from the specimen do not fit with the clinical impression, a new specimen may be necessary.***
- ***When opting for concurrent cytologic and STD testing, providers should consider risk and clinical history (e.g., disease prevalence, patient age, sexual history or pregnancy) as well as specimen suitability (e.g., exudates or bleeding) that can impact diagnostic reliability.***

The BD ProbeTec methodology utilizes strand displacement assay nucleic acid amplification techniques and nucleic acid hybridization for the detection of Chlamydia trachomatis or the Neisseria gonorrhoeae plasmid DNA directly in clinical specimens

Both SurePath and Thin Prep Liquid Based Paps (LBP) have been validated and both specimens are good for up to 3 weeks at room temperature following collection.

Unit Code 2228, C. Trachomatis (Chlamydia) by LBP, CPT 87491.

Unit Code 2229, N. Gonorrhea by LBP, CPT 87591.

REFERENCES:

1. Lee, Kr, et al. Comparison of convention Papanicolaou smears and a fluid-based, thin-layer system for cervical cancer screening. Obstet Gynecol 1997; 90:278-284
2. Corkill M, et al. Specimen adequacy of Thin Prep sample preparations in a direct-to-vial study. Acta Cytologica 1997; 41:39-44.
3. ThinPrep 2000 System Operator's Manual Addendum, 70354-001-B001 Rev. A

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