CLINICAL PATHOLOGY LABORATORIES
A Sonic Healthcare Company

# Urgent Client Notice: Changes in HPV Testing

*Offering our clients state-of-the-art testing is part of CPL's ongoing commitment to excellence.*

With the ongoing COVID-19 pandemic testing consuming numerous resources, the laboratory industry and its technology vendors are experiencing critical shortages of consumables used across a variety of molecular diagnostic platforms. In particular, the pipette tips used in the automation of numerous robotic fluid transfers are in backlog while manufacturing facilities are brought online to meet CPL's requirements in Women's Health nucleic acid-amplification testing (NAAT). In this context CPL, will need to urgently migrate certain HPV testing from polymerase chain reaction (PCR, offered by Roche) performed on DNA to transcription mediated amplification (TMA, offered by Hologic) performed on mRNA. The literature and CPL medical leadership support the conclusion that the two technologies are virtually equivalent from a clinical perspective.

**Given the immediate nature of the supply shortage, CPL will substitute HPV mRNA analysis for HPV DNA analysis as required to meet appropriate turnaround requirements. For short backlogs, specimens will be protected and archived until adequate supplies are available. Affected test codes subject to substitution are given in the chart below:**

| | Testing Temporarily Discontinued | | Replacement Testing | |
|---|---|---|---|---|
| Clinical Indication | Unit Code | Test Description | Unit Code | Test Description |
| Age-Based Pap Test (with algorithm-driven HPV and CT/NG) | 8141 | Pap Test, Age-Based Testing, HPV DNA | 8142 | Pap Test, Age-Based Testing, HPV mRNA |
| HPV Co-Testing | 8038 | HPV High Risk with Genotype, ThinPrep | 8145 | HPV mRNA E6/E7 High Risk, Reflex Genotype, ThinPrep |
| HPV Reflex ASCUS | 9988 | HPV High Risk if ASCUS, ThinPrep | 9914 | HPV mRNA, Reflex Genotype if ASC, ThinPrep |
| HPV Reflex All Epithelial Abnormality | 9911 | HPV High if Abnormal ThinPrep | 9916 | HPV mRNA, Reflex Genotype, if Abnormal, Thinprep |

The HPV DNA report format is suitable to acceptable HPV mRNA results with comments applied to all affected testing as follows:

Note: Testing is performed on Hologic Panther platform (using mRNA TMA method) in place of Roche Cobas platform (using DNA PCR method) due to national supply shortage of test consumables.

- Results reported under HPV 18 represent a Hologic combination of HPV Genotype 18 and 45 reactivity.
- Results reported under HPV, HR, other genotypes are interpreted as positive if Hologic High-Risk HPV reagent is positive but Genotypes 16 and 18/45 are negative.

Testing methodology is transcription-mediated amplification (TMA) for E6/E7 mRNA transcript using the Hologic Aptima assay. The test detects Genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68. A positive HPV screen result indicates the presence of at least one High-Risk HPV type. HPV 16 and 18/45 are individually assessed and reported.

A negative result does not rule out the presence of HPV not included in the high risk set, current or future dysplasia, a low level of infection, interfering substances or specimen sampling error. For negative screen results, genotyping is not indicated.

We apologize for the inconvenience that this may cause. Please contact your Account Representative should you have any questions.

**References:**
https://www.nytimes.com/2020/07/23/health/coronavirus-testing-supply-shortage.html
https://www.beckershospitalreview.com/supply-chain/shortage-of-pipette-tips-is-slowing-us-covid-19-testing-2.html

*Thank you for supporting Clinical Pathology Laboratories*