



## HPV<sup>H</sup>

### HPV High Risk RNA w/ 16 & 18/45 by Hologic® Aptima®

<b>GA Test Code</b>	<b>395H</b>
<b>Method</b>	<i>FDA-approved</i> Hologic® Aptima® HPV 16 18/45 Genotype Assay <b>Note:</b> HPV detections will automatically be tested to determine if they are types <b>16, 18</b> and/or <b>45</b> . To identify a specific HPV type other than 16, 18, or 45, order Test #7575 <b>HPV Genotyping</b> (RLU/cutoff value must be at least 5.0)
<b>Specimens</b>	<b>ThinPrep:</b> 2.0 mL (1.0 mL), store and ship ambient (up to 3 months). <b>SurePath:</b> 2.0 mL (1.0 mL), store and ship ambient (14 days). <b>Note:</b> <i>Cervical specimens must be collected prior to the application of acetic acid or iodine if colposcopic examination is being performed.</i>
<b>Causes for Rejection</b>	Quantity not sufficient (QNS) for analysis; time and/or temperature instructions not followed; cervical sample collected after application of acetic acid or iodine.
<b>Reference Range</b>	Not Detected
<b>Turnaround Time</b>	24-48 hours
<b>CPT Codes</b>	87624; If <b>Detected</b> , add 87625 x 3

#### Clinical Utility

HPV is responsible for more than 99% of all cervical cancers, which is one of the most common types of cancer affecting women throughout the world.

The Aptima® HPV assay has the same excellent sensitivity and improved specificity compared to DNA-based tests, allowing clinicians to maximize the benefits of screening while minimizing potential harm.

The Aptima® HPV assay identifies high-risk HPV infections by targeting E6/E7 mRNA. Studies have shown that targeting E6/E7 mRNA identifies the presence and activity of a high-risk HPV infection. As such, you will experience fewer equivocal results and fewer positives, especially in women ages 25-29, where HPV DNA is present but the virus is not actively replicating.

Patients that are positive for high-risk HPV are reflexed to the Aptima® HPV genotyping assay to specifically identify if highly oncogenic types 16, 18, and/or 45 are present. The assay can differentiate HPV 16 from HPV 18 and/or HPV 45, but does not differentiate between HPV 18 and HPV 45.

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#### *Genetic Assays, Inc.*