HPV OncoTect™ E6, E7 mRNA Kit
A highly specific molecular test for early detection of cervical cancer
Recent studies confirm that HR HPV DNA detection has a percentage of False Negative rate due to cross reactivity with LR HPV types as well as non-oncogenic HPV types not included in the panel of 13 types of high risk types (2,3). Also, only a small percentage of HR HPV infections result in to high grade precancerous lesions (CIN2 or above)(4). Advanced studies now demonstrate that HPV E6 and E7 mRNA is a more specific indication of cellular transformation leading to CIN2 or higher grade of cervical cancer (5-10).
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NOW AVAILABLE: The HPV OncoTect™ E6, E7 mRNA Kit is a unique detection method that measures both the number of transforming cells and the quantity of E6, E7 mRNA in each cell. These two measurements precisely assess the over-expression of E6, E7 mRNA in routine patient samples collected in ThinPrep® and Surepath™ vials to further refine accuracy and specificity of HPV testing.

Flow cytometry simplified:
• No requirement for extraction of nucleic acid, eliminating cross contamination
• Results available in 3 hours for fast turnaround time
• Variable batch sizes (24 or 96 specimens) for flexible throughput
• Result output is clearly stated to indicate positive or negative
• Adaptable to most flow cytometers

Clinical Performance of HPV OncoTect™ E6, E7 mRNA Kit:
• Equivalent clinical sensitivity to HR HPV DNA Tests (95% detection of ≥CIN2)
• Significant increase in specificity
• Unique specimen adequacy feature:
  > Quantifies number of ectocervical and endocervical cells
  > Quantifies the presence of obscuring inflammatory cells
Overexpression of E6, E7 within the cell makes the difference

Many women with positive test results from a HR HPV DNA Test will have normal biopsy. The HPV Oncotect™ E6, E7 mRNA Test is only positive if there is overexpression of E6, E7. In the life cycle of the human papillomavirus, the overexpression of E6, E7 mRNA in a cell is the molecular switch leading to cervical cancer.(4, 5)

The HPV DNA response varies during the course of CIN progression. HPV Oncogenic response of E6 & E7 genes exhibited by overexpression of mRNA steadily rises or maintained high during CIN 2 development leading to invasive cancer.
### Product Design Features

<table>
<thead>
<tr>
<th>Feature</th>
<th>Specification</th>
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<tbody>
<tr>
<td><strong>Analytical Sensitivity</strong></td>
<td>5-10 E6, E7 mRNA copies per cell</td>
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<tr>
<td><strong>Clinical Decision Point</strong></td>
<td>2% of cells expressing</td>
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<td><strong>Specimens</strong></td>
<td>ThinPrep®, SurePath™</td>
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<tr>
<td><strong>Specimen Adequacy Control</strong></td>
<td>Quantification of minimum level of endocervical cells and cells per microliter (FSC versus SSC)</td>
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<td><strong>External Controls</strong></td>
<td>Preserved cell lines well characterized as positive or negative</td>
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<tr>
<td><strong>Result Interpretation</strong></td>
<td>Positive or Negative, based on clinical decision cut-off</td>
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<tr>
<td><strong>Input Volume</strong></td>
<td>500 uL</td>
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### HPV Products Available

**C12100** Kit includes all reagents and FL-labeled HPV probes (100-Test Kit)

**Controls** Positive and Negative Control Cells in LBC preservative

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