Testing Advantages of Transcription-Mediated Amplification (TMA) Methodology

- Detects 14 high-risk HPV genotypes, including 16 and 18, in a single analysis.
- Positive HPV TMA screen results can be reflexed for 16 and 18/45 genotypes.
- Genotyping test (ARUP test code 2007894) specifically detects HPV16 and HPV 18/45.
- Provides all required HPV results for most current cervical cancer screening guidelines.
- Requires only 1 mL sample volume, reducing patient callback for insufficient specimen.

Testing Advantages of PCR Methodology

- Detects 14 high-risk HPV genotypes, including 16 and 18, in a single analysis.
- Discriminates HPV16 and HPV18 from other high-risk types.
- Provides all required HPV results for current cervical cancer guidelines.
- Is FDA approved for HPV primary screening (ARUP test code 2011940).
- Requires only 1.5 mL sample volume, reducing patient callback for insufficient specimen.
- Includes internal quality control to identify false-negative results due to poor collection.

Additional Resources

Human Papillomavirus Screening in Cervical Specimens

Human papillomavirus (HPV) is the most common sexually transmitted viral infection in the United States. Nearly all sexually active men and women will contract it at some point in their lives. Most HPV infections are benign and resolve on their own, usually within two years, but persistent infection with any of the high-risk HPV genotypes increases a woman’s risk for developing cervical cancer.

**HPV prevalence:** approximately 79 million Americans are currently infected with HPV.

**HPV incidence:** approximately 14 million people become newly infected each year.

**Cervical cancer:** more than 11,000 women are diagnosed with cervical cancer annually in the U.S.

### Testing Recommendations

ARUP offers the following FDA approved tests for HPV:

<table>
<thead>
<tr>
<th>Test Description</th>
<th>Code</th>
</tr>
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<tbody>
<tr>
<td>Human Papillomavirus (HPV), High Risk by PCR, ThinPrep</td>
<td>2011947</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep</td>
<td>2011940</td>
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<tr>
<td>Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep</td>
<td>2007893</td>
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<tr>
<td>Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep</td>
<td>2007894</td>
</tr>
<tr>
<td>Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep</td>
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<td>Human Papillomavirus (HPV), High Risk by PCR, SurePath</td>
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<tr>
<td>Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath</td>
<td>2011933</td>
</tr>
</tbody>
</table>

- **ARUP offers the following FDA approved tests for HPV:**

  - **Human Papillomavirus (HPV), High Risk by PCR, ThinPrep**
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology for women ≥30 years.
    - Follow-up test for abnormal cytology results in women ≥21 years.

  - **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, ThinPrep**
    - FDA-approved platform for primary HPV screening in women ≥25 years.
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology for women ≥30 years.

  - **Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), ThinPrep**
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology for women ≥30 years.
    - Follow-up test for abnormal cytology results in women ≥21 years.

  - **Human Papillomavirus (HPV) Genotypes 16 and 18/45 by Transcription-Mediated Amplification (TMA), ThinPrep**
    - FDA-approved test for triaging women ≥30 years with negative cervical cytology (NILM Pap smear) and positive HPV test.

  - **Human Papillomavirus (HPV), High Risk by Transcription-Mediated Amplification (TMA), with Reflex to HPV Genotypes 16 and 18/45 by TMA, ThinPrep**
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology (Pap smear) in women ≥30 years.
    - Genotyping performed for triaging women who are cytology-negative (NILM) and HPV-positive to colposcopy.

  - **Human Papillomavirus (HPV), High Risk by PCR, SurePath**
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology (Pap smear) for women ≥30 years.
    - Follow-up test for abnormal cytology results in women ≥21 years.

  - **Human Papillomavirus (HPV), High Risk with 16 and 18 Genotype by PCR, SurePath**
    - FDA-approved test for routine cervical cancer screening in combination with cervical cytology (Pap smear) for women ≥30 years.
    - Follow-up test for abnormal cytology results in women ≥21 years.