Testing Advantages of Transcription-Mediated Amplification (TMA) Methodology

- Detects 14 high-risk HPV genotypes, including 16 and 18, in a single analysis.
- Targets mRNA for HPV oncogenes E6/E7.
- 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

1. Center for Disese Control. Genital HPV Infection Fact Sheet. **www.cdc.gov/STD/HPV/STDFact-HPV.htm** (accessed on January 12, 2016).

2. ARUP Consult. Human Papillomavirus (HPV) **www.arupconsult.com/Topics/HPV.html** (accessed on January 12, 2016).

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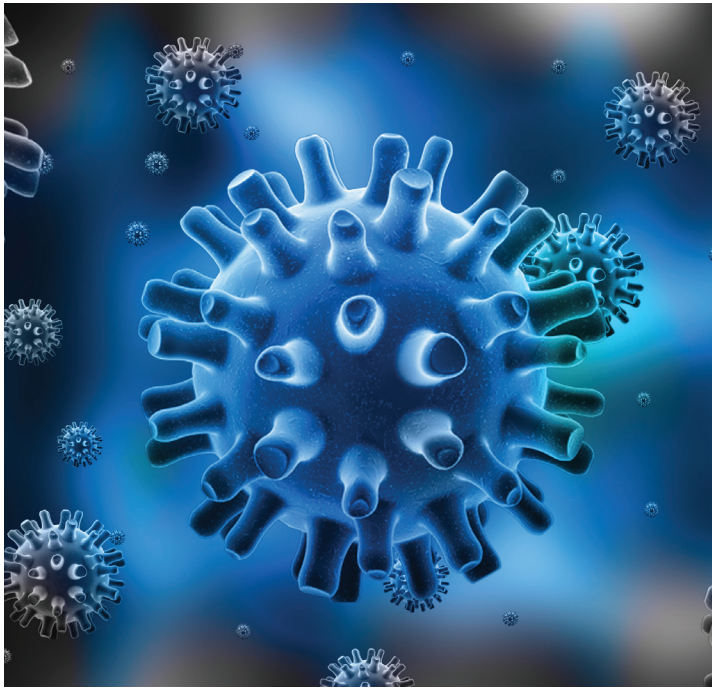
Test Highlight Information

Human Papillomavirus Screening in Cervical Specimens



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A NONPROFIT ENTERPRISE OF THE UNIVERSITY OF UTAH AND ITS DEPARTMENT OF PATHOLOGY

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:

Human Papillomavirus (HPV), High Risk by PCR, ThinPrep	2011947	- 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	2011940	- 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	2007893	- 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	2007894	- 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	2007890	- 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	2011942	- 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 abd 18 Genotype by PCR, SurePath	2011933	- 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.