

Human Papillomavirus (HPV), High-risk - Transcription-Mediated Amplification

Use

To screen women 25 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results for high-risk human papillomaviruses (hrHPV) to determine the need for referral to colposcopy.

Note: HPV testing of standard-risk women aged 21-24 years with ASC-US cervical cytology results is no longer recommended; however, it is acceptable if done. See the updated [American Society for Colposcopy and Cervical Pathology \(ASCCP\) Consensus Screening Guidelines](#).

To screen women 30-65 years old adjunctively with cervical cytology to assess for presence/absence of hrHPVs. Other uses of this test may include those indicated by consensus guidelines for cervical cancer screening and the management of women with abnormal cervical cytology and/or hrHPV results, such as those from the [ASCCP](#); clinical indications must be explicitly documented on the requisition form.

Clinical Significance

hrHPVs detected by the assay are associated with cervical pre-cancerous and cancerous lesions.

Methodology

Transcription-mediated amplification of E6/E7 viral mRNA from 14 hrHPVs: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

Specimen Type

- ThinPrep® Pap specimens

Minimum Volume/Size

- 1 mL

Collection Instructions

Collect cervical specimens in ThinPrep® Pap Test vials containing PreservCyt Solution with broom-type or cytobrush/spatula collection devices according to the manufacturer's instructions.

Specimens received at the OSDH PHL are assessed for acceptability based on patient's age and ThinPrep® Pap Test results as indicated in the table below. In addition, healthcare providers may request hrHPV testing for certain patients in their care based on best clinical management practices.

	< 21 Years Old	21 to < 25 Years Old		25 to < 30 Years Old		30 to 65 Years Old	
Cytology Results	-	Negative	ASC-US	Negative	ASC-US	Negative	ASC-US
Per Provider Order	Reject	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable
Reflex	Reject	Reject	Reject	Reject	Acceptable	Acceptable	Acceptable
Co-Testing	Reject	Reject	Reject	Reject	Reject	Acceptable	Acceptable
HPV Not Indicated	Reject	Reject	Reject	Reject	Reject	Reject	Reject

Common Causes for Rejection

- Specimen collection > 30 days prior to receipt at 2 to 30°C
- Specimen collection > 24 months prior to receipt at -20 to -70°C
- Patient < 21 years of age (unless provider requested)
- > 65 years old unless prior abnormal or provider order

- Insufficient cellularity
- QNS: < 1 mL ThinPrep liquid cytology specimen
- Discordance between provider test order and patient's age (see table above)

Shipping and Storage

Store and ship ThinPrep® liquid cytology specimens at 2°C to 30°C for delivery within 30 days from DOC. If longer storage is needed, the ThinPrep® liquid cytology specimen or the ThinPrep® liquid cytology specimen diluted into the Aptima® Specimen Transfer tube may be stored at -20°C to -70°C for up to 24 months. Place each specimen in an individually sealed bag.

Turn-around Time

Within 7 working days of receipt

Reference Range

High-risk HPV Negative

Reportable Results

- High-risk HPV Not Detected
- High-risk HPV Detected
- Invalid

Interpretation

A positive result may be due to the presence of one or more hrHPV types. Infection with HPV is not an indicator of cytologic HSIL or underlying high-grade CIN, nor does it imply that CIN2/3 or cancer will develop; most women infected with hrHPV do not develop CIN2/3 or cancer. False positive results may occur; some cross-reactivity is exhibited with low-risk HPV types 26, 67, 70, and 82. A negative result does not exclude the possibility of underlying or future cytologic abnormalities, CIN2, CIN3, or cancer, infection with low levels of hrHPV, or other HPV types not detected by this assay. Detection of HPV is dependent on adequate specimen collection and handling, absence of inhibitors, and sufficient levels of virus. Results should be interpreted in conjunction with other laboratory and clinical data. Consensus guidelines for cervical cancer screening and the management of women with abnormal cervical cytology and/or hrHPV results should be followed, such as those from the [ASCCP](#).

Limitations/Interferences

- Not intended for use in cases of suspected sexual abuse or for screening for anal and penile cancers.
- The performance of the Aptima HPV assay has not been evaluated for HPV vaccinated individuals.
- Some cross-reactivity has been observed with low-risk HPV types 26, 67, 70, and 82.
- Substance interferences include:
 - Personal lubricants containing polyquaternium 15 at concentrations > 0.025% of test sample.
 - Anti-fungals containing tioconazole at concentrations > 0.075% of test sample.
- Effects of other potential variables, such as vaginal discharge, use of tampons, douching, etc. and specimen collection variables, have not been evaluated.

CPT Code

87624

Notes

Currently, ability to order this test is restricted to County Health Departments in Oklahoma.

This test is approved for *in vitro* diagnostic use by the U.S. Food and Drug Administration.