Overview

Useful For
Management and triage of patients, age 21 or greater, with abnormal Pap results

Screening for detection of high-risk (HR) human papillomavirus (HPV) genotypes associated with the development of cervical cancer

Aids in triaging women with abnormal Pap smear results

Individual genotyping of HPV-16 and HPV-18, if present

Aids in triaging women with positive HR-HPV but negative Pap smear results

Reflex Tests

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Reporting Name</th>
<th>Available Separately</th>
<th>Always Performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>HPV</td>
<td>HPV with Genotyping, PCR, ThinPrep</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>TPSPC</td>
<td>Physician Interp Screen</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

Testing Algorithm

When this test is ordered, a ThinPrep Pap screen will be performed. If the results include the criteria below, a high-risk human papillomavirus test will be performed:

- Atypical cells of undetermined significance (ASCUS), and the patient is 21 years or older

- Atypical squamous cells, cannot exclude high-grade squamous intraepithelial lesion (ASC-H) and the patient is 21 years or older

- Low-grade squamous intraepithelial lesion (LSIL), and the patient is 50 years or older

- Inadequate endocervical/transformation zone component, negative for intraepithelial lesion or malignancy, and the patient is 30 years or older

If ThinPrep Pap results are abnormal, a pathologist will review the case at an additional charge.

Special Instructions
- [Gyn-Cytology Patient Information](#)

Method Name

ThinPrep Pap Cytology Screening by Light Microscopy with HPV High-Risk DNA Detection with Genotyping by Real-Time Polymerase Chain Reaction

NY State Available
Yes
Specimen

Specimen Type
Varies

Advisory Information
Mayo Clinic Laboratories' clients need prior laboratory approval to order Cytology testing.

Necessary Information
1. An acceptable cytology request form must accompany specimen containers and include the following: Patient’s name, medical record number, date of birth, sex, source (exact location and procedure used), date specimen was taken, name of ordering physician and pager number.

2. Submit any pertinent history or clinical information.

Specimen Required

Patient Preparation: For optimal interpretation, Papanicolaou smears should be collected near the middle of the menstrual cycle. No douching, lubricant use, and sexual intercourse for 24 hours prior to specimen collection.

Only 1 aliquot may be removed from PreservCyt sample vial prior to performing the ThinPrep Pap Test, regardless of the volume of the aliquot (maximum aliquot volume: 4 mL).

Submit only 1 of the following specimens:

Supplies: Thin Prep Media with Broom Kit (T056)

Specimen Type: Cervical

Collection Container/Tube: ThinPrep

Specimen Volume: 16 mL

Collection Instructions:

1. Obtain adequate sampling from cervix using a broom-like collection device. If desired, use lukewarm water to warm and lubricate the speculum. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction 5 times.

2. Rinse the broom as quickly as possible into the PreservCyt solution vial by pushing broom into bottom of vial 10 times, forcing the bristles apart.

3. As a final step, swirl broom vigorously to further release material. Discard the collection device.

4. Tighten cap on vial so that the torque line on the cap passes the torque line on the vial.

5. Specimen vial must be labeled with a minimum of 2 unique identifiers (patient's name and medical record number or date of birth).

Supplies: Thin Prep Media with Spatula and Brush Kit (T434)
**Specimen Type:** Ectocervix and endocervix

**Collection Container/Tube:** ThinPrep

**Specimen Volume:** 16 mL

**Collection Instructions:**

1. Obtain an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.

2. Rinse spatulas quickly as possible into the PreservCyt solution vial by swirling spatula vigorously in vial 10 times. Discard the spatula.

3. Next, obtain an adequate specimen from endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate one quarter or one half turn in 1 direction. **Do not overrotate.**

4. Rinse the brush as quickly as possible in the PreservCyt solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall.

5. Swirl brush vigorously as final step to further release material. Discard the brush.

6. Tighten the cap so that the torque line on the cap passes the torque line on the vial.

7. **Specimen vial must be labeled with a minimum of 2 unique identifiers** (patient's name and medical record number or date of birth).

**Forms**

Gyn-Cytology Patient Information Sheet (T601) in Special Instructions

**Specimen Minimum Volume**

See Specimen Required

**Reject Due To**

<p>| | |</p>
<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Hemolysis</td>
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**Specimen Stability Information**

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<th>Time</th>
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<td>42 days</td>
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<tr>
<td></td>
<td>Refrigerated</td>
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</table>
Clinical and Interpretive

Reference Values
ThinPrep PAPANICOLAOU

Satisfactory for evaluation. Negative for intraepithelial lesion or malignancy.

Note: Abnormal results will be reviewed by a pathologist at an additional charge.

HUMAN PAPILLOMAVIRUS (HPV)

Negative for HPV genotypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68

Interpretation

Cytology:

Standard reporting, as defined by the Bethesda System (TBS) is utilized.

Human papillomavirus (HPV):

A positive result indicates the presence of HPV DNA due to 1 or more of the following genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68.

A negative result indicates the absence of HPV DNA of the targeted genotypes.

For patients with atypical squamous cells of undetermined significance (ASC-US) Pap smear result and who are positive for high-risk HPV (HR-HPV), consider referral for colposcopy, if clinically indicated.

For women aged 30 years and older with a negative Pap smear result but who are positive for HPV-16 or HPV-18, consider referral for colposcopy, if clinically indicated.

For women aged 30 years and older with a negative Pap smear, positive HR-HPV test result, but who are negative for HPV-16 and HPV-18, consider repeat testing by both cytology and a HR-HPV test in 12 months.

Cautions

The Pap test is a screening test for cervical cancer with inherent false-negative results. A negative human papillomavirus (HPV) test or Pap smear result does not preclude the presence of carcinoma or intraepithelial lesion. The false-negative rates of the Pap test range from 15% to 30%.

The cobas HPV test detects DNA of the high-risk types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. This test does not detect DNA of HPV low-risk types (eg, 6, 11, 42, 43, 44) since these are not associated with cervical cancer and its precursor lesions.

The cobas HPV test is not recommended for evaluation of suspected sexual abuse.

Prevalence of HPV infection in a population may affect performance. Positive predictive values decrease when testing populations with low prevalence or individuals with no risk of infection.

Infection with HPV is not an indicator of cytologic high-grade intraepithelial lesion (HSIL) or underlying high-grade cervical intraepithelial neoplasia (CIN), nor does it imply that CIN2-3 or cancer will develop. Most women infected
with 1 or more HR-HPV types do not develop CIN2-3 or cancer.

A negative HR-HPV result does not exclude the possibility of future cytologic HSIL or underlying CIN2-3 or cancer.

**Clinical Reference**


**Performance**

**Method Description**

A ThinPrep Pap specimen is collected, processed on a T2000 or T3000 processor, and stained with a Pap stain. Cases are examined microscopically and those with appropriate cytologic diagnoses are referred to the Virology Laboratory for human papillomavirus (HPV) testing if the patient is 21 or older. (Instruction manuals: ThinPrep 2000 System, Cytex, Marlboro, MA; ThinPrep 3000 Processor, Cytex, Marlboro, MA)

The Cobas HPV test targets and detects nucleic acid from the L1 region of the HPV genome using real-time polymerase chain reaction (PCR) technology. The Cobas HPV test is used for the in vitro qualitative detection of 14 high-risk HPV types commonly associated with cervical cancer. The assay is able to specifically assess for the presence or absence of HPV genotypes 16 and 18, while concurrently detecting the remaining 12 high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). The Cobas HPV test is used in conjunction with the Cobas 4800 System. The Cobas 4800 System comprises the Cobas x 480 instrument and Cobas z 480 analyzer that fully automates the Cobas HPV from sample extraction through amplification, detection, and data reduction. (Instruction manual and package insert: Cobas HPV test, Roche Diagnostics, Indianapolis, IN, version 05641268001-01EN)
PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; Varies

Analytic Time
5 days

Maximum Laboratory Time
8 days

Specimen Retention Time
14 days after report issued if HPV testing has not been performed. 1 week if HPV testing has been performed.

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer's instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
G0123
88142
88141- TPSPC (if appropriate)

LOINC® Information

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