Test Definition: TPRPS

ThinPrep Screen

Overview

Useful For

Screening for cervical carcinoma or intraepithelial lesions

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
TPSPC	Physician Interp Screen	No	No

Testing Algorithm

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

NY State Available

Yes

Specimen

Specimen Type

Varies

Advisory Information

1. Mayo Clinic Laboratories' clients need prior laboratory approval to order cytology testing.

2. If the patient has been previously diagnosed with an abnormal Pap result or is at high risk, consider ordering the diagnostic test TPRPD / ThinPrep Diagnostic.

3. Specimen submitted as endocervical curettage or endocervical brushing need to be ordered as CYTNG / Cytology Non-Gynecologic.

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, Pap smears should be collected near the middle of the menstrual cycle. Avoid 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:

Specimen Type: Cervical

Supplies: Thin Prep Media with Broom Kit (T056)

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 to warm water 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).

Specimen Type: Ectocervix and endocervix

Supplies: Thin Prep Media with Spatula and Brush Kit (T434)

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 to warm water 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 one 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 (T601) in Special Instructions

Specimen Minimum Volume

See Specimen Required

Reject Due To

SurePath vial	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Varies	Ambient (preferred)	42 days	THIN PREP
	Refrigerated	42 days	THIN PREP

Clinical and Interpretive

Clinical Information

The ThinPrep Pap test is an alternative preparation method for the cervical Pap screening test. The method utilizes a liquid-based technique that replaces the direct smear method of the conventional Pap screen. This method is one of several technologies developed to improve visualization of cellular material by reducing smearing trauma, air drying artifact, and obscuring blood and inflammation. In addition, variability in smearing technique is eliminated as the majority of processing and preparation is performed in the laboratory under controlled conditions.

Squamous cell carcinoma of the cervix is believed to develop in progressive stages from normal through precancerous (dysplastic) stages, to carcinoma in situ, and eventually invasive carcinoma. This sequence is felt to develop over a matter of years in most patients.

Follow-up of the cervical Pap abnormality atypical squamous cells of undetermined significance (ASCUS) is costly and frustrating to patients and clinicians because a large percentage of these patients have normal colposcopic and biopsy findings. Yet, a significant percentage (10%-15%) will have an underlying high-grade squamous intraepithelial lesion (HSIL).

Reference Values

Satisfactory for evaluation. Negative for intraepithelial lesion or malignancy.

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

Interpretation

Standard reporting, as defined by the Bethesda System (TBS) is utilized.(1)

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%.

Supportive Data

Studies have shown overall increased adequacy (as measured by decreased "unsatisfactory" and "satisfactory but limited by rates") as compared to the conventional smear method. Some studies showing increased detection rates for epithelial cell abnormalities (low-grade squamous intraepithelial lesions and high-grade squamous intraepithelial lesions) as well as decreased indeterminate rates (atypical squamous cells of undetermined significance and atypical glandular cells of undetermined significance) have been reported in both split specimen (ThinPrep and conventional smears) and direct-to-vial comparison studies.

Clinical Reference

1. Solomon D: The Bethesda System for Reporting Cervical Cytology: Definitions, Criteria, and Explanatory Notes. Third edition. Edited by R Nayar, DC Wilbur. New York, Springer 2015

2. Austin RM, Ramzey I: Increased detection of epithelial cell abnormalities by liquid-based gynecologic cytology preparations. A review of accumulated data. Acta Cytol 1998;42:178-184

3. Guidos BJ, Selvaggi SM: Use of the ThinPrep Pap test in clinical practice. Diagn Cytopathol 1999;20:70-73

4. Kurman RJ: The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses: Definitions, Criteria, and Explanatory Notes for Terminology and Specimen Adequacy. Edited by D Soloman. New York, Springer-Verlag, 1994

5. Gay JD, Donaldson LD, Goellner JR: False-negative results in cervical cytologic studies. Acta Cytol 1985;29:1043-1046

6. Saslow D, Solomon D, Lawson HW, et al: American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. J Low Genit Tract Dis 2012;16(3):175-204

Performance

Method Description

The ThinPrep Pap specimen is processed on a T2000 or T3000 processor, producing a slide that is stained with a Papanicolaou stain. The stained slides are examined microscopically.(Instruction manuals: ThinPrep 2000 System, Cytyc, Marlboro, MA; ThinPrep 3000 Processor, Cytyc, Marlboro, MA)

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

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, approved or is exempt 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

Test ID	Test Order Name	Order LOINC Value
TPRPS	ThinPrep Screen	In Process

Result ID	Test Result Name	Result LOINC Value
71286	Interpretation	69965-2
71287	Participated in the Interpretation	19768-1
71288	Report electronically signed by	19139-5
71289	Addendum	35265-8
71290	Gross Description	22634-0
CY027	Pap Test Source	22633-2
CY028	Clinical History	22636-5
CY029	Menstrual Status (LMP, PM, Pregnant)	8678-5
CY030	Hormone Therapy/Contraceptives	8659-5

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Result ID	Test Result Name	Result LOINC Value
71574	Disclaimer	62364-5
71820	Case Number	80398-1