Labcorp Surgical Pathology and Cytology Client Manual for:

Saint Luke’s Health System
4401 Wornall Road
Kansas City, MO 64171

Updated 3-1-2023
Fine Needle Aspiration Cytology

**TEST: 009001  CPT: 88173**

**Synonyms**
- Breast
- Breast Cyst Fluids
- Lymph Nodes
- Salivary Gland
- Thyroid
- Thyroid Cysts

**Test Includes**
Cytologic evaluation of specimens obtained by fine needle aspiration from lesions of all body sites

**Special Instructions**
Include patient's name, date of birth, Social Security number, source, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information on the test request form.

It is recommended to do an aspirate only on a palpable mass. (“Blind” sticks are discouraged except for those under radiologic guidance.) A **minimum** of two separate passes should be done, preferably more (inadequate specimens result in false-negative diagnosis).

It is very important to specify the source of the specimen along with clinical history and clinical impression. If a cyst is aspirated, indicate this fact on the test request form; it will most likely be hypocellular but will not be a false-negative. If the patient has a known diagnosis of malignancy, please include that information on the test request form. Whatever the specimen source, please include your clinical impression and reason for doing the aspiration (eg, “fine-needle aspiration on lymph node: suspect lymphoma vs metastatic carcinoma vs infectious process”).
If an infectious process is in the differential, please submit a portion of the specimen to microbiology in an appropriate sterile medium or transport container. Once the specimen is smeared and/or put in an alcohol container, it is unsuitable for culture.

**Expected Turnaround Time**

Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Documents**

For more information, please view the literature below.

*Thyroid Testing: Assessing Thyroid Disease in Your Patients*

**SPECIMEN REQUIREMENTS**

**Specimen**

Aspirated material

**Container**

Slide(s), Coplin jar(s)

**Collection**

Use a small gauge (eg, 25-g or 22-g) needle to avoid dilution with blood. Immobilize the palpable mass with your nondominant hand. Using a syringe holder will allow you to keep your nondominant hand on the mass. Insert the needle into the mass and pull back on the syringe plunger, creating negative pressure, using it as a cutting tool. Make short 5 mm “in-and-out” motions until you see material coming into the hub of the needle. **When you start to see material in the hub, stop, release negative pressure on the syringe, and pull out to make the slides.** Do not aspirate material into the syringe or dilute with blood or saline. This interferes with making good direct smears. (See preparation of slides below.) If you do not see any material at all in the hub or syringe, continue the short 5 mm strokes until you have done 15 to 20 strokes. Pull out and attempt to express material on slides (see below). Repeat the above procedure again using a clean needle for a second pass (and more passes if needed). Many physicians use no local anesthesia. If you decide to give a local, please avoid aspirating the local anesthetic into the needle. It will dilute as well as distort the specimen.

Making direct smears (preferred method):

- Using a graphite pencil, label 8 to 10 slides with the patient’s name before starting the procedure.

- After aspiration, make sure to have positive pressure in the syringe (if need be, remove the needle, pull back the plunger, then reattach the needle to gain positive pressure). **Avoid aspirating the material from the needle into the syringe.**
• Touch the end of the needle to the end of the glass slide and express one to two drops of material. (If too much material is expressed, the slides will be too thick for optimal interpretation. A thin monolayer of cells is desired.)

• Place a second slide on top of the first, allowing the drop to spread, then gently pull slides apart toward opposite end. **Fix immediately in 95% ethyl alcohol.** Note: It is imperative to fix the slides immediately to avoid air drying. Continue making more slides in this fashion until all the material in the needle is used.

• Do not discard the needle yet. Rinse the needle in a labeled container of balanced salt solution and an equal volume of 50% ethanol. Send all material to the lab.

Alternative to making direct smears (less desirable, but acceptable): Express the specimen directly into a balanced salt solution and an equal volume of either 50% ethyl alcohol or Saccomanno fixative. Send to the laboratory for slide preparation.

If a cyst is aspirated, use the alternative method outlined above. The laboratory will spin the specimen for concentration.

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>Refrigerate</th>
</tr>
</thead>
</table>

| Causes for Rejection | Improper labeling; improper fixation; air-drying artifact; specimen submitted in vial that expired according to manufacturer's label |

**TEST DETAILS**

| Use | Diagnose primary or metastatic malignant neoplasms; differential diagnosis of benign versus malignant processes |
| Methodology | The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, thin preps, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed. |
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### Bronchial Washings Cytology

**TEST: 009035  CPT: 88112**

**Test Includes**  Bronchial washings; bronchoalveolar lavage specimens

**Special Instructions**  Include type of specimen and pertinent clinical information (i.e., patient's name, age, Social Security number, clinical impression, past diagnoses, radiographic findings, and history of radiation or chemotherapy) on the request form.

**Expected Turnaround Time**  Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

### SPECIMEN REQUIREMENTS

**Specimen**  Bronchial washings or bronchoalveolar lavage (BAL) specimens obtained by physician

**Volume**  Not less than 1 to 2 mL for washings

**Container**  50 mL disposable centrifuge tube

**Collection**  Washings or aspirates collected during the endoscopic examination should be collected and mixed with an equal volume of 50% ethyl alcohol or Saccomanno fixative. Specimens should be properly labeled and delivered immediately to the laboratory. Submit specimens in their original collection containers. **(Note:** Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are **not** acceptable for microbiology testing.)
Storage Instructions

Refrigerate

Causes for Rejection

Improper labeling; improper fixative; specimen submitted in vial that expired according to manufacturer's label; frozen specimen

TEST DETAILS

Use

Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of respiratory infections with herpesvirus, cytomegalovirus, Aspergillus, Coccidioides, Candida, Actinomyces, Cryptococcus, Histoplasma, Blastomyces, Phycomycetes, Pneumocystis carinii, and Strongyloides; aid in the diagnosis of asbestosis

Limitations

Allowing fluid to stand for a prolonged period before processing may cause deterioration and artifact.

Methodology

The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed.

Aftercare

Postbronchoscopy sputum for cytology should be collected, as it sometimes yields more diagnostic cells than are obtained during the bronchoscopy.

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Pleural Fluid Cytology

**TEST:** 009043  CPT: 88112

### Synonyms
- Pleural Effusions

### Special Instructions
Include patient's name, date of birth, sex, Social Security number, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information, including history of alcohol abuse, on the request form.

### Expected Turnaround Time
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Pleural fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>50 mL or more</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>More than 5 mL</td>
</tr>
<tr>
<td>Container</td>
<td>1200-cc Cardinal Health Guardian™ disposable hard canister or 120-mL BD Vacutainer® sterile urine collection cup with integrated sampling device available from the courier service</td>
</tr>
<tr>
<td>Collection</td>
<td>Label the container with patient's name, hospital number, room number, date, and type of specimen. Deliver immediately to the Cytology Laboratory. If more than a 24-hour delay is anticipated between collection and receipt in the laboratory, please add the following: 1 mL</td>
</tr>
</tbody>
</table>
(1000 units) of heparin for each 300 mL of collected fluid. To the entire volume (up to 1 liter) add an equal volume of 50% ethyl alcohol or Saccomanno fixative. (Note: Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are not acceptable for microbiology testing.)

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>After hours, place in the laboratory refrigerator.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Preparation</td>
<td>In order to suspend the cells in the fluid, move the patient into several different positions. Perform the paracentesis.</td>
</tr>
<tr>
<td>Causes for Rejection</td>
<td>Improper labeling; contamination due to spillage; improper fixation; specimen submitted in vial that expired according to manufacturer's label; frozen specimen</td>
</tr>
</tbody>
</table>

**TEST DETAILS**

**Use**

Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of rheumatoid pleuritis, fungal and parasitic infestation of serous cavities

**Limitations**

Allowing fluid to stand for prolonged period before processing may cause deterioration and artifact. First tapping of fluids of long duration may be degenerated and require a second tap after reaccumulation. Clots may contain diagnostic cells which are unavailable for sampling.

**Methodology**

The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed.
## Abdominal Fluid Cytology

**TEST:** 009050  \( \text{CPT: 88112} \)

### Synonyms
- Abdominal Effusion Cytology
- Paracentesis
- Pelvic Washings

### Special Instructions
Include patient's name, date of birth, sex, Social Security number, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information, including history of alcohol abuse, on the request form.

### Expected Turnaround Time
**Within 1 day**

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Abdominal fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>50 mL or more</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>More than 5 mL</td>
</tr>
<tr>
<td>Container</td>
<td>1200-cc Cardinal Health Guardian™ disposable hard canister or 120-mL BD Vacutainer® sterile urine collection cup with integrated sampling device available from the courier service</td>
</tr>
</tbody>
</table>
**Collection**

Label the container with patient's name, hospital number, room number, date, and type of specimen. Deliver immediately to the cytology laboratory. If more than a 24-hour delay is anticipated between collection and receipt in the laboratory, please add the following: 1 mL (1000 units) of heparin for each 300 mL of collected fluid. To the entire volume (up to 1 liter) add an equal volume of 50% ethyl alcohol or Saccomanno fixative. *(Note: Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are not acceptable for microbiology testing.)*

**Storage Instructions**

After hours, place in the laboratory refrigerator.

**Patient Preparation**

In order to suspend the cells in the fluid, move the patient into several different positions. Perform the paracentesis.

**Causes for Rejection**

Improper labeling; gross contamination due to spillage; improper fixation; specimen submitted in vial that expired according to manufacturer's label

**TEST DETAILS**

**Use**

Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of fungal and parasitic infestation of serous cavities

**Limitations**

Allowing fluid to stand for a prolonged period before processing may cause deterioration and artifact. First tapping of fluids of long duration may be degenerated and require a second tap after reaccumulation.

**Methodology**

The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed.
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Urine Cytology

**TEST: 009068  CPT: 88112**

**Synonyms**
- Urine, Bladder Washings/Lavage

**Special Instructions**
Include patient's name, date of birth, sex, Social Security number, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information, including history of alcohol abuse, on the request form. A first morning voided specimen is **not suitable**.
Collection method **must** be identified. For CMV Study, indicate chemotherapy or immunosuppression.

**Expected Turnaround Time**
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**SPECIMEN REQUIREMENTS**

**Specimen**
Second morning specimen; voided or catheterized urine; intraoperative washings of urinary bladder, urethra, ureters, or renal pelvis

**Volume**
Not less than 20 mL

**Container**
Sterile plastic urine container

**Collection**
Have patient drink one glass (6 oz) every 15 minutes for two to three hours. At the end of two hours, have the patient void or catheterize. Discard specimen.
**Technique I** (routine): One hour after collection of discarded specimen, have patient void and save the specimen. Send labeled specimen to the laboratory immediately.

**Technique II** (when residual bladder urine is present): Thirty minutes to one hour after collection of discarded specimen, catheterize bladder. Send labeled specimen to the laboratory immediately.

**Technique III** (for detection of upper urinary tract lesions): Catheterize ureters to pelvis for suspected renal or pelvic lesions. Repeat procedure using either ureter for control. For ureteral lesion, catheterize ureter to a point just below the level of the suspected lesion. Catheterize other ureter for control. Collect urine for 30 minutes. Label appropriately, right and left ureteral or pelvic specimen. Ship specimen immediately to the laboratory.

**Storage Instructions**
If collected after hours, add equal amount of 50% ethyl alcohol or Saccomanno fixative and place in the laboratory refrigerator. (Note: Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are not acceptable for microbiology testing.) Specify source of specimen.

**Patient Preparation**
Hydrate patient (give several glasses of water 30 minutes to one hour prior to collection).

**Causes for Rejection**
Improper labeling; improper fixation; 24-hour collection; undue delay in transport; specimen submitted in vial that expired according to manufacturer’s label; frozen specimen

**TEST DETAILS**

**Use**
Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of infections with herpesvirus, cytomegalovirus, Blastomyces, and Schistosoma; evaluate malacoplakia; establish the presence of cytomegalic inclusion disease

**Limitations**
Low-grade papillary transitional cell or urothelial carcinomas may not be diagnosed by cytologic examination. Calculi or recent instrumentation may produce atypical changes in urothelial cells simulating malignancy. Chemotherapy and radiation may also produce changes stimulating neoplasia. Viral culture is the method of choice for the diagnosis of CMV but cytology can provide faster results.

**Methodology**
The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed.
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Sputum Cytology Series

**TEST: 009076**  CPT: 88108

**Synonyms**
- Cytology, Sputum

**Special Instructions**
Include patient's name, date of birth, sex, Social Security number, previous malignancy, drug therapy, radiation therapy, exposure to carcinogen, and all other pertinent clinical information on the request form. For induced sputa, contact Inhalation Therapy. Include admitting diagnosis and pertinent clinical history (ie, age, clinical diagnosis, exposure to carcinogen) on the request form.

**Expected Turnaround Time**
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Expectorated sputum, <strong>not saliva or nasal aspirates</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>30 mL</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>3-5 mL</td>
</tr>
<tr>
<td>Container</td>
<td>Plastic sputum container with Saccomanno fixative added</td>
</tr>
</tbody>
</table>
**Collection**

Patient should perform oral hygiene and collect first morning sputum directly into Saccomanno or 50% ethyl alcohol fixative in container for three consecutive mornings. (Note: Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are **not** acceptable for microbiology testing.) Close container and shake vigorously after collection.

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>Maintain specimen at room temperature.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Preparation</td>
<td>Instruct the patient to thoroughly cleanse mouth before collection.</td>
</tr>
<tr>
<td>Causes for Rejection</td>
<td>Improper labeling; specimen without fixative; saliva or nasal aspirates; frozen specimen</td>
</tr>
</tbody>
</table>

**TEST DETAILS**

| Use | Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of respiratory infections with herpesvirus, *Cryptococcus, Coccidioides, Histoplasma, Blastomyces, Phycomycetes, Strongyloides, Echinococcus, Paragonimus*, and asbestosis. |
| Limitations | If pulmonary macrophages are not identified, specimen will be reported as unsatisfactory for adequate evaluation. |
| Methodology | Direct smears or slides prepared using the Saccomanno method. Pap stained: microscopic examination is performed. |

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Miscellaneous Smear Cytology

**TEST: 009126  CPT: 88161**

**Synonyms**
- Anal Smear
- DES
- Endocervical Aspiration Smears
- Endometrial Aspiration Smears
- Herpes Cytology
- Herpetic Inclusion Bodies Cytology
- Inclusion Body Stain
- Ocular Cytology
- Oral Cytology
- Prostatic Massage, Skin Lesion
- Tzanck Smear
- Vaginal Wall Cytology
- Viral Study, Herpes

**Test Includes**
Routine cytologic evaluation of prepared smear(s)

**Special Instructions**
Include patient's name, date of birth, Social Security number, source, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information on the request form. Can be requested as stat procedure if active herpes infection is suspected at time of labor prior to vaginal delivery. Specify viral study and body site on the request form.

**Expected Turnaround Time**
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Smear(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>One slide(s)</td>
</tr>
<tr>
<td>Container</td>
<td>Cardboard or plastic slide holder(s), Coplin jar(s)</td>
</tr>
</tbody>
</table>

**Collection**
Prepare smears and immediately fix each with spray fixative or in 95% ethyl alcohol. Label each slide with patient's name and source of smear(s).

**Storage Instructions**
Maintain specimen at room temperature.

**Causes for Rejection**
Improper labeling; improper fixation; air-drying artifact; frozen specimen

### TEST DETAILS

**Use**
Establish the presence of herpesvirus infection; aid in the diagnosis of pemphigus, vesiculobullous skin or mucosal disorders

**Methodology**
Pap stained: microscopic examination

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## Breast Discharge Cytology

**TEST: 009134  CPT: 88161**

### Synonyms
- Breast Smear
- Nipple Discharge

### Special Instructions
Include patient's name, date of birth, sex, Social Security number, previous malignancy, drug therapy, radiation therapy, mammogram, and all other pertinent clinical information on the request form.

### Expected Turnaround Time
- Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Nipple discharge</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>Pea-size drop</td>
</tr>
<tr>
<td>Container</td>
<td>Cardboard or plastic slide holder(s), Coplin jar(s)</td>
</tr>
<tr>
<td>Collection</td>
<td>Gently grip subareolar area and nipple with thumb and forefinger. When secretion occurs, allow pea-sized drop to accumulate on apex of nipple. Touch a clean slide to the nipple and withdraw quickly. Immediately spray slide with fixative or place slides in 95% ethyl alcohol. Repeat procedure until all secretions from nipple are collected on two or more slides. Using a graphite pencil, label the frosted end of the slide with the patient's name.</td>
</tr>
</tbody>
</table>
Storage Instructions

Maintain specimen at room temperature.

Causes for Rejection

Improper labeling; improper fixative; air-drying artifact

TEST DETAILS

Use

Diagnose primary or metastatic malignant neoplasms; differential diagnosis of benign versus malignant processes; aid in the diagnosis of infectious and inflammatory disease

Limitations

Drying of smear(s) before fixation will render specimen unsatisfactory for evaluation.

Methodology

Pap stained: microscopic examination
Miscellaneous Fluid Cytology

**TEST: 009159  CPT: 88112**

**Synonyms**
- Anal Specimens
- Colon Wash Cytology
- Cyst Fluid Cytology
- Endometrial Aspiration Samples
- Gastric Washing Cytology
- HALO™ Ocular Cytology
- Joint/Synovial Fluid Cytology
- Nipple Fluid Aspiration
- Ovarian Fluid Cytology
- Spinal Fluid Cytology

**Test Includes**
Routine cytologic evaluation of smears, monolayers, filters, and cell block when indicated

**Special Instructions**
Include patient's name, date of birth, Social Security number, source, previous malignancy, drug therapy, radiation therapy, and all other pertinent clinical information on the request form.

**Expected Turnaround Time**
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Documents**
For more information, please view the literature below.

*Microbiology Specimen Collection and Transport Guide*
### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Fluid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1 to 2 mL</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>1 mL</td>
</tr>
<tr>
<td>Container</td>
<td>Sterile container; nongynecologic liquid-based cytology vial</td>
</tr>
<tr>
<td>Collection</td>
<td>Mix entire specimen with an equal volume of 50% ethyl alcohol or Saccomanno fixative. <em>(Note: Specimens prepared with fixatives that contain 50% ethyl alcohol, eg, Saccomanno fixative, are not acceptable for microbiology testing.)</em> Specify source of specimen.</td>
</tr>
<tr>
<td>Storage Instructions</td>
<td>Refrigerate immediately after collection and ship to laboratory as soon as possible.</td>
</tr>
<tr>
<td>Causes for Rejection</td>
<td>Improper labeling; improper fixation; specimen submitted in vial that expired according to manufacturer's label; frozen specimen</td>
</tr>
</tbody>
</table>

### TEST DETAILS

| Use | Diagnose primary and metastatic malignant neoplasms; differential diagnosis of benign versus malignant processes |
| Methodology | The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed. |
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Anal (Rectal) Cytology, Liquid-based Preparation

**TEST: 009160  CPT: 88112**

**Synonyms**
- Anal Pap (LBP)

**Expected Turnaround Time**
Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**SPECIMEN REQUIREMENTS**

**Specimen**
Rectal

**Volume**
Minimum of 1-2 mL

**Container**
Vial with PreservCyt® solution, ThinPrep® vial; vial with CytoRich™ fixative, SurePath™ vial

**Collection**
An anal-rectal cytology (ARC) specimen is collected using a swab (Fisher Scientific Catalog No. 22363173; LabCorp PeopleSoft No. 123926). Moisten the swab in tap water and insert as far as possible into the anal canal. Slowly rotate the swab in one direction with gentle pressure on the walls as the swab is slowly being withdrawn. Care should be taken to ensure that the transition zone is sampled. Vigorously rotate the swab in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the swab vigorously to release additional material. Discard the swab. Tighten the cap on the ThinPrep® PreservCyt® solution container so that the torque line on the cap passes the torque line on the vial. When using the TriPath SurePath™ method, place the cytobrush or swab head into the CytoRich™ fixative into
SurePath™ collection vial and tightly cap the vial. Record the patient's name and ID number on the vial, and place it and the test request form in a specimen bag for transport to the laboratory. Specify source of specimen on the test request form.

**Storage Instructions**
Maintain specimen at room temperature.

**Patient Preparation**
No special preparation is needed for the patient, though the patient may be advised to refrain from receptive anal intercourse or use of intra-anal preparations before examination. The sample can be collected with the patient in either the lateral recumbent or dorsal lithotomy position.

**Causes for Rejection**
Improper labeling; specimen more than 21 days old (from collection date) in liquid-based preservative; specimen submitted in vial that expired according to manufacturer's label; frozen specimen

**TEST DETAILS**

**Use**
Diagnose primary and metastatic malignant neoplasms; differential diagnosis of benign versus malignant processes.

**Methodology**
ThinPrep® vial; BD SurePath™

**References**
# Bronchial Brushings

**TEST: 009332**  CPT: 88104

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>• Brushings Cytology</th>
</tr>
</thead>
</table>

**Special Instructions**

Specify the site brushed and include type of specimen and pertinent clinical data (ie, patient's name, age, patient's Social Security number, clinical impression, past diagnoses, bronchoscopic and radiographic findings, admitting diagnosis, history of carcinoma, and history of radiation or chemotherapy) on the request form.

**Expected Turnaround Time**

Within 1 day

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Brush from lesion area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>Minimum of two slides</td>
</tr>
<tr>
<td>Container</td>
<td>Glass slides or centrifuge tubes containing brushes</td>
</tr>
<tr>
<td>Collection</td>
<td>Roll brush over glass slide to cover the area of a dime and fix immediately with spray fixative or fix in 95% ethyl alcohol. Label bottle with exact body site, patient's name, hospital number, room number and date. Using a graphite pencil, label frosted slide with patient's name. If more than one slide is used, separate them with a paper clip. Disposable bronchial brushes should be submitted in saline with sheath removed and sent to the laboratory immediately.</td>
</tr>
<tr>
<td><strong>Storage Instructions</strong></td>
<td>Room temperature. Smears and brushes should be placed in 95% ethyl alcohol; slides may be spray fixed.</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Causes for Rejection</strong></td>
<td>Improper labeling; improper fixation; air-drying artifact; specimen submitted in vial that expired according to manufacturer's label</td>
</tr>
</tbody>
</table>

## TEST DETAILS

**Use**

Establish the presence of primary or metastatic neoplasms; aid in the diagnosis of certain infections with herpesvirus, cytomegalovirus, *Aspergillus*, *Coccidioides*, *Candida*, *Actinomyces*, *Cryptococcus*, *Histoplasma*, *Blastomyces*, *Phycomycetes*, *Pneumocystis carinii*, and *Strongyloides*; aid in the diagnosis of asbestosis.

**Limitations**

Allowing smears and brushes to air dry before they are fixed will render them unsatisfactory for cytologic evaluation.

**Methodology**

The fluid will be centrifuged, supernatant poured off, and diagnostic cells aspirated from the remaining material. Filters, monolayers, and/or cytospins will be made along with a cell block, if applicable. Microscopic examination is performed.

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**CPT Statement/Profile Statement**

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# Gynecologic Pap Test (Image-guided), Liquid-based Preparation

**TEST: 1930000  CPT: 88175**

## Special Instructions
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are not included.)

<table>
<thead>
<tr>
<th>Expected Turnaround Time</th>
<th>1 - 5 days</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.</td>
</tr>
</tbody>
</table>

## Related Information
- **Cervical / Vaginal Specimens**
SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Volume</th>
<th>Entire vial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimum Volume</td>
<td>1 mL</td>
</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial or SurePath™ vial</td>
</tr>
</tbody>
</table>

Collection:

**ThinPrep® Vial – Broom or Brush/Spatula:**

*Broom-like collection technique:* Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

*Brush/spatula technique:* Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush $\frac{1}{4}$ to $\frac{1}{2}$ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**SurePath™ Vial:** When using the SurePath™ vial, the cervical broom must be used for specimen collection. Insert the broom into the cervical os and rotate five times. Place the broom head into the CytoRich™ preservative fluid in the SurePath™ collection vial. Tightly cap the vial.

Storage Instructions: Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection.

Patient Preparation: Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period. Excessive use of lubricating jelly will interfere with cytologic examination.
<table>
<thead>
<tr>
<th>Causes for Rejection</th>
<th>Improperly labeled vial; specimen more than 21 days old (from collection date) in liquid-based preservative; specimen submitted in vial that expired according to manufacturer's label; frozen specimen</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th><strong>TEST DETAILS</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Limitations</strong></td>
<td>Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.</td>
</tr>
<tr>
<td><strong>Methodology</strong></td>
<td>Image-guided liquid-based Pap test</td>
</tr>
</tbody>
</table>
Gynecologic Pap Test—Age-based Guideline for Cervical Cancer (Aptima®)

**TEST: 193065**  CPT: Call client services.

### Synonyms
- Age-based Guideline for Cervical Cancer
- Cervical Cancer Screening

### Special Instructions
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

### Expected Turnaround Time
2 - 5 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
### SPECIMEN REQUIREMENTS

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Cervical cells collected by one of the methods described below.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>ThinPrep® vial</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.</td>
</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial</td>
</tr>
<tr>
<td>Collection</td>
<td><strong>ThinPrep® Vial – Broom or Brush/Spatula</strong></td>
</tr>
</tbody>
</table>

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotating the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Preparation</td>
<td>Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.</td>
</tr>
</tbody>
</table>
Causes for Rejection
Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial.

TEST DETAILS

**Use**
Diagnose primary or metastatic neoplasm. High-risk HPV is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type. When the age guideline includes possible genotyping, the residual specimen will be tested individually for high-risk HPV genotypes 16 and 18,45 if the Pap evaluation is within normal limits and the initial HPV test is positive. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

**Limitations**
Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection, since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. Reflex testing for genotypes 16 and 18,45 may be indicated based on patient age and other test results.

**Methodology**
Image-guided liquid-based Pap test; nucleic acid amplification (NAA). LabCorp protocol is based on the ACOG guidelines.1,2 Aptima® is a registered trademark of Gen-Probe Inc.

**Footnotes**
**Gynecologic Pap Test—Age-based Guideline for Cervical Cancer (Aptima®) Plus Chlamydia/Gonococcus**

**TEST: 193070**  CPT: Call client services.

<table>
<thead>
<tr>
<th>Synonyms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age-based Guideline for Cervical Cancer Plus <em>Chlamydia/Gonococcus</em></td>
</tr>
<tr>
<td>Cervical Cancer Screening Plus <em>Chlamydia/Gonococcus</em></td>
</tr>
</tbody>
</table>

**Special Instructions**

Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are not included.)

**Expected Turnaround Time**

3 - 7 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
For more information, please view the literature below.

Clinical Guideline Management for Cervical Cancer and STD Screening

**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Cervical cells collected by one of the methods described below.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>ThinPrep® vial</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen.</td>
</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial</td>
</tr>
</tbody>
</table>

**Collection**  
**ThinPrep® Vial – Broom or Brush/Spatula**

* **Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotating the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

* **Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Storage Instructions**  
Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within three months of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus*. 
**Patient Preparation**

Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

**Causes for Rejection**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than three months old in ThinPrep® vial. **For Chlamydia trachomatis and Neisseria gonorrhoeae:** liquid-based cytology specimen more than seven days old.

**TEST DETAILS**

**Use**

Diagnose primary or metastatic neoplasm; detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type. When the age guideline includes possible genotyping, the residual specimen will be tested individually for high-risk HPV genotypes 16 and 18,45 if the Pap evaluation is within normal limits and the initial HPV test is positive. This information, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of this test are not intended to prevent women from proceeding to colposcopy.

**Limitations**

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection, since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. Reflex testing for genotypes 16 and 18,45 may be indicated based on patient age and other test results. Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires that special procedures be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted.

**Methodology**

Image-guided liquid-based Pap test; nucleic acid amplification (NAA). LabCorp protocol is based on the ACOG guidelines.¹,² Aptima® is a registered trademark of Gen-Probe Inc.

**Footnotes**


References

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Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA

**TEST: 196402**  CPT: 87491; 87591; 88175

**Special Instructions**
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

**Expected Turnaround Time**
2 - 5 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Information**
- Cervical / Vaginal Specimens
- **Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Maturation Index**
**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Cervical cells collected by one of the methods described below.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>ThinPrep® vial or ThinPrep® vial with optional additional Aptima® swab collection kit (for <em>Chlamydia/Gonococcus</em>)</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>A minimum volume cannot be determined for the ThinPrep® vial because it varies depending on the cellularity of the specimen. Specimens collected with the Gen-Probe® Aptima® swab collection kit must arrive intact.</td>
</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial or ThinPrep® vial and Aptima® swab collection kit (for <em>Chlamydia/Gonococcus</em>)</td>
</tr>
<tr>
<td>Collection</td>
<td><strong>ThinPrep® Vial – Broom or Brush/Spatula</strong></td>
</tr>
</tbody>
</table>

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush $\frac{1}{4}$ to $\frac{1}{2}$ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Optional Dedicated Specimen for *Chlamydia and Gonococcus***: Use the Gen-Probe® Aptima® swab collection kit. **(Note: Do not use the Gen-Probe® PACE DNA probe collection kit.)** Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for...
10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.

**Storage Instructions**

Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus*; if the Aptima® swab transport is used, it must be tested within 60 days.

**Patient Preparation**

Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

**Causes for Rejection**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For Chlamydia trachomatis and Neisseria gonorrhoeae:** liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the blue-shafted collection swab.

**TEST DETAILS**

**Use**

Diagnose primary or metastatic neoplasma; detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

**Limitations**

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing. Any time a transport device used for molecular testing is processed, the chance of cross-specimen contamination increases. Aptima® transports can be placed directly on the analyzer, limiting the possibility of cross-specimen contamination.
<table>
<thead>
<tr>
<th>Methodology</th>
<th>Image-guided liquid-based Pap test; nucleic acid amplification (NAA) (Chlamydia/Gonococcus)</th>
</tr>
</thead>
</table>
Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U

**TEST: 199300**  CPT: 88175

**Special Instructions**
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

**Expected Turnaround Time**
2 - 5 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Documents**
For more information, please view the literature below.
**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Cervical cells in liquid-based cytology transport</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>ThinPrep® vial</td>
</tr>
<tr>
<td>Minimum Volume</td>
<td>A minimum volume cannot be determined for the ThinPrep® vial, because it varies depending on the cellularity of the specimen.</td>
</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial</td>
</tr>
</tbody>
</table>

**Collection**

- **ThinPrep® Vial – Broom or Brush/Spatula**

  **Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

  **Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush $\frac{1}{4}$ to $\frac{1}{2}$ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Storage Instructions**

- Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.

**Patient Preparation**

- Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.
Causes for Rejection

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than 21 days old in ThinPrep® vial.

**TEST DETAILS**

**Use**

Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an ASCUS Pap test result. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type.

**Limitations**

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types and cannot determine the specific HPV type present.

**Methodology**

Image-guided liquid-based Pap test; nucleic acid amplification (NAA)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®)

**TEST:** 199330  CPT: 87624; 88175

**Special Instructions**
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are not included.)

**Expected Turnaround Time**
2 - 6 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Documents**
For more information, please view the literature below.
# Sample Report

## Specimen Requirements

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**Collection**  

**ThinPrep® Vial – Broom or Brush/Spatula**

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Storage Instructions**  

Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within 21 days of collection for HPV.
<table>
<thead>
<tr>
<th>Patient Preparation</th>
<th>Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.</th>
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<tr>
<td>Causes for Rejection</td>
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</tr>
</tbody>
</table>

**TEST DETAILS**

| Use | Diagnose primary or metastatic neoplasm. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type. |
| Limitations | Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. |
| Methodology | Image-guided liquid-based Pap test; nucleic acid amplification (NAA) |

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CPT Statement/Profile Statement

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Gynecologic Pap Test (Image-guided), Liquid-based Preparation and

*Chlamydia/Gonococcus/Trichomonas*, NAA and Human Papillomavirus (HPV) (Aptima®) Detection With Reflex to HPV Genotypes 16 and 18,45 on High-risk Positive Specimens

**TEST:** 199334  CPT: 88175; 87591; 87624; 87661; 87491

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**Special Instructions**

Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)
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Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**SPECIMEN REQUIREMENTS**

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<th>Specimen</th>
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<tr>
<td>Volume</td>
<td>ThinPrep® vial</td>
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<td>Minimum Volume</td>
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</tr>
<tr>
<td>Container</td>
<td>ThinPrep® vial</td>
</tr>
<tr>
<td>Collection</td>
<td>ThinPrep® Vial – Broom or Brush/Spatula</td>
</tr>
</tbody>
</table>

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Optional Dedicated Specimen for Chlamydia, Gonococcus, and Trichomonas:** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove
the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.

**Storage Instructions**

Maintain liquid-based cytology and Aptima® swab transport specimens at room temperature. Pap processing must be done within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within 21 days of collection for HPV. Liquid-based cytology specimens must be tested within seven days for *Chlamydia/Gonococcus/Trichomonas*; if the Aptima® swab transport is used, it must be tested within 60 days.

**Patient Preparation**

Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.

**Causes for Rejection**

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer’s label; frozen specimen; SurePath™ vial. **For Pap**: liquid-based cytology specimen more than 21 days old. **For HPV**: specimen more than 21 days old in ThinPrep® vial. **For Chlamydia, Gonococcus, and Trichomonas vaginalis**: liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.

**TEST DETAILS**

**Use**

Diagnose primary or metastatic neoplasm; detect *Chlamydia trachomatis, Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type. If the initial high-risk HPV test is positive, then the residual specimen will be tested for HPV types 16 and 18,45; type 18 cannot be differentiated from type 45.

**Limitations**

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing.

A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. When reflex conditions are met, HPV type 16 and 18,45 testing is performed.
Testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis* testing.

**Methodology**  
Image-guided liquid-based Pap test; nucleic acid amplification (NAA)

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**CPT Statement/Profile Statement**

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Gynecologic Pap Test (Image-guided), Liquid-based Preparation With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U With Reflex to HPV Genotypes 16 and 18,45

**TEST:** 199340  CPT: Call client services.

**Special Instructions**
Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are not included.)

**Expected Turnaround Time**
2 - 4 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
## SPECIMEN REQUIREMENTS

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<tr>
<th>Specimen</th>
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<td>Container</td>
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</tbody>
</table>

**Collection**

**ThinPrep® Vial – Broom or Brush/Spatula**

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Storage Instructions**

Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.

**Patient Preparation**

Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.
Causes for Rejection

Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in a vial that expired according to the manufacturer's label; frozen specimen; SurePath™ vial. **For Pap:** liquid-based cytology specimen more than 21 days old. **For HPV:** specimen more than 21 days old in ThinPrep® vial.

**TEST DETAILS**

**Use**

Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an ASCUS Pap test result. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68. If the initial high-risk test is positive, then the residual specimen will be tested for HPV types 16 and 18,45; type 18 cannot be differentiated from type 45.

**Limitations**

Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. When reflex conditions are met, HPV type 16 and type 18,45 testing is performed.

**Methodology**

Image-guided liquid-based Pap test; nucleic acid amplification (NAA)
### Gynecologic Pap Test (Image-guided), Liquid-based Preparation and Human Papillomavirus (HPV) (Aptima®) Detection With Reflex to HPV Genotypes 16 and 18,45 on High-risk Positive Specimens

**TEST: 199344**  CPT: 88175; 87624

<table>
<thead>
<tr>
<th>Special Instructions</th>
<th>Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.</th>
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**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, LabCorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

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<th>Expected Turnaround Time</th>
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<td>Collection</td>
<td><strong>ThinPrep® Vial – Broom or Brush/Spatula</strong></td>
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**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do **not** over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>Maintain liquid-based cytology specimen at room temperature. Pap processing must be performed within 21 days of collection. Specimens in ThinPrep® vials must be processed for testing within 21 days of collection for HPV.</th>
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<tbody>
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<td>Patient Preparation</td>
<td>Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.</td>
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Causes for Rejection
Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. For Pap: liquid-based cytology specimen more than 21 days old. For HPV: specimen more than 21 days old in ThinPrep® vial.

TEST DETAILS

Use
Diagnose primary or metastatic neoplasm. High-risk HPV test is used for types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68, without differentiation of the individual type. If the initial high-risk HPV test is positive, then the residual specimen will be tested for HPV types 16 and 18,45; type 18 cannot be differentiated from type 45.

Limitations
Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results.

The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result. This test detects only the 14 most common high-risk HPV types. When reflex conditions are met, HPV type 16 and 18,45 testing is performed.

Methodology
Image-guided liquid-based Pap test; nucleic acid amplification (NAA)
Gynecologic Pap Test (Image-guided), Liquid-based Preparation and *Chlamydia/Gonococcus*, NAA With Reflex to Human Papillomavirus (HPV) (Aptima®) When ASC-U With Reflex to HPV Genotypes 16 and 18,45

**TEST:** 199354  CPT: 87491; 87591; 88175

**Special Instructions**

Include date of birth, Social Security number (or other identification number), previous malignancy, drug therapy, radiation therapy, last menstrual period (LMP), postmenopausal patient (PMP), surgery (including surgical biopsies), exogenous hormones, abnormal vaginal bleeding, abnormal Pap results, IUD, and all other pertinent clinical information on the cytology test request form.

**Note:** In accordance with criteria established by CLIA, Pap tests will be referred for pathologist review if laboratory personnel suspect:

- Reactive or reparative cellular changes
- Atypical squamous or glandular cells of undetermined significance
- Cells in the premalignant or malignant category

In these cases, Labcorp will charge for the associated service. (Slides that are routinely reviewed by a pathologist for quality control purposes are **not** included.)

**Expected Turnaround Time**

3 - 6 days
Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.

**Related Documents**

- Sample Report

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</table>

**Broom-like collection technique:** Obtain a sample from the cervix using a broom-like device by inserting the brush portion into the cervical os and then rotate the brush five times. Rinse the collection device in the PreservCyt® solution by pushing the brush into the bottom of the vial 10 times, forcing the bristles to bend apart to release the cervical material. As a final step, twirl the brush between the thumb and forefinger vigorously to release additional cellular material. Discard the collection device. Tighten the cap on the ThinPrep® vial so that the torque line on the cap passes the torque line on the vial.

**Brush/spatula technique:** Insert the brush into the endocervical canal until only the bottommost fibers are exposed. Slowly rotate the brush ¼ to ½ turn in one direction. Do not over-rotate the brush. Then, rotate the brush in the PreservCyt® solution 10 times while pushing against the wall of the ThinPrep® vial. Swirl the brush vigorously to release additional material. Discard the brush. Obtain an adequate sample from the ectocervix using a plastic spatula. Swirl vigorously in the ThinPrep® vial 10 times and discard the spatula. Tighten the cap on the ThinPrep® container so that the torque line on the cap passes the torque line on the vial.

**Optional Dedicated Specimen for Chlamydia and Gonococcus:** Use the Gen-Probe® Aptima® swab collection kit. Clean the cervix using the larger, white-shafted swab supplied in the Gen-Probe® Aptima® swab collection kit and discard. Insert the smaller, blue-shafted swab into the cervix and rotate for 10 to 30 seconds to ensure good sampling. Carefully withdraw the blue-shafted swab, avoiding contact with the vaginal mucosa. Remove the cap from the swab.
specimen transport tube and immediately place the specimen collection swab into the transport tube. Break the swab shaft at the scoreline, using care to avoid splashing contents. Recap the swab specimen transport tube tightly.

<table>
<thead>
<tr>
<th>Storage Instructions</th>
<th>Maintain specimen at room temperature. Specimens must be processed for testing within 21 days of collection for Pap.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Preparation</td>
<td>Patient should avoid douches 48 to 72 hours prior to examination. Specimen should not be collected during or shortly after menstrual period.</td>
</tr>
<tr>
<td>Causes for Rejection</td>
<td>Improper collection; inadequate specimen; improper labeling; specimen leaked in transit; quantity not sufficient for analysis; name discrepancies; specimen submitted on male patient; specimen submitted in vial that expired according to manufacturer's label; frozen specimen; SurePath™ vial. <strong>For Pap:</strong> liquid-based cytology specimen more than 21 days old. <strong>For HPV:</strong> specimen more than 21 days old in ThinPrep® vial. <strong>For Chlamydia trachomatis and Neisseria gonorrhoeae:</strong> liquid-based cytology specimen more than seven days old; Aptima® specimen more than 60 days old; Gen-Probe® Aptima® collection tube with multiple swabs, white-shafted cleaning swab, or any swab other than the collection swab.</td>
</tr>
</tbody>
</table>

**TEST DETAILS**

**Use**
Diagnose primary or metastatic neoplasm. This test aids in the diagnosis of sexually transmitted HPV infection and in the triage of patients with an ASCUS Pap test result. Detect *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. High-risk HPV test is used for types 16,18,31,33,35,39,45, 51,52,56,58,59,66, and 68, without differentiation of the individual type. Positive high risk HPV test results reflex the sample for genotyping of types 16 and 18/45.

**Limitations**
Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Excessive use of lubricating jelly on the vaginal speculum will interfere with cytologic examination and may lead to unsatisfactory Pap results. The use of the liquid-based cytology specimen for multiple tests may limit the volume available for Pap reprocessing or HPV testing. A negative result does not exclude the possibility of an HPV infection since very low levels of infection or sampling error may produce a false-negative result.

Testing for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* requires special procedures to be used in the processing of the cytology specimen; therefore, testing for these organisms cannot be added on after the specimen has been submitted. The liquid-based cytology specimen must be processed for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* testing.

**Methodology**
Image-guided liquid-based Pap test; nucleic acid amplification (NAA)
CPT Statement/Profile Statement

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Histopathology

**TEST: 500918**

CPT: 88300; 88302; 88304; 88305; 88307; 88309; 88311; 88312; 88313; 88314; 88319; 88321; 88323; 88325; 88342 (CPT codes are assigned by the pathologist when the case is complete; the codes listed here [in combination and with the appropriate multipliers] are most commonly used for histopathology.)

<table>
<thead>
<tr>
<th>Synonyms</th>
<th>• Biopsy</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Gross and Microscopic Pathology</td>
</tr>
<tr>
<td></td>
<td>• Microscopic Section</td>
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<tr>
<td></td>
<td>• Pathologic Examination</td>
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<td>• Pathology</td>
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<td></td>
<td>• Skin Lesion(s) Tissue Examination</td>
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<tr>
<td></td>
<td>• Surgical Pathology</td>
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<tr>
<td></td>
<td>• Tissue Pathology</td>
</tr>
</tbody>
</table>

**Test Includes**

Gross examination only and/or gross and microscopic examination and diagnosis

**Special Instructions**

Test request form must state operative diagnosis and source of specimen.

LabCorp test number is for tracking purposes only. Additional test numbers may be entered upon receipt of specimen(s) at the test facility.

**Expected Turnaround Time**

1 - 2 days

Turnaround time is defined as the usual number of days from the date of pickup of a specimen for testing to when the result is released to the ordering provider. In some cases, additional time should be allowed for additional confirmatory or additional reflex tests. Testing schedules may vary.
**SPECIMEN REQUIREMENTS**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>Entire specimen; paraffin embedded (FFPE) tissue block(s) or slide(s) sectioned from FFPE tissue block(s) at 4-5 microns</td>
</tr>
<tr>
<td>Container</td>
<td>Jars of assorted size containing 10% buffered formalin</td>
</tr>
<tr>
<td>Collection</td>
<td>Small biopsy specimens are to be placed immediately in 10% formalin solution. Use approximately 10 to 20 times as much formalin solution as the bulk of the tissue. Small tissues such as those from bronchoscopic biopsy, bladder biopsy, and endometrium can be compromised in a short time by placing in saline or allowing to dry. The following tissues should always be placed in formalin: small skin tumors and moles; uterine curettings; cervical biopsy; breast biopsy; prostate tissue from transurethral resection (TUR); bladder tumors and calculi; nerves and ganglia; rectal polyps; ear, nose, and throat (ENT) biopsy; lymph nodes (except those to be cultured); bone tumors; intervertebral disc; gallbladder; liver biopsy; bronchoscopic biopsy; fallopian tube segments; and any biopsy from any other site not listed. Organ and larger tissue resections are to be placed in larger containers and covered with adequate amounts of formalin. Specimens such as colons, urinary bladders, and uteri require opening to expose the mucosal surfaces to formalin. Gallbladders undergo rapid degeneration; therefore, they require immediate fixation in 10% formalin solution; an incision made in the gallbladder will aid in more rapid fixation. All specimens should be sent to the pathology department as soon as convenient to expedite the processing that leads to the eventual microscopic diagnosis.</td>
</tr>
<tr>
<td>Storage</td>
<td>Fix in 10% buffered formalin solution.</td>
</tr>
<tr>
<td>Instructions</td>
<td></td>
</tr>
<tr>
<td>Causes for Rejection</td>
<td>Lack of medical history; improper labeling; unlabeled specimen; no surgical specimen request form</td>
</tr>
</tbody>
</table>

**TEST DETAILS**

| Use            | Histologic diagnosis |
Methodology  See individual test components.
Renal Biopsy Protocol

Renal Biopsy Kit:

- Laboratory Paperwork: Patient Information Sheet, Clinical Data Form
- Two Bottles Of Fixatives: Michel's Fixative – Green Top, Formalin – White Top
- Fedex Packaging To Return Biopsy Sample: Fed Ex Clinical Pak, Pre- Paid, Pre-addressed FedEx mailer

Renal Biopsy Protocol:

**Reagents**

All are stable at room temperature.
Do not freeze or use dry ice.

Formalin: Light Microscopy And Electron Microscopy - White Top

Michel's Fixative: Immunofluorescence Transport Solution - Blue Top

**Biopsy Handling Protocol**

1. **Two separate cores:** (Multiple cores recommended for transplants). Place one core in Formalin for Light and Electron Microscopy studies. Place one core in Michel's fixative for Immunofluorescence studies.

2. **Single core/scant material:** The core should either be divided in half for Light and Immunofluorescence, or submitted entirely for Light Microscopy.

Weekend Policy:

**If you have an emergency case you would like read, the following steps must be taken:**

You must call our office on Friday. In order to process Saturday biopsies, we must be informed of all incoming biopsies by 5:00 p.m. on Friday. Please also provide us with a weekend contact number for the nephrologist on call.

You must be sure that the Saturday Delivery is checked on the FedEx air bill.

Thank you for giving us the opportunity to evaluate your renal biopsies.
This option is best for biopsies from elderly patients and/or those suspected to have an inflammatory myopathy.

If the biopsy is from a pediatric patient or an adult patient suspected to have a metabolic myopathy, please contact us so we can discuss the triage of the sample.

Ideal muscle biopsy from surgeon is sharply dissected approximately 1.5 cm length and 1.0 width, with muscle fibers oriented longitudinally. Avoid injecting biopsy tissue with anesthetic. Avoid site of prior needle EMG trauma. Avoid stretching and cautery as much as possible.

1. No separation of specimen

   Wrap the specimen in gauze or telfa that has been barely dampened with saline solution and place in a tightly closed water-tight container. We will separate the material upon arrival

2. If you are comfortable separating the specimen — Preferred Method

   Separate fresh tissue specimen into 3 parts:

   Part 1 – Wrap an intact portion of the specimen (a nice belly of muscle) in gauze or telfa that has been barely dampened with saline solution and place this in a tightly closed water-tight container with cool packs. We will snap freeze the sample upon arrival.

   NOTE: Please be sure that the tissue IS NOT floating in saline or that the gauze is dripping as this will produce a suboptimal specimen that may interfere with analysis and diagnosis.

   Part 2 – Place portion of specimen in tightly closed vial containing formalin fixative.

   Part 3 – Place portion of specimen in tightly closed vial containing glutaraldehyde fixative. If glutaraldehyde fixative is not available, we will utilize a portion of formalin-fixed tissue for EM.

Shipping: Place specimen in shipping container with enough cool packs to last for the anticipated one day transport time.

We accept specimens Monday through Saturday. Contact client relations to let us know that you are sending a sample for evaluation at (501) 604-2695.

NOTE: If transporting a specimen for Saturday delivery please be sure to let us know by Friday at 5:00 PM CST and check the shipping label with the following:
   -Saturday delivery
   -Priority overnight

Please note that it is essential that the tissue be collected and immediately triaged to avoid any deterioration of the tissue. A timely and well-performed triage allows for the most accurate pathologic evaluation of these specimens.