

PETERSON LABORATORY SERVICES, P.A.

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PETERSON LABORATORY SERVICES, P.A.

GYN CYTOLOGY

PAP TESTING

I. REQUISITION:

Peterson Laboratory Services is a Clinical Laboratory Improvement Amendment (CLIA) certified laboratory. Our certification is your assurance of the highest possible testing standards.

In compliance with CLIA regulation, guidelines have been established for the acceptance or rejection of cytology specimens. Appropriately labeled specimens must be accompanied by a cytology requisition. **Information appearing on the slide or ThinPrep vial and the requisition MUST match identically.**

Complete a cytology requisition (yellow, form 15) noting the following information:

1. **PATIENT NAME:** Patient name on the requisition must exactly match the patient name as it appears on the slide or ThinPrep vial label.
2. **DATE OF COLLECTION**
3. **PATIENT'S DATE OF BIRTH**
4. **PATIENT ADDRESS:** If the ordering physician/practitioner participates in the Pap Reminder system, patient address is needed to generate the patient reminder letter.
5. **PHYSICIAN/PRACTITIONER NAME**
6. **SOCIAL SECURITY NUMBER/PATIENT ID:** Please provide patient social security number or other patient identifier.

It is helpful if you would advise Peterson Laboratory Services if you become aware of name changes.

7. **PERTINENT CLINICAL INFORMATION:** The following information is required by regulation for accurate interpretation of the specimen:

- a) Date of last menstrual period
- b) Source of material submitted (cervix, endocervix or vagina)
- c) Hormonal status (pregnant, post-partum, post-menopausal, etc)
- d) Exogenous hormone therapy (birth control pills, estrogen therapy, etc.)
- e) History of abnormal cytology
- f) Date of last gynecological testing and the diagnosis
- g) Any other pertinent history

II. SPECIMEN LABELING:

ThinPrep Vial: Using a permanent marker, record patient name and ID number on the vial

Conventional Slide: Using a Number 2 lead pencil, record the patient's first and last name on the frosted end of the slide.

IMPORTANT:

If the name on specimen requisition does not exactly match the name on the slide or ThinPrep vial, the specimen will be rejected and returned to the originating facility. Please correct the discrepancy and re-submit the specimen.

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III. Conventional PAP SMEAR SPECIMEN COLLECTION

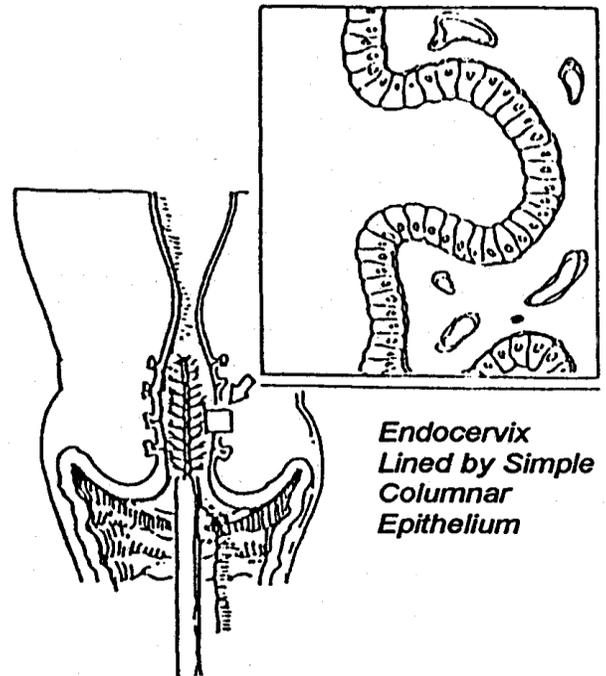
A. PATIENT PREPARATION

1. It is advisable for the patient to avoid using vaginal suppositories, creams or douches for twenty-four (24) hours prior to collection.
2. Water may be used to lubricate and warm the speculum; however, lubricant jellies **should not be used**. Position the speculum so that the entire face of the cervix appears at the end of the speculum. A sample from this area is necessary for adequate specimen collection.

B. SAMPLE COLLECTION

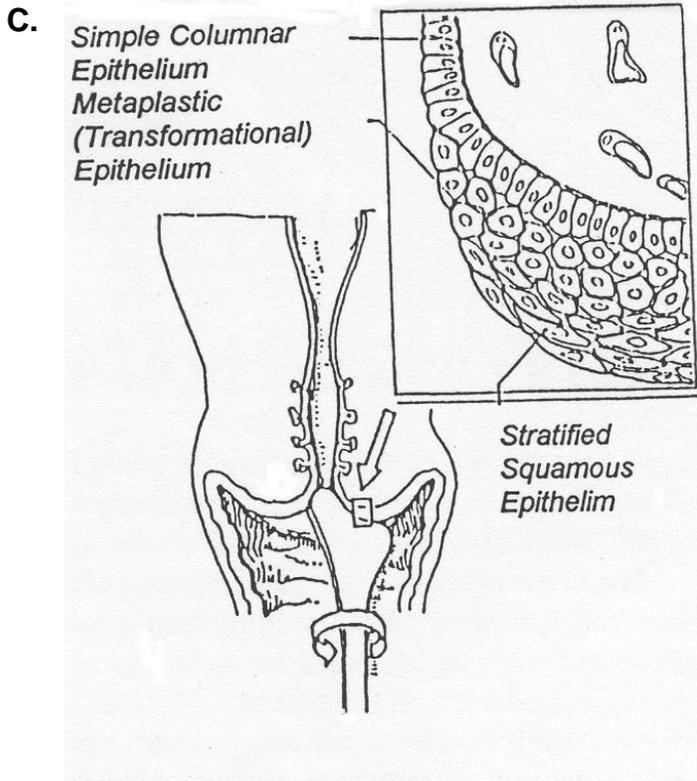
1. For a sample to be considered adequate, it is necessary to obtain a specimen from both the ectocervix and the endocervix. Successful collection requires careful inspection of the cervix and localization of the transformation zone.
2. To sample the endocervix, an endocervical brush is gently inserted into the endocervix, turned 360 degrees and withdrawn. The cytobrush is **NOT** recommended for use on pregnant patients. Vigorous scrubbing of the endocervix should be avoided as bleeding and patient discomfort may result.

3. It is important to obtain a smear that is not obscured by blood, mucus or inflammatory exudate. If there is mucus or other discharge present, gently remove with a swab. Discard swab. Do not clean the cervix by washing with saline as it may result in an acellular smear.



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4. To sample the ectocervix, use a scraper to gently, but firmly scrape the transformation zone (squamocolumnar junction). Be careful to avoid removing pieces of tissue with the scraper.



2. Fix the smears **immediately** using the cytology spray fixative. Failure to fix smears immediately may result in smears that are unsatisfactory for evaluation.

NOTE: Care must be taken to fix the smear as quickly as possible. Air drying begins within seconds of applying the smear to the slide. Air drying produces artifacts, cellular distortion and may lead to misinterpretation of smears.

The fixative provided is 95% alcohol with carbowax added to prevent drying of the sample. The nozzle of the spraying apparatus should be held approximately twelve (12) inches from the slide. Adequate amounts of fixative should be applied to completely wet the surface.

PLACEMENT OF MATERIAL ON SLIDE

ONE SLIDE TECHNIQUE:

1. Once both specimens have been collected, the endocervical brush should be rolled on the label half of the slide. The ectocervical scraping should be spread on the remaining half of the entire slide.

2. Fix the smear immediately using cytology spray fixative. Failure to fix smears immediately may result in smears that are unsatisfactory for evaluation.

TWO SLIDE TECHNIQUE

1. The endocervical brush and ectocervical scraping are each spread on individual slides as soon as they are obtained.

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COLLECTION PREPARATION

Thinprep Collection Techniques

The detection of cervical cancer and its precursors as well as other gynecologic abnormalities is the primary purpose of obtaining a cervical cell sample. In general, the guidelines state that it is important to obtain a specimen that is not obscured by blood, mucus, inflammatory exudates or lubricant.

Patient Information

- The patient should be tested 2 weeks after the first day of her last menstrual period, and definitely not when she is menstruating.

Even though ThinPrep reduces obscuring blood, clinical studies have demonstrated that excessive amounts of blood may still compromise the test and possibly lead to an unsatisfactory result.

- The patient should not use vaginal medication, vaginal contraceptives or douches during the 48 hours before the exam.

Specimen Collection Preparation

- Lubricant jellies should not be used to lubricate the speculum (see next page for acceptable list of lubricants to use if necessary)

Even though lubricant jellies are water soluble, excessive amounts of jelly may compromise the test and possibly lead to an unsatisfactory result.

- Remove excess mucus or other discharge present before taking the sample. This should be gently removed with ring forceps holding a folded gauze pad.

The excess cervical mucus is essentially devoid of meaningful cellular material and when present in the sample vial may yield a slide with little or no diagnostic material present.

- Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry 2 x 2 inch piece of gauze over the cervix and peeling it away after it absorbs the exudates or by using a dry protoswab or scopette.

The excess inflammatory exudate is essentially devoid of diagnostic cellular material and when present in the sample vial may yield a slide with little or no diagnostic material present.

- The cervix should not be cleaned by washing with saline or it may result in a relatively acellular sample

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ThinPrep® Pap Test Lubricant Compatibility List

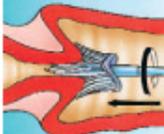
| LUBRICANT | MANUFACTURER | CONTAINS CARBOMER? |
|--|---|---------------------------|
| <u>PREFERRED</u> | | |
| PAP Test Lubricating Jelly | Aseptic Control Products | No |
| Surgilube Surgical Lubricant | HR Pharmaceuticals | No |
| <u>COMPATIBLE</u> | | |
| K-Y Jelly (Physician Formula) | Johnson & Johnson | No |
| Surgel | Ulmer Pharmacal | No |
| <u>INCOMPATIBLE</u> | | |
| Aquagel Lubricating Gel | Parker Laboratories, Inc. | Yes |
| Astroglide (Physician Formula) | BioFilm, Inc. | No |
| Astroglide (Personal Formula) | BioFilm, Inc. | No |
| Crystelle | Deltex Pharmaceuticals, Inc. - FDA injunction in 2011; no longer in operation | Unknown |
| HR Lubricating Jelly | HR Pharmaceuticals, Inc. | Yes |
| Lubricating Gel | Henry Schein | Yes |
| Lubricating Jelly | McKesson | Yes |
| MediChoice Lubricating Jelly | Owens & Minor | Yes |
| PDI Lubricating Jelly I and II | PDI Healthcare | Yes |
| PSS Select (also known as Triad) | PSS World Medical, Inc. | Yes |
| Rite Aid Pharmacy Lubricating Gel | Rite Aid Corp. | Yes |
| Allegiance | Medline Industries, Inc. (formerly Triad/H&P Industries) | Yes |
| Aplicare Sterile Lubricating Jelly (also known as Operand Lubricating Jelly) | Aplicare Inc./Clorox Professional | Yes |
| Aqua Lube Personal Lubricant** | Mayer Laboratories | No |
| DynaLube Lubricating Jelly | Dynarex Corporation | Yes |
| E-Z Lubricating Jelly | Chester Packaging | Yes |
| IMCO Lubricating Jelly | Medline Industries, Inc. (formerly Triad/H&P Industries) | Yes |
| Lubricating Jelly | DUKAL Corporation | Yes |
| Lubri-Gel | Sheffield Pharmaceuticals | Yes |
| Maxilube Personal Lubricant | Mission Pharmacal | Yes |
| NovaPlus | Medline Industries, Inc. (formerly Triad/H&P Industries) | Yes |
| Pro Advantage Lubricating Jelly | National Distribution & Contracting, Inc. | Yes |
| ReliaMed Lubricating Jelly | ReliaMed | Yes |

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THINPREP SPECIMEN COLLECTION: BROOM-LIKE DEVICE

EMAIL PRINT

Broom-Like Device Protocol



Obtain...

...an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.¹ Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.



Rinse...

...the broom as quickly as possible into the PreservCyt solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.



Tighten...

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



Record...

...the patient's name and ID number on the vial, and the patient information and medical history on the cytology requisition form.



Place...

...the vial and requisition in a specimen bag for transport to the laboratory.



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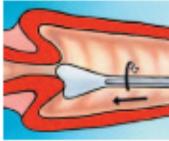
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THINPREP SPECIMEN COLLECTION: BRUSH/SPATULA

Brush/Spatula Protocol



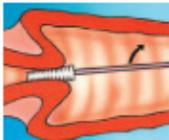
Obtain...

...an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary.¹ Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.



Rinse...

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



Obtain...

...an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.



Rinse...

...the brush as quickly as possible in the PreservCyt solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.



Tighten...

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



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IV. INTERPRETATION OF PAP TESTING REPORTS

The following information specifically describes epithelial cell abnormalities.

A. ADEQUACY

Adequacy and diagnosis should be used in conjunction with clinical history to determine appropriate patient follow-up. The condition of the specimen received and the presence or absence of endocervical and/or squamous metaplastic cells is noted. The presence of excessive red blood cells, inflammation, scanty cellularity, or poor fixation of cells is also noted. ADEQUACY IS NOT A DIAGNOSIS

B. PATHOLOGIST REVIEW POLICY

Pap Smears with an atypical diagnosis will be reviewed by a pathologist. A separate charge will be made for the pathologist over read.

C. INFECTIOUS DISEASE SCREENING

Specimens are screened for cytologic evidence of infectious diseases, such as

trichomonas, herpes, candida and human papillomavirus (HPV).

HPV testing can be performed from the ThinPrep specimen vial. HPV testing will determine the presence of HIGH-RISK HPV factors.

HIGH RISK HPV types are associated with warts, low-grade lesions and high-grade lesions (including cancer).

Guidelines developed by the American Society for Colposcopy and Cervical Pathology (ASCCP) recommend HPV high risk testing only ordered on patients with atypical squamous cells of undetermined significance (ASCUS). The test must be ordered within 3 weeks of ThinPrep vial specimen collection.

Chlamydia trachomatis and Neisseria Gonorrhoeae testing by can also be performed from ThinPrep specimen collection vials. The Cytology Department must have a written request to run either HPV or CT/GC testing. If testing is desired, fax a request (form available on our website) to 785-537-3592, attention CYTOLOGY.

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V. PAP REMINDER SYSTEM

Peterson Laboratory Services holds quality patient care to the highest standard. A patient reminder system is offered at no additional cost.

NORMAL PAP PATIENT LETTER

Letters are prepared by Peterson Laboratory Services and mailed directly from our facility to those patients with negative pap test results. The letters are addressed to the patient and appear as if they were sent from the office of the attending physician. The letter explains to the patient that their pap test has been interpreted as "normal." The patient is instructed to telephone the attending physician's office if they have questions or concerns. The name of the laboratory does not appear on the correspondence.

If there is a question about if a letter was sent to a patient, please refer to the patient report. A single asterisk (*) under the pathologist's name on the left side indicates that a letter was sent. If no asterisk appears, it indicates that a letter was not sent.

PAP REMINDER LETTERS

Letters reminding patients that they are due for a repeat Pap test are prepared and sent to the physician's office on a monthly basis. The letters are prepared with the physician name and telephone number for the patient to phone to make an appointment and make no reference to Peterson Laboratory Services. The attending physician may use the reminder letters as they desire; however, double window envelopes are furnished with the letters to facilitate mailing.

The reminder letters are prepared nine (9) months following a negative report.

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NON-GENITAL CYTOLOGY

I. COLLECTION / HANDLING PROCEDURES

The most accurate testing is achieved with highest quality specimens. Please submit at next courier pickup.

| SOURCE | SPECIMEN REQUIREMENTS |
|---|---|
| BODY FLUIDS (pleural, ascitic, etc.) | Fresh specimen needs to be refrigerated or submit in Cytolyt solution at room temperature. Submit the entire specimen. |
| BREAST CYST ASPIRATE | Fresh specimen needs to be refrigerated or submit in Cytolyt solution at room temperature. Refrigerate. |
| BRONCHIAL WASHINGS | Fresh specimen needs to be refrigerated or submitted in equal amounts of Cytolyt at room temperature. |
| BRUSHINGS | Place brush(s) in small container with normal saline. Refrigerate. |
| CEREBROSPINAL FLUID | Fresh specimen needs to be refrigerated or submit in Cytolyt solution at room temperature. Refrigerate. |
| FINE NEEDLE ASPIRATE | Refer to following special collection procedure. |
| SPUTUM | First morning deep-cough specimen is recommended. Generally three (3) separate specimens are collected. |
| URINE | Fresh urine needs to be refrigerated or if collected in PreservCyt solution @ 2:1 urine-to-PreservCyt ratio, or 3:1 urine-to-Cytolyt ratio, send at room temperature. DO NOT COLLECT FIRST MORNING SAMPLE. Indicate on requisition if sample is voided or catheterized, as appropriate. |
| BLADDER WASHINGS | Fresh specimen needs to be refrigerated or submit in Cytolyt solution at room temperature. Refrigerate. |
| SMEARS (including Tzanck) | Spray fix immediately. If collected from the head/neck/lymph area, please submit 2 air-dried slides also. |

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NON-GENITAL CYTOLOGY

A. LABELING

1. Label glass slides with the following information:
 - a. Patient first and last name
 - b. Date of collection
2. Label the container with the following information:
 - a. Patient first and last name
 - b. Anatomic location of specimen
 - c. Date of collection
3. Indicate on the label the solution the specimen has been collected in i.e. saline, Cytolyt, etc.
2. Additional required information in the NON-GENITAL CYTOLOGY area of the request form:
 - a. Anatomic Location of Specimen
 - b. Pertinent medical history
 - c. Diagnosis

B. REQUISITION:

1. Complete a green PLS cytology requisition (GP3) with the following demographic information:
 - a. Patient First and Last Name
 - b. Physician
 - c. Date of Birth
 - d. SEX of patient

C. HANDLING:

1. Place slides in slide folders
2. Place slide folders and specimen container in PLS specimen transport bag
3. Fold requisition and place in side pocket of PLS specimen transport bag
4. Transport to PLS

NOTE: *Slide containers and spray fixative are furnished upon request. Please contact the laboratory if you require supplies or additional information.*

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NON-GENITAL CYTOLOGY

II. FINE NEEDLE ASPIRATE

COLLECTION/HANDLING PROCEDURE

Fine needle aspirate specimens may be submitted in Cytolyt or submitted as slides.

A. SLIDES:

1. 22-25 gauge needle
2. 20 mL syringe
3. Clean glass slides with frosted ends
4. Spray fixative or 95% alcohol
5. Pre-filled Cytolyt preservative tube
6. Slide holder(s)

B. COLLECTION:

1. The aspiration is usually performed under aseptic technique without local anesthesia. If local anesthesia is used, insert the needle adjacent to, but not into the lesion. Anesthetizing solution could dilute or distort the specimen.
2. Attach a 22-25 gauge needle to the 20 mL syringe.
3. Place the plunger of the syringe at the 5 ml mark. Secure the mass with one hand. Use the other hand to insert the needle into the mass.
4. Draw negative pressure to the 20 mL mark, move needle in short stabbing

motions, changing the angle of direction within the lesion.

5. Return the plunger to the 5 mL mark to release the suction before withdrawing the needle. NEVER INJECT AIR!
6. After withdrawing the needle, remove the needle from the syringe. Fill the syringe with air.
7. Reattach the needle and carefully express one drop of specimen onto a glass slide. Use another glass slide or the needle tip to spread the specimen.
8. IMMEDIATELY (within a few seconds) spray the slides with the fixative. Any delay will cause air drying and cellular distortion, thus rendering the specimen unsatisfactory for evaluation.
9. If a lipoid lesion or lymph node is being examined, two (2) additional slides maybe prepared and allowed to air dry without fixative.
10. The contents of the needle and syringe should be expressed/ rinsed into a Cytolyt tube.
11. Submit the glass slides and Cytolyt container for cytology studies.