PHHS Cytology Services

5201 Harry Hines Blvd., Dallas, TX
Main: 469-419-7277
Fax: 469-419-3021
CLIA No. 45D0701957
Department of Cytology Overview

The Cytology Department specializes in the screening of gynecologic and exfoliative cytology, fine needle aspiration biopsy. The Cytology Department offers FNA consultation services at the FNA Clinic located in the PHHS Outpatient 6th Floor A/B Clinic.

Hours of Operation

Medical Director: Joel Thibodeaux, M.D. 469-419-1535
Cytology Supervisor: Tara Good, MHA, CT (ASCP) 469-419-1554
Clinical Laboratory Specialist: Stephanie Nobles, MHA, CT (ASCP) 469-419-1531
AP Manager: Darnetta Miles, MT (ASCP) 469-419-1542
Location: NPH 02-602
Hours: 8:00 AM - 5:00 PM, Monday-Friday
Main Telephone: 469-419-7277 (7-PAPS)
Fax: 469-419-3021

Cytology Specimen Acceptance Criteria and Specimen Rejection

The PHHS Cytology Department has strict acceptance criteria for accepting specimens and a well-defined procedure for rejecting specimens. The purpose is to protect specimen integrity and assure accurate diagnoses and patient care.

- Specimens are accepted only when ordered by physicians or other persons authorized by law.

- In order to accept the specimen, each sample must have an accompanying requisition form completed by the authorized provider. The following information is required on the requisition:
  a. Patient demographics
  b. Date and time of collection
  c. Practitioner’s name, ID number, and pager number
  d. Specimen source
  e. Clinic location

- The provider must properly label specimen containers with an EPIC demographic label, indicate the source on the container, and initial and date the label. Submitted slides must have 2 patient identifiers written on the frosted end of the slide.

- In order to accept a specimen for processing, we require a completed requisition accompanied by a labeled specimen. All information must match. When specimens do not meet our acceptance criteria, they will not be processed. The following are reasons for specimen rejection:
  a. Unlabeled specimen containers or slides
  b. Incomplete requisition forms
  c. Specimen not accompanied by a requisition
  d. Mismatched information
  e. Specimens received in an inappropriate fixative
  f. Specimens not meeting storage and transport temperatures
  g. Specimens submitted in expired reagents

- The PHHS Cytology Department mandates laboratory specimen requirements to provide staff with a course of action for specific problems. If it is determined that a specimen is to be rejected, Cytology processing staff will complete a Specimen Rejection/Unable to Process form.

- After the form is completed by the Cytology processing personnel, the clinician is paged and verbally notified that the specimen has been rejected and why. The event is entered into the Safety Center.

- Rejected specimens are retained in the lab for a period of 3 weeks, and then discarded.
Gynecologic Cytology Samples: Liquid-Based Pap Tests

The Pap Test is not a diagnostic procedure and should not be used as the sole means to detect cervical cancer. It is a screening procedure to aid in the detection of cervical cancer and its precursors. Both false negative and false positive results have been experienced.

To ensure the best possible results of a Pap Test, be sure the patient:

- Abstains from sexual intercourse for 24-48 hours prior to the examination
- Abstains from using vaginal medication, vaginal contraceptives, or douches for 24-48 hours prior to the examination.
- Is not currently on her menstrual period, if so, the patient should be rescheduled, if possible.
- The optimal time for a Pap test is around day 16-18 of the menstrual cycle.

Screening Paps

Screening Paps for the early detection of cervical cancer are covered when ordered by a physician under one of the following conditions:

Routine: The patient has not had a Pap test during the preceding two years, no symptoms, no abnormal history, and no risk factors.

Clinical High Risk for Cervical Cancer: There is evidence from the patient’s medical history or other findings that the patient is at high risk of developing cervical or vaginal cancer and the patient's physician recommends that the Pap test be performed more frequently.

The high risk factors for Clinical High Risk of Cervical Cancer are:

- Infrequent Paps (3 negative Paps in 7 years)
- Multiple sex partners (5 partners)
- History of DES exposure
- History of STDs (including HIV)
- Early onset of sexual activity (16 yrs old)

Diagnostic Paps

Diagnostic Paps are used to find the absence or presence of trauma, infection, carcinogens and/or viruses and are eligible for reimbursement under the following circumstances:

- Previous cancer of the cervix, uterus, or vagina that has been or is presently being treated
- Previous abnormal Pap test
- Any abnormal finding of the vagina, cervix, uterus, ovaries, or adnexa
- Any signs or symptoms that might be reasonably related to a gynecologic disorder
- Any significant complaint by the patient related to the female reproductive system.

ICD-10 Codes

It is required to provide an ICD-10 code on the pap requisition on all outpatients to indicate the reason for the test. Please refer to an ICD-10 Coding book or if you have access to the PHHS Intranet under Spot Light, click on ICD-10 Code Search http://intranet.pmh.org/Home/ICD94.htm

Materials Required for Gynecologic Testing

- ThinPrep® Test Collection kits may be ordered from Material Services Warehouse:

<table>
<thead>
<tr>
<th>MRD #</th>
<th>Description</th>
<th>Order Unit</th>
</tr>
</thead>
<tbody>
<tr>
<td>23022</td>
<td>Preservcyt® Solution &amp; Wallach/Pappette</td>
<td>25 tests/kit</td>
</tr>
<tr>
<td>23023</td>
<td>Preservcyt® Solution &amp; Cytobrush/Spatula</td>
<td>25 tests/kit</td>
</tr>
</tbody>
</table>

- GYN Cytology Requisitions may be ordered from Standard Register online at Smartworks.com (Form ORD132).
Gynecologic Cytology Services

Gynecologic Requisition Requirements: A Gynecologic Cytology Chart Order Form/Requisition must be legibly and accurately filled out before obtaining the cellular sample. The requisition requests the following information:

- Patient’s demographics including Age and/or date of birth.
- Menstrual status (LMP, hysterectomy, pregnant, postpartum, hormone therapy).
- Previous abnormal cervical cytology result, previous treatment, biopsy, or surgical procedure.
- Source of specimen; e.g., cervix, vagina
- Practitioner’s name, identification number, and pager number.
- Clinic location
- Appropriate clinical history provided by the physician on the requisition should including Hormone/contraceptive use and relevant clinical findings (abnormal bleeding, grossly visible lesion, etc.).
- ICD-10 Code for all outpatients

Gynecologic Test Requested: Please indicate the laboratory test requested

- Liquid-Based Pap & Reflex to High Risk HPV DNA Test (Recommended by the ASCCP)
- Liquid-Based Pap
- Liquid-Based Pap & High Risk HPV DNA Test
- High Risk HPV DNA Test
- Conventional Pap Smear

Gynecologic Cytology Ordering Guidelines

<table>
<thead>
<tr>
<th>Test Recommended</th>
<th>Patient Criteria</th>
<th>HPV Exclusion Criteria (HPV not performed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liquid-Based Pap &amp; Reflex HPV*</td>
<td>Patients ≥ 21 years of age</td>
<td>• Patients &lt; 21 years of age</td>
</tr>
<tr>
<td>*Performed on:</td>
<td></td>
<td>• History of a Positive HPV in past 12 months</td>
</tr>
<tr>
<td>-ASC-US ≥ 21 of age</td>
<td></td>
<td>• Pap is Unsatisfactory</td>
</tr>
<tr>
<td>-LSIL ≥ 50 years of age</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Liquid-Based Pap Only</td>
<td>• Patients &lt; 21 years</td>
<td>• N/A</td>
</tr>
<tr>
<td></td>
<td>• Any age patient where HPV is not clinically</td>
<td></td>
</tr>
<tr>
<td></td>
<td>indicated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Patient who has had a positive HPV in past 12</td>
<td></td>
</tr>
<tr>
<td></td>
<td>months</td>
<td></td>
</tr>
<tr>
<td>Liquid-Based Pap &amp; HPV</td>
<td>• HPV testing performed regardless of pap result</td>
<td>• Pap is Unsatisfactory</td>
</tr>
<tr>
<td></td>
<td>• Screening Pap &amp; HPV for women ≥ 30 years</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-Optional screening strategy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>-No repeat for 5 years if both negative</td>
<td></td>
</tr>
</tbody>
</table>

Gynecologic Specimen Requirements:

The current methodology used is The ThinPrep Pap Test®. The ThinPrep® Preservcyt® specimen vial must be affixed with the patient’s specimen label and contain the patient’s name and medical record number. If handwritten, the patient’s first and last names, medical record number, and date of birth are required. The patient information on the vial must match the patient information on the ThinPrep® specimen vial.

Unacceptable Conditions:

- ThinPrep Preservcyt specimen vial exceeding the expiration date printed on the container.
- Prior to specimen collection vials must be stored (without specimen) at 59-86° F (15-30 °C)
- Specimens stored or transported outside of required temperature range 59-86° F (15-30 °C)
- Unlabeled specimen containers
- A mismatch between the specimen label and the requisition
- A leaking specimen that is not salvageable
- Incomplete requisition
- A specimen received > 6 weeks past the date of collection
Delivery of Gynecologic Specimens

All gynecologic specimens are usually sent to Lab Central and should be received daily or within 72 hours of collection. Rush specimens can be delivered directly to the Cytology Department between 8 A.M. - 5 P.M., Monday through Friday.

Conventional Pap Smears – Spatula and Endocervical Brush Protocol

The vaginal fornix and ectocervix should be sampled before the endocervix/transformation zone. First, a sample of the ectocervix is taken using a plastic (or wooden) spatula. The notched end of the spatula that corresponds to the contour of the cervix is rotated 360° around the circumference of the cervical os, retaining the sample on the upper surface of the spatula. The spatula is held with the specimen face up while the endocervical sample is collected. Sampling of the endocervix requires insertion of the endocervical brush into the endocervical canal until only the bristles closest to the hand are visible. The brush is rotated 45-90° and removed. At this time, the sample on the spatula is spread evenly and thinly lengthwise down one half of the labeled slide surface (the slide must be labeled with the patient’s name using a lead pencil), using a single uniform motion. The endocervical brush is then rolled along the remaining half of the labeled slide surface by turning the brush handle and slightly bending the bristles with gentle pressure. The brush should not be smeared with force or in multiple directions. The entire slide is then rapidly fixed by immersion into 95% alcohol or spray with cytologic fixative.

Conventional Paps must be labeled with the patient’s first and last name on the frosted end of the glass slide. The slide should be placed in a plastic or cardboard slide carrier and labeled with the patient’s EPIC demographic label. The slide is placed in the main pocket of the biohazard bag and the requisition placed in the side pocket.

Liquid-Based Pap Test Collection

The Liquid-Based Pap Sample may be obtained by the Endocervical Brush/Spatula Protocol or the Broom-Like Device Protocol. The current methodology employed by the PHHS Cytology Lab is the ThinPrep Pap Test.


Obtain...
...an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endo-cervical 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.

Record...
...place the patient’s name and medical record number on the vial. Affix Epic label...the patient information and medical history on the Cytology Requisition form

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

Place...
...the vial and requisition in a specimen biohazard bag for transport to the laboratory.
ThinPrep® Pap Test Quick Reference Guide
Endocervical Brush/Spatula Protocol

Obtain…
…an adequate sampling from the endocervix using a plastic spatula

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 bottom-most fibers are exposed. Slowly rotate ¼ or ½ turn in one direction. DO NOT OVER ROTATE.

Rinse…
…the brush as quickly as possible into the Preservcyt® Solution vial 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.

Record…
…place the patient’s name and medical record number on the vial
…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.
**Gynecologic TAT**

Gynecologic Pap results are usually completed in approximately 10 working days.

**Gynecologic Results and Reporting**

Gynecologic cytology specimens are interpreted in keeping with The Bethesda System for Reporting Cervical Cytology. The following illustrates the nomenclature for reporting.

**Negative for Intraepithelial Lesion or Malignancy**

**Organisms:**
- *Trichomonas vaginalis*
- Fungal organisms morphologically consistent with *Candida* spp
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with *Actinomyces* spp.
- Cellular changes consistent with herpes simplex virus

**Other Nonneoplastic findings:**
- Reactive cellular changes associated with:
  - inflammation (includes typical repair)
  - radiation
  - intrauterine contraceptive device (IUD)
- Glandular cells status post hysterectomy
- Atrophy

**Other**
- Endometrial cells (*in a woman ≥ 45 years of age*)

**Epithelial Cell Abnormalities**

**Squamous Cell:**
- Atypical squamous cells
  - of undetermined significance (ASC-US)
  - cannot exclude HSIL (ASC-H)

- Low-grade squamous intraepithelial lesion (LSIL) encompassing: HPV/mild dysplasia/CIN 1
- High-grade squamous intraepithelial lesion (HSIL) encompassing: moderate and severe dysplasia, CIS/CIN 2 and CIN 3 with features suspicious for invasion (*if invasion is suspected*)
- Squamous cell carcinoma

**Glandular Cell**
- Atypical
  - endocervical cells (NOS or specify in comments)
  - endometrial cells (NOS or specify in comments)
  - glandular cells (NOS or specify in comments)
- Atypical
  - endocervical cells, favor neoplastic
  - glandular cells, favor neoplastic
- Endocervical adenocarcinoma in situ
- Adenocarcinoma
  - endocervical
  - endometrial
  - extrauterine
  - not otherwise specified (NOS)
High Risk Human Papilloma Virus (HPV) DNA Testing

Reflex High Risk HPV testing for high-risk oncogenic types is performed to facilitate the management and treatment of the following Pap abnormalities:

- Atypical Squamous Cells of Undetermined Significance (ASC-US) for patients ≥ 21 years of age
- Low Grade Squamous Intraepithelial lesion (LSIL) for patients ≥ 50 years of age

**Exclusion to REFLEX HPV TESTING:** Reflex HPV DNA testing will not be performed for any Pap abnormality if there has been a positive HPV DNA test for that patient during the preceding 12 months or for a patient who is <21 years of age.

A High Risk HPV DNA Test may also be ordered as a standalone test or in conjunction with the Pap Test and will be performed regardless of the Pap Result (Exception is an Unsatisfactory Pap).

The current test methodology used is the Cervista Human Papillomavirus (HPV) High Risk (HR). It is an in-vitro diagnostic test that uses Invader chemistry, a signal amplification method for detection of specific nucleic acid sequences. Cervista HPV HR is a test for the qualitative detection of DNA from 14-high risk HPV types (16/18/31/33/35/39/45/51/52/56/58/59/66/68) in cervical specimens when collected in ThinPrep Preservcyt solution. The testing of vaginal samples is considered off label by the FDA and the analytical performance characteristics have been determined by the Parkland Cytology Department.

The Cervista HPV HR test is not intended for use as a screening device for women under age 30 with normal cervical cytology or a substitute for regular cervical screening. The Cervista HPV HR test is designed to enhance existing methods for the detection of cervical disease and should be used in conjunction with clinical information derived from other diagnostic and screening tests, physical examinations, and full medical history in accordance with appropriate patient management procedures.


**The Clinical Cut-off of the Cervista HPV HR Test:** For a Positive HR HPV results, an HPV FOZ ratio cut-off of ≥1.525 or a minimum HPV FOZ value of ≥1.93 for all three reaction mixes were selected as the cut-off values for the test. The table below taken from the Cervista HPV HR Package Insert shows the Interpretation of Cervista HPV HR test results.

<table>
<thead>
<tr>
<th><strong>Table 4:</strong> Interpretation of Cervista™ HPV HR Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cervista™ HPV HR Test Result</strong></td>
</tr>
<tr>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>POS</td>
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<tr>
<td>NEG</td>
</tr>
</tbody>
</table>
Non-Gynecologic Cytology Services

Non-gynecologic specimens are collected from a variety of body sites for the detection of malignant and benign processes. The site from which the sample is collected dictates the method of collection, and the method of collection can affect the morphology of the cellular samples.

Requisition Requirements for Submission of Non-Gynecologic Cytology

A laboratory requisition must be legibly and accurately filled out before obtaining the cellular sample. The requisition requests the following information:

- Patient's demographics.
- Date and time of collection.
- Practitioner's name, identification number, and pager number.
- Clinic location.
- Source.
- Fixation method
- Relevant clinical history or findings.
- Valid ICD-9 code.

For outpatient cases

Non-Gynecologic Specimen Labeling Requirements:

All specimen vials, containers, and prepared slides must be labeled and identified with an EPIC patient demographic label. The information on the specimen vial must match the information on the requisition. Specimen containers must be labeled with the source and dated and initialed by collection staff. Submitted slides must be labeled with two patient identifiers.

Collection of Non-Gynecologic Specimens

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Submission to Cytology Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anal Cytology</td>
<td></td>
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<tr>
<td><strong>Anal Pap</strong></td>
<td>The Dacron swab should be moistened with water.</td>
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<tr>
<td></td>
<td>This swab is inserted 1 to 1.5 inches into the anal canal and is rotated firmly as it is</td>
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<tr>
<td></td>
<td>being slowly pulled out of the canal, applying some pressure to the wall of the anus,</td>
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<td></td>
<td>rotating the swab in a spiral motion along the way. (The squamocolumnar transition zone</td>
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<tr>
<td></td>
<td>is about 1 inch from the anal verge).</td>
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<td></td>
<td>The swab should be rinsed into a 20-ml vial of ThinPrep® Preservcyt® by swirling the</td>
</tr>
<tr>
<td></td>
<td>swab vigorously in the vial 10 times.</td>
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<tr>
<td>Body Fluid Cytology</td>
<td></td>
</tr>
<tr>
<td>Serous or Body Cavity Fluids</td>
<td>Serous or body cavity fluids are usually collected with an aseptic technique by needle</td>
</tr>
<tr>
<td>Pleural Fluid</td>
<td>puncture and aspiration of the body cavity fluid. Fluids are best collected into a dry</td>
</tr>
<tr>
<td>Pericardial Fluid</td>
<td>container and submitted with 3 ml of heparin to 1000 ml of fluid. If a longer delay is</td>
</tr>
<tr>
<td>Peritoneal Fluid</td>
<td>anticipated, partial fixation at the time of collection with 50% ethanol equal to</td>
</tr>
<tr>
<td>Synovial Fluid</td>
<td>specimen volume is suggested followed by refrigeration. Any added fixative should be</td>
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<tr>
<td></td>
<td>noted on the requisition. For small fluid accumulations the entire specimen is submitted</td>
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<tr>
<td></td>
<td>for laboratory evaluation. For larger effusions, a minimum of 50 ml of well-mixed fluid</td>
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<tr>
<td></td>
<td>should be sent for cytologic examination; however, the entire specimen is also acceptable.</td>
</tr>
<tr>
<td>Breast Ductal Lavage</td>
<td>Breast Ductal Lavage fluid is collected by infusing portions of the breast ductal system</td>
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<tr>
<td></td>
<td>with a small amount of saline. A total of 10-20 ml saline is introduced in 2-4ml increments.</td>
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<tr>
<td></td>
<td>The fluid collected is transferred to a vial containing and equal volume of Cytolyt®. Each</td>
</tr>
<tr>
<td></td>
<td>duct fluid must be submitted separately. Do no pool samples. The specimen and requisition</td>
</tr>
<tr>
<td></td>
<td>must be labeled with the patient demographic label and indicate right or left breast and the</td>
</tr>
<tr>
<td></td>
<td>ductal coordinates. The specimen should be refrigerated at 2-8 degrees Celsius and sent to</td>
</tr>
<tr>
<td></td>
<td>the lab as soon as possible.</td>
</tr>
<tr>
<td>Specimen</td>
<td>Submission to Cytology Lab</td>
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<tr>
<td>----------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Brushings</strong></td>
<td>After a brushing is performed, the brush is rolled across the slide in an area approximately 2.5 centimeters in diameter (the size of a quarter) to produce a thin evenly layered smear. <strong>The slide should be fixed immediately.</strong> Immediate fixation of the cellular sample is necessary to prevent air-drying. <strong>Fixation can be by immersion (preferably) in 95% alcohol or spray fixation.</strong> Two patient identifiers must be written on the slides. Material obtained from a brushing may be submitted in the ThinPrep® Preservcyt® vial solution. The adherent cellular material on the brush may be rinsed vigorously into the media. The container must be clearly labeled with an EPIC demographic label. The source must be written on the label and the date and initials of the collecting staff. The specimen container should be a leak proof container with enough fluid to cover the brush.**</td>
</tr>
</tbody>
</table>
| **Cerebral Spinal Fluid (CSF)**  | CSF specimens must be collected in a sterile container and sent to the lab immediately.* If a delay is anticipated, an equal volume of 50% alcohol may be added to the specimen and refrigerated. A minimum of 1 mL is preferred.  

*STAT CSF labels are available from the Cytology Dept.**  |
| **Fine Needle Aspiration Biopsy (FNAB)** | Fine needle aspirates (FNAB) may be performed on any body site that can be reached with a fine needle. A fine or thin needle is defined as 22 or higher gauge. FNAB may be performed on palpable (superficial) lesions or with radiologic, endoscopic, or bronchoscope guidance (deep lesions). The operator should be prepared to obtain material for ancillary tests, such as cell block preparation, molecular studies, flow cytometry studies or microbiologic studies. FNA collection should be as follows: **Prior to the procedure, slides should be labeled with the patient’s name.** The cellular material is expressed onto the slide and the material is smeared using a second slide. Often, a paired smear is used, smearing the material between two slides, making a mirror image pair. One of the slides is often fixed and the other air-dried. Alternatively, push smears, pull smears, and one- or two-step smearing techniques are used.**  

Prepared smears may either be air-dried or fixed in 95% ethanol  

Collected material may also be submitted in Cytologic fixative; Cytolyt®, Preservcyt®, or 95% ethanol.**  |
| **Miscellaneous Smears**         | Any prepared smears must be fixed immediately either by spraying with cytologic spray fixative or immersing in 95% ethanol. Slides must be labeled with two patient identifiers.**  

Tzanck Specimens are traditionally submitted as fixed smears. However, the scraped specimen material may also be immersed into a 20 ml vial of Preservcyt®.**  |
| **Sputum Cytology (Deep Cough Sputum)** | Sputum is submitted in a standard sterile sputum cup. The sample should be an expectorated sputum, not saliva or nasal secretions. Sputums should be sent immediately to the Cytology Lab after collection. If a delay is anticipated, add 50% alcohol and refrigerate.**  |
| **Urinary Cytology**            | a) Urine, bladder, and/or renal pelvic washings-The preferred collection method is to collect the urinary specimen in a sterile specimen container, then transfer the sample to a prefilled Urinary Fixative collection container (provided by Cytology) that contains Preservcyt® (a methanol based fixative). The volume of urinary specimen transferred to the prefilled Urinary fixative container should be a minimum volume of 33 ml and the total urinary volume should not exceed 66 ml. Urinary specimens may also be submitted fresh in sterile containers and should be refrigerated after collection until delivery to the lab.  

b) UroVysion FISH testing is available as a standalone test, ordered in conjunction with the urine cytology Request, or as a Reflex UroVysion to the Urine Cytology Test. Please indicate testing preferences on the requisition. A reflex UroVysion FISH Test is performed on a Urine Cytology Diagnosis of Atypical or Suspicious.**  |

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*For consultation, call 630-513-6902.

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Last Revision 05/12/16 by S. Nobles, CLS
Specimen Submission to Cytology Lab

<table>
<thead>
<tr>
<th>Washings Cytology</th>
<th>Submission to Cytology Lab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastric Bronchial Common Bile Duct Colon Esophageal Peritoneal/Pelvic</td>
<td>Washing specimens can be collected from various body sites. Small aliquots of balanced saline solution are washed over a directly visualized area and removed immediately with suction. Washings are usually submitted unfixed to the laboratory. If a delay is anticipated, they may be partially fixed in 50% ethanol equal to specimen volume. Any added fixative should be noted on the requisition.</td>
</tr>
</tbody>
</table>

**Delivery of Non-Gynecologic Specimens**

Once the sample has been placed in the specimen vial, the labeled specimen container and completed Non-Gynecologic Cytology requisition or FNA requisition should be placed in a biohazard specimen bag. The vial should be placed in the main body of the bag and the requisition should be placed in the side pocket of the specimen bag.

The specimen should be delivered directly to the PHHS Cytology Department or to Rapid Response Lab. Rush or STAT specimens should be clearly identified and should be delivered directly to the Cytology Department between the hours of 8 a.m.– 5 p.m., Monday through Friday.

**Non-Gynecologic Resulting and Reporting**

Non-Gynecologic cases are usually signed out and reported within 48 hours of receipt (excluding weekends and holidays). Cases referred for ancillary testing, special stains, immunohistochemical staining, and/or prognostic markers may have a longer turnaround time.

**PHHS Fine Needle Aspiration Biopsy (FNAB) Outpatient Clinic**

In order to consolidate requests for fine needle aspiration biopsy procedure, a Pathology FNA Clinic has been established. The Cytology Department provides FNA consultation services twice a week. The indication for FNA is a discrete, defined lesion where the physician wants to rule in or rule out certain differential diagnoses.

- **Location:** PHHS 6th Floor Clinic A/B (OPH)
- **Hours:** 9am-12pm, 1pm-4pm, WEDNESDAYS
- **Limit:** Up to 10 patients per day
- **Ordering:** The Cytology Department requires specific patient information in order to conduct FNA consultation service. Consultation requests are ordered in EPIC by the provider. The FNA request should be for a specific, palpable mass with indications for fine needle aspiration.

**CT-Guided/Ultrasound Fine Needle Aspiration Biopsy (FNAB) Service**

Procedures requiring a cytotechnologist or pathologist to perform/assist with a CT-Guided or Ultrasound-Guided FNA or a procedure on a floor unit must be scheduled with the Cytology Department between 8 a.m. to 5 p.m., Monday to Friday. Please call the main Cytology number, 469-419-7277, to schedule the procedure. On rare occasions and/or emergency situations, a floor or CT-guided FNA may be scheduled outside of our regular hours. This will be at the discretion of the attending pathologist.

**Her-2 FISH Requests**

Her2 FISH (Fluorescence in situ Hybridization) for Breast and Gastric cases area currently referred out for testing.

**Ordering**

These tests are generally ordered by the pathologists based on established reflex protocols that have been developed with the clinicians. Panels may also be ordered by clinicians.

**TAT**

FISH testing turnaround time is ~ 7-10 days after the initial Cytologic or Surgical Diagnosis.
November 1, 2012

Re: Lubricant use during Pap sample collection

Dear Colleague,

On occasion, Hologic personnel are asked to provide information concerning the use of lubricants when collecting a Pap sample using the ThinPrep® Pap Test. As part of Hologic’s continuing education for clinicians and laboratorians, this bulletin addresses the proper preparation of the cervix for an adequate Pap sample collection pertaining to the ThinPrep Pap Test and the use of lubricants on the speculum. Steps taken by the clinician, from patient education to improved sampling technique, may ensure that the sample collected maximizes the potential of the Pap test.1,2

Patient Education:

Women should be counseled to refrain from intercourse, douching, using tampons, or using intravaginal medication for at least 48 hours before the examination to decrease the possibility that the number of exfoliated cells will be diminished or obscured by personal lubricants or spermicides. In addition, the patient should avoid scheduling her appointment during heavy menstrual bleeding. If you would like Hologic patient education materials for your office, please visit www.hologiccustomersolutions.com.

Sample Collection Options for Lubricating the Speculum:

1. **Lukewarm Water**: For a patient without physical or physiologic reasons for needing lubricant, lukewarm water may be used to warm and lubricate the speculum. This protocol has the least risk to the quality of the Pap sample collected. Professional organizations including ACOG and CLSI recognize that excessive use of lubricant may contaminate or obscure the Pap sample.

2. **Lubricant Gels**: If lubricant must be used due to patient discomfort or other circumstances, lubricant should be used sparingly and applied only to the exterior sides of the speculum blades, **avoiding contact with the tip of the speculum**. (see pictures below) When a lubricant is used sparingly and appropriately, it poses little risk to the quality of the Pap sample. However, when a lubricant is used in excess, it can adversely affect the Pap sample. Hologic evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial. Hologic recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly as described below.
Appropriate Use of Lubricant for Pap Collection

Apply a dime-sized amount of lubricant gel.

Apply only to exterior sides of the speculum, avoiding the tip.

Should you have further questions regarding this topic, please refer to the CLSI guidelines or contact Hologic Technical Support Department at 1-800-442-9892, option 6.

Sincerely,

Edward Evantash
Medical Director

5. Hologic internal study, Data on file.

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