



Title: CYTOLOGY SPECIMEN COLLECTION MANUAL AND SUBMISSION GUIDELINES

CAP Checklist: GEN.04115

Document Type: Standard Operating Procedure

COMPLIANCE STATEMENT:

This Standard Operation Procedure defines how to submit specimens to the Cytology Laboratory, University of Colorado, Department of Pathology.

The specimen collection manual for cytopathology specimens includes instructions for all of the following elements, as applicable:

1. Preparation of the patient
2. Special timing for collection
3. Type of collection container and amount of specimen to be collected
4. Types and amounts of fixatives (e.g., 10% neutral phosphate-buffered formalin) or special media (e.g., RPMI for flow cytometry), as appropriate, including instructions for fill volume and proper mixing
5. Special handling and transport of specimens (e.g., triaging of tissue especially if limited need for refrigeration, immediate delivery)
6. Proper specimen labeling
7. Appropriate clinical data, when indicated.

LABORATORY POLICY:

- Written instructions for handling of various cytologic specimens are available in this SOP, sections below.
- Cytology Laboratory maintains an electronic copy of the Cytology Specimen Collection Manual and Submission Guidelines, which is reviewed and updated by the Cytology Medical Director, at least biennially.
- Cytology Supervisor: Katharine A. Nejkauf, MSQA, SCT(ASCP), email: Katharine.Nejkauf@cuanschutz.edu, phone: 720-484-4697
- **Cytology Laboratory is located in Anschutz Inpatient Pavilion -1 (AIP-1), third floor, Room 3.000. Phone: 720-848-4361 Fax: 720-848-0924 Tube Station: #661, #681 Cytology Laboratory is open from 8:00 am to 5:00 p.m., Monday through Friday. The lab is closed on weekends and holidays.**

Stat, Rush and Routine Specimens

- **STAT cytology specimens** require immediate processing due to an **emergent** patient care situation, when the cytologic diagnosis will immediately affect or alter the plan of treatment. Ancillary special stains (most), immunostains, and cellblock preparations cannot be performed in a STAT manner. Typically, results are delivered within approximately 2 hours of receipt. If the specimen type also requires cellblock preparation, a preliminary result will be delivered, and, as deemed necessary by the cytopathologist, same day cellblock processing can be requested.
- **STAT specimens must be walked directly to Cytology Lab, AIP (1), 3rd. floor, Room 3.000 and the Cytology Lab must be notified by phone (x 84361) that a STAT specimen is being sent.**
- **All STAT specimens must include the name and phone number of the clinician who will receive the results.**
- **Rush cytology specimens** require expedited processing due to an urgent patient care situation. If received in the cytology lab by late afternoon, these cases are reported out in the morning of the next



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business day.

- **Routine cytology specimens** are those in which there is no immediate need for patient results. Most routine specimens will have results reported within four business days. Routine specimens received after-hours or on weekends should be sent to, and will be stored in the main Clinical Laboratory, second floor, Leprino Building. They will be delivered to Cytology Laboratory the next business day.
 - **After hours STAT specimens** (outside 8 am -5 pm, and weekends) e.g. BAL specimens, which must be urgently evaluated for Pneumocystis jiroveci (carinii) will be processed and read out by the surgical pathologist on-call: <https://www.amion.com/Scheduling.shtml>

General Considerations for Cytology Specimens

- Specimens should be sent to the cytology laboratory FRESH, as quickly as possible, after removal from the patient.
- Specimens should be refrigerated if a time lapse of one (1) hour or more is expected before delivery to the cytology lab.
- Each specimen must be labeled with:
 - a) Patient’s full name
 - b) Hospital number (medical record number)
 - c) Anatomic source and site of the specimen (i.e., pleural fluid, right.) This information must be on a label on the container itself, NOT on the lid of the container.
- Additional specimens must be placed in separate and properly labeled containers.
- **A printed-paper copy of the Epic order or a handwritten paper requisition must accompany each specimen.**
- All Pathology orders must be placed in Epic and printed-out using one of the following lab orders:

LAB3421	Surgical Pathology Request	Biopsy/Tissue Surgical Specimens
LAB3422	Cervical Vaginal Cytology Request	Pap Test Specimens
LAB3423	Non-Gyn Cytology Request	All Fluids/Washings (CSF, Pleural Fluid, Urine, Etc.)

- To print an Epic order, if Epic orders do not print automatically:
 1. Go to Chart Review (Path) and click on the order
 2. Scroll down to the bottom of the order and click on: View Order Information
 3. Scroll down to the bottom of the page and click on: Reprint Requisitions
 4. Click on the printer icon to print to the selected local printer
- Paper Cervical/Vaginal Cytology Requisition and Non-Gynecologic Cytology Requisition forms can be obtained from the Cytology Laboratory, x 84361, AIP (1) Room 3.000.
- Requisition forms must be legible and filled out thoroughly , to include:
 - a. Patient’s full name
 - b. Medical Record Number (MRN)
 - c. Date of birth
 - d. Submitting Clinic Location
 - e. The referring Provider or the name of the responsible physician
 - f. Phone or pager number for the physician requesting the lab work



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- g. Date and time the specimen was collected
 - h. Specimen anatomic source/ site and laterality (i.e., pleural fluid, right)
 - i. Pertinent clinical history, including history of malignancy and any radiation or chemotherapy, infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)
 - j. Referral Number - if required by patient's insurance
- Hospital transport delivers specimens from the main Clinical Laboratory to Cytology Laboratory through the day, between the hours of 8:00 am and 4:30 p.m.
 - STAT specimens must be walked directly to Cytology Lab, AIP (1), 3rd. floor, Room 3.000.
 - Routine specimens can be tubed to Cytology (tube station # 661 or # 681). Specimens must be double- bagged and accompanied by the corresponding order/requisition form. To prevent leakage, all lids must be securely tightened. The specimen bag should be labeled with a Cytology sticker or handwritten instructions that the specimen is for the Cytology Laboratory (not Surgical Pathology).
 - Sputa must be submitted in ThinPrep vials for non-gynecologic specimens, containing CytoLyt fixative. Collection containers can be obtained from the Cytology Laboratory, x 84361, AIP (1) Room 3.000.
 - If used, fixatives are always added in equal volume to the volume of specimen (i.e., for 5 mL of specimen, add 5 mL of fixative). The requisition **MUST** be marked to indicate the type of fixative that was used. If the slide is improperly stained based on incorrect information, it may be rendered unreadable.
 - For fixation of specimens in formalin, (FNA specimens for cellblock, cores) specimens must be fully submerged with the optimal formalin to approximate specimen volume of 10:1 or higher, or if not feasible (e.g., large specimens) at least 4:1.
 - For specimens clinically suspected or otherwise known to contain malignancy, that are likely to be submitted for ancillary testing, (e.g. breast carcinoma, gastroesophageal carcinoma), it is **required to record on the requisition:**
 - **the cold ischemia time** (time between specimen removal and placement in fixative)
 - **the time the specimen is placed in fixative**
 - Because of the importance of clinical information in the practice of cytopathology, **pertinent clinical information for these specimens must be available to the laboratory.**
 - ALL SPECIMENS MUST BE SUBMITTED IN PROPERLY LABELED, SEALED CONTAINERS, AND PACKAGED PER UNIVERSAL PRECAUTIONS.

CYTOLOGY LABORATORY WILL NOT PROCESS:

SPECIMENS WITH NEEDLES

SPUTA RECEIVED WITHOUT FIXATIVE

SPECIMENS RECEIVED IN GLASS BOTTLES

SPECIMENS IN PLEUR-EVAC CONTAINERS

SPECIMENS IN EXCESS OF 500 ML IN VOLUME



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Non-Gynecological Specimens

Specimen	Bronchial Washings	
1.	Preparation of the patient	N/A
2.	Special timing for collection	N/A
3.	Types of collection container and optimal amount of the specimen	Sterile Specimen Cup, 20 mL of sample
4.	Types and amounts of fixatives	FRESH / UNFIXED
5.	Special handling and transport	Specimens should be sent to the cytology laboratory as quickly as possible, after removal from the patient. Specimens should be refrigerated if a time lapse of one (1) hour or more is expected before delivery to the cytology lab.
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, anatomic source, site, and laterality of the specimen. This information must be on a label on the container itself, NOT on the lid of the container.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)

Specimen	Esophagus or Gastric Brushings	
1.	Preparation of the patient	N/A
2.	Special timing for collection	N/A
3.	Types of collection container and optimal amount of the specimen	Submit brush(es) in a sterile container with 20 mL of CytoLyt fixative or normal saline. The brushes should be completely submersed in the fixative and the brush handles should be cut off a few centimeters above the brush bristles.
4.	Types and amounts of fixatives	CytoLyt or Normal Saline
5.	Special handling and transport	Specimens should be sent to the cytology laboratory as quickly as possible, after removal from the patient. Specimens should be refrigerated if a time lapse of one (1) hour or more is expected before delivery to the cytology lab.
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, anatomic source, site, and laterality of the specimen. This information must be on a label on the container itself, NOT on the lid of the container.



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7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)
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Specimen	Cerebrospinal Fluid	
1.	Preparation of the patient	N/A
2.	Special timing for collection	N/A
3.	Types of collection container and optimal amount of the specimen	Preferable specimen volume is three (3) mL of CSF.
4.	Types and amounts of fixatives	FRESH/ UNFIXED
5.	Special handling and transport	Specimens MUST be delivered as quickly as possible to the main Clinical Laboratory, Leprino Building, Room 253. CSF specimens are initially processed by Hematology in the Clinical Laboratory and then sent to Cytology for review. In case of an after-hours STAT CSF, page the on-call pathology resident to notify them of the STAT specimen.
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, source of the specimen. This information must be on a label on the container itself, NOT on the lid of the container.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)

Specimen	Effusions and Body Fluids	
	Specimens types include: a) Ascites or peritoneal fluid b) Pleural or thoracentesis fluid c) Pericardial fluid d) Synovial fluid e) Cyst fluid f) Pelvic washings	
1.	Preparation of the patient	N/A
2.	Special timing for collection	N/A
3.	Types of collection container and optimal amount of the specimen	Specimens should be sent to cytology fresh, in a plastic 60 mL capped syringe (no needle), 120 mL screw top specimen cup, 80 mL screw top urine cup, or other non-glass container. If the specimen is collected in a larger container, it should be divided, and no more than 500 mL submitted to Cytology.



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		Prior to pouring-off a cytology aliquot, the specimen should be gently agitated by inverting the container 5-10 times. Minimum volume of at least 150 mL of specimen is preferable.
4.	Types and amounts of fixatives	FRESH. Do not add anticoagulant or fixative.
5.	Special handling and transport	Deliver to Cytology Laboratory (AIP (1), 3rd Floor, Room 3.000) as soon as possible. Refrigerate if specimen cannot be delivered within one hour. Specimens with needles, in excess of 500 mL, specimens in Pleur-Evac containers, or in glass containers will not be accepted.
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, anatomic source, site, and laterality of the specimen. This information must be on a label on the container itself, NOT on the lid of the container.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)

Specimen	Sputum	
1.	Preparation of the patient	N/A
2.	Special timing for collection	An early morning deep cough specimen is to be collected in a container with sputum fixative.
3.	Types of collection container and optimal amount of the specimen	ThinPrep Non-Gyn Test vials for sputa collection / fixation are available in the Cytology Lab, AIP -1, 3rd. Floor, Room 3.000; phone 720-848-4361.
4.	Types and amounts of fixatives	CytoLyt
5.	Special handling and transport	Sputum specimens received without fixative will be rejected. Deliver to Cytology Laboratory (AIP (1), 3rd Floor, Room 3.000)
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, specimen type. This information must be on a label on the container itself, NOT on the lid of



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		the container.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)

Specimen	Urine	
1.	Preparation of the patient	Provide patient education on the clean catch technique
2.	Special timing for collection	The second voided specimen in the morning is preferred, after the patient has been up and active. Patients should be encouraged to come to the hospital to void fresh specimen for best results.
3.	Types of collection container and optimal amount of the specimen	Urine Collection Cup. For males, a simple voided specimen is satisfactory. For females, a mid-stream clean catch (after cleaning urethra with an alcohol wipe) specimen is preferred. 50-80 mL of urine is considered optimal. To prevent leakage, the lid must be securely tightened.
4.	Types and amounts of fixatives	FRESH/ UNFIXED.
5.	Special handling and transport	Deliver to Cytology Laboratory (AIP (1), 3rd Floor, Room 3.000) as soon as possible. Refrigerate if specimen cannot be delivered within one hour. If the specimen cannot be refrigerated, equal volume of cytology fixative, CytoLyt, may be to the specimen as a last resort. Adding fixative dilutes the specimen and may result in a less than satisfactory reading.
6.	Proper specimen labeling	Label with a patient sticker or patient's name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, specimen type on a label on the container itself, NOT on the lid of the container.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)



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Specimen	Anal Pap Test	
1.	Preparation of the patient	<p>Patients are asked not to douche or have an enema or insert anything into their anus for 24 hours prior to an anal cytology exam.</p> <p>Lubricants should not be used prior to obtaining a cytology sample because the lubricant may interfere with the processing and interpretation of the sample.</p>
2.	Special timing for collection	<p>Sample is obtained with the patient lying on their left side, but other positions are acceptable. The buttocks are retracted to visualize the anal opening and a Dacron or polyester tipped swab moistened in tap water is inserted for approximately 2 to 3 inches into the anus.</p> <p>The swab can be felt to pass through the internal sphincter so the sample is obtained from the junction of the anus and rectum, which is where most of the HPV- related lesions are believed to originate.</p> <p>The swab is rotated 360 degrees with firm lateral pressure applied to the end of the swab, such that it is bowed slightly and then it is slowly withdrawn over a period of 15 to 30 seconds from the anus, continuing to rotate the swab in a circular fashion.</p> <p>The lateral pressure ensures that the mucosal surface, rather than rectal contents are sampled.</p>
3.	Types of collection container and optimal amount of the specimen	<p>The swab is placed in a ThinPrep Non-Gyn vial and vigorously agitated to disperse the cells for liquid based cytology. The sample must be fixed quickly within 15 seconds in order to avoid drying artifact, which occurs easily and makes interpretation difficult.</p>
4.	Types and amounts of fixatives	Cytolyt
5.	Special handling and transport	Deliver to cytology laboratory (AIP (1), 3rd Floor, Room 3.000.
6.	Proper specimen labeling	<p>Label with a patient sticker or patient’s name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, anatomic source of the specimen on the label on the container itself, NOT on the lid of the container.</p>
7.	Appropriate clinical data	Provide pertinent clinical history, including history of



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		malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B, or C, tuberculosis).
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Specimen	Fine Needle Aspirations (FNA) and Core Biopsies	
1.	Preparation of the patient	N/A
2.	Special timing for collection	Notify Cytology at 720-848-1793 of the FNA requiring cytology assistance, within 5 -10 minutes of the patient being placed in the room and prepped/ asleep for the procedure. Provide advance notification via phone or email for urgent/complex cases that will need to be rushed, or require special handling.
3.	Types of collection container and optimal amount of the specimen	A Cytotechnologist will assist with FNA procedure, prepare slides, and collect for cellblock and triage the sample for ancillary testing as needed: Direct Smears or Core Touch Preps – glass slides Needle rinse(s) or cores for Cellblock – Formalin conical tubes Needle rinse(s) and/or dedicated passes for ancillary tests <ul style="list-style-type: none"> • RPMI – Lymphoproliferative disorders • RPMI – Cytogenetics • RPMI – Tissue Banking • Saline – Thyroglobulin Assay • Saline – Parathyroid Hormone • Saline – Calcitonin
4.	Types and amounts of fixatives	95% alcohol to fix slides for Papanicolaou staining 10% Buffered formalin for cellblock (CB)
5.	Special handling and transport	For fixation of specimens in formalin, specimens must be fully submerged with the optimal formalin to approximate specimen volume of 10:1 or higher, or if not feasible (large specimens) at least 4:1. For specimens clinically suspected or otherwise known to contain malignancy, that are likely to be submitted for ancillary testing, (breast carcinoma, gastroesophageal carcinoma), it is required to record on the requisition: <ul style="list-style-type: none"> • Time out of body • Time the specimen is placed in formalin Record pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis), mass location, shape and size. If known, record information reg. prior procedures and/or specimen testing requested. If applicable, record COMIRB # for research cases Cytologist will bring the entire FNA case back to the Cytology Laboratory and hand off to the non-gyn bench, including a verbal confirmation of any special requests and processing



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		<p>instructions.</p> <p>Refer to the following SOPs in MediaLab Cytology Manual:</p> <ul style="list-style-type: none"> • Lymphoma Tissue Banking • Pancreatic Cyst SOP • Breast Protocol CB and End-Of-The-Day CB • CMOCO Samples • Choroidal Melanoma Protocol • BTS Protocol for Cytology Laboratory • Ancillary Testing From Cytology Specimens
6.	Proper specimen labeling	<p>Label with a patient sticker or patient’s name and date of birth or Medical Records Number (two unique identifiers). Record date of collection, anatomic source, site, and laterality for each specimen. This information must be on a label on the container itself, NOT on the lid of the container, and must match the information recorded on the FNA Requisition.</p> <p>Refer to FNA Specimen Procurement, and FNA Error Prevention SOPs, for detailed labeling instructions.</p>
7.	Appropriate clinical data	<p>On the FNA Requisition, provide all available pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis), research participation or special studies.</p>

Fine Needle Aspiration, (FNA)

- For Cytology assistance call : **phone 720-848-1793**
- Cytology Supervisor: phone: 720-848-4697
- A Cytotechnologist will assist with FNA procedure, prepare slides, and collect for cellblock and ancillary testing, whenever possible.
- Cytology Resident, Fellow, and the Cytopathologist on service will be contacted for Rapid On-Site Evaluation (ROSE)
- **AFTER HOURS FNA-COLLECTION KIT** is available for FNA procedures done after normal working hours: before 8 am, after 5 p.m. weekdays, or on weekends.
 - Use **one kit per site** sampled
 - Place 2-3 FNA passes into the conical vial containing 10% Formalin
 - Place 2-3 FNA passes into the conical vial containing CytoLyt™ fixative
 - Label each specimen vial with the patient's sticker and the body site
 - Fill out the corresponding paper requisition form. Provide the following information:
 - a) Patient’s name
 - b) Patient’s medical record number
 - c) Specimen site/s and laterality
 - d) Specimen type (brushing, FNA, Core BX)
 - e) Date and time the specimen was collected.
 - f) Name of the performing physician
 - g) Contact information for the ordering physician



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- h) Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease (i.e., HIV, Hepatitis B or C, tuberculosis)
 - o Deliver completed kit to the Clinical Laboratory in the Leprino Bldg.
 - o **If lymphoproliferative disorder is suspected by the performing clinician, please obtain a tube of RPMI / Flow transport media and a requisition from the Clinical Laboratory at 720-848-4401. Place one or two FNA passes into RPMI, and return to the Clinical Lab.**
**Note: It is OK to rinse the sample out of the FNA needle with minimal amount of sterile saline into formalin, CytoLyt™, or RPMI tubes.*
- **FOR EMERGENT AFTER HOURS FNA procedures:** contact **Cytopathology Fellow at 720-848-4442, or Cytology Resident at 720-848-0473** to arrange coverage for the procedure.
 - o **For weekend coverage, please call the scheduled On-Call Surgical Pathologist and Resident:** <https://www.amion.com/Scheduling.shtml>
 - o Alternatively, the specimen may be collected in a container with 10% formalin, labeled with patient identifiers and specimen source, labeled for Cytology, and sent to the Clinical Lab with the corresponding Non-Gynecologic Cytology Request.
 - o For urgent questions or consultations, contact the available cytopathologist, as needed.



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Quick Reference for Cytology Non-Gyn Specimen Collection

Epic Order: LAB3423

Specimen	Fixative	Quantity	Storage	Deliver To
CSF	None	3-5 mL	Refrigerate	Clinical Laboratory—Attn: Hematology (within 30 min)
Body Fluids: Pleural, Pericardial, Ascitic / Peritoneal Fluid	None	150 mL	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Bronchial Brushing	CytoLyt	Brush in 5- 10 mL CytoLyt or Saline	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Bronchial Washing	None	20 mL	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Sputum	CytoLyt	5-10 mL in ThinPrep Non-Gyn vial	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Cyst Aspiration	None	< 150 mL	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Urine / Bladder Washings	None	50-80 mL	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Pelvic Washings	None	150 mL	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681
Anal Pap	CytoLyt	Sample in ThinPrep Non- Gyn vial	Refrigerate	Cytology Lab, M-F, 8:00 am – 5 p.m. AIP-1, Room. 3.000 Tube station 661 or 681



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Gynecological, Pap Test Specimen Collection

Specimen	Pap Test	
1.	Preparation of the patient	Advise the patient to avoid intercourse, vaginal creams, suppositories, medicine and douches two days before the scheduled Pap Test, as these may obscure abnormal cells.
2.	Special timing for collection	The best time to schedule the Pap Test, is two weeks after the first day of the last menstrual period.
3.	Types of collection container and optimal amount of the specimen	ThinPrep Liquid Based Preparation (LBP), collection vial SurePath Liquid Based Preparation (LBP), collection vial Refer to the sections below for each type of LBP.
4.	Types and amounts of fixatives	ThinPrep – Methanol-based LBP, 20 mL vial SurePath – Ethanol-based LBP, 10 mL vial
5.	Special handling and transport	Each Pap Test specimen must be accompanied by a printed out Cervical Vaginal Cytology Request, Epic Order: LAB3422, or a handwritten Cervical/Vaginal Cytology Requisition. Deliver to cytology laboratory (AIP (1), 3rd Floor, Room 3.000, or Clinical Laboratory in the Leprino Building, after hours.
6.	Proper specimen labeling	Record date of collection, anatomic source, site, and laterality of the specimen (Cervical/Endocervical or Vaginal; Right / Left Cervix, if applicable). This information must be on a label on the container itself, NOT on the lid of the container and must match the paper copy of the Epic test order. The use of pre-printed patient labels is preferred, if possible. Specimen vial should be labeled in the presence of the patient, at the time of the procedure.
7.	Appropriate clinical data	Provide pertinent clinical history, including history of malignancy, radiation, chemotherapy, or infectious disease. Information required on a Gyn Cytology Requisition: <ol style="list-style-type: none"> 1. Patient’s full name 2. Patient’s date of birth 3. Medical Records Number (MRN) 4. Specimen collection date / Encounter date 5. Specimen source (Endocervical/Cervical or Vaginal) 6. Pertinent History (Birth control method, LMP, STD) 7. Previous Pap Test / Biopsy/ Treatment (Specify date and results) 8. Screening factors (Normal, High Risk) 9. Visit Type (Routine Screening, Diagnostic)



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		<ol style="list-style-type: none"> 10. Requesting Clinic Location with contact name & pager 11. Requesting Clinician 12. Requested Procedure <ol style="list-style-type: none"> a. Pap Test only b. Cotest - Pap Test with HPV c. Pap Test with Reflex HPV (if ASCUS) d. Include GC/Chlamydia to Above Request e. HPV Testing Only (No Pap Test) f. GC/Chlamydia Testing Only (No Pap Test) 13. Insurance information 14. Referral Number - if required by insurance
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Conventional Gynecological Smears (rare)

Protocol for Endocervical, Ectocervical, Vaginal and combined Smears

- Each slide must be labeled with patient’s name, DOB, or MRN, and the site of the smear.
- Smears must have cells from the squamo-columnar junction to be adequate.
- If a lesion is visible, a slide should be made of this area first.
- Spread cells evenly and quickly over the slide and fix by immersing the slide IMMEDIATELY in 95% ethanol. Cytology spray fixative may be used instead. When spraying, the aerosol can, should be held about twelve (12) inches from the slide to avoid damaging the cells. If a pump spray is used, pump 3-4 times at a distance of 6-8 inches.

Protocol for Vulvar, Labial Smears

- A scrape should be made of the specified area, smeared, and labeled as above.
- Requisition filled out as indicated above.



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Collection of Thin Prep Gynecological Specimens

- Visit <https://www.hologic.com/thinprep> for detailed information on the collection of the ThinPrep liquid-base Gyn specimen, including:
 - ThinPrep Pap Test Collection Video
 - Pap collection Guide Brush/Spatula Broom
 - Pap Collection Guide Rovers Cervex Brush Combi
 - Customer Letter Pap Collection Lubricant
 - Lubricant Compatibility List
 - Lubricant Information Memo
 - Patient Exam Checklist
 - ThinPrep Collection Techniques
- The patient should be tested two weeks after the first day of her last menstrual period, and definitely not when she is menstruating. 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, vaginal creams, vaginal jellies, or douches during the 48 hours before the exam.
- The patient should refrain from intercourse 48 hours prior to the exam.
- For patients without physical or physiological need for lubricant, lukewarm water should be used to warm and lubricate the speculum. Water lubrication has the fewest risks to the quality of the Pap sample collected.
- The use of lubricants with the ThinPrep Pap test is not recommended. However, if a lubricant is necessary, a **carbomer-free lubricant** may be used sparingly on the exterior of the speculum. Consult the list of common lubricant brands for compatibility.

Preferred Lubricant	Manufacturer
PAP TEST Lubricating Jelly	Aseptic Control Products
Surgilube Surgical Lubricant	HR Pharmaceuticals
Compatible Lubricant	Manufacturer
K-Y Jelly (Physician Formula)	Johnson & Johnson
Surgel	Ulmer Pharmacal

- Excess mucus or other discharge if present should be removed before taking the sample. The excess cervical mucus is essentially devoid of cellular material, and when present in the sample vial, may yield a slide unsatisfactory for interpretation.
- Inflammatory exudate from the cervical canal should be removed before taking the sample by placing a dry 2-by-2 inch piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry procto swab or Scopette® swab. 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 specimen.
- The sample should be obtained before the application of acetic acid.



Title: CYTOLOGY SPECIMEN COLLECTION MANUAL AND SUBMISSION GUIDELINES

CAP Checklist: GEN.04115

Document Type: Standard Operating Procedure

Endocervical Brush/Spatula Protocol

- a) Obtain an adequate sampling from the ectocervix using a plastic spatula.
- b) Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.
- c) Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times and pressing the sides of the spatula on the sides of the collection container.
- d) Discard the spatula.
- e) Obtain an adequate sampling from the endocervix using an endocervical brush device.
- f) Insert the brush into the cervix until only the bottom-most fibers are exposed.
- g) Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT TWIRL OR OVER-ROTATE.
- h) Rinse the brush as quickly as possible in the PreservCyt Solution by rotating the device vigorously in the solution 10 times while pushing against the PreservCyt vial wall (paint the side of the container vial with the brush). Press the brush vigorously to the sides of container to further release material.
- i) Discard the brush.
- j) Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- k) Label the vial with the patient's sticker or record the patient's name and ID number on the vial.
- l) Record the patient information and medical history on the cytology requisition form.
- m) Place the vial and requisition in a specimen bag for transport to the laboratory.

Broom-Like Device Protocol

- a) Obtain an adequate sampling from the cervix using a broom-like device.
- b) 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.
- c) Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix.
- d) Push gently, and rotate the broom in a clockwise direction five times.
- e) Rinse the broom as quickly as possible into the PreservCyt® Solution vial by vigorously pushing the broom into the bottom of the vial 10 times, forcing the bristles apart.
- f) Swirl the broom vigorously, to further release material.
- g) Discard the collection broom.
- h) Tighten the cap so that the torque line on the cap passes the torque line on the vial.
- i) Label the vial with the patient's sticker or record the patient's name and ID number on the vial.
- j) Record the patient information and medical history on the cytology requisition form.
- k) Place the vial and requisition in a specimen bag for transport to the laboratory.



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Collection of SurePath Gynecological Specimens

- Visit: <https://www.bd.com/en-us/offerings/capabilities/cervical-cancer-screening/cervical-sample-collection/surepath-liquid-based-pap-test> for detailed information including educational videos:
 - BD SurePath Collection Vial introduction video
 - Rovers Cervex-Brush overview video
 - Rovers Cervex-Brush Combi collection procedure video
- Obtain a sample according to the standard collection procedure provided by the manufacturer of the sampling device(s).
- Using the thumb and forefinger of gloved hand, disconnect the head of the device from the handle and insert the head in the collection vial.
- Discard the handle of the sampling device. Do not touch head of device.
- Cap the vial tightly.
- Label the specimen vial with the patient's sticker.
- Send the specimen containing the head of the sampling device, with appropriate paperwork, to the cytology laboratory.

Ancillary testing from a Liquid-Based Pap Test Vial:

Human Papilloma Virus (HPV) Testing

Gonococcus/Chlamydia Testing

- Collect a gynecologic sample by one of the methods described above.
- Printout a Cervical Vaginal Cytology Request from **Epic, Order: LAB3422**, or fill-out a handwritten Cervical/Vaginal Cytology Requisition.
- Select a testing option:
 - Pap Test only
 - Cotest - Pap Test with HPV
 - Pap Test with Reflex HPV (if ASCUS)
 - Include GC/Chlamydia to Above Request
 - HPV Testing Only (No Pap Test)
 - GC/Chlamydia Testing Only (No Pap Test)



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LABORATORY SPECIMEN REJECTION POLICY:

Specimens submitted to cytology laboratory may be rejected for any of the following reasons:

- Specimen was received from an unknown clinic or facility. Only legally authorized physicians and facilities may submit specimens for processing.
- Specimen was received unlabeled, mislabeled (e.g. specimen and request order form have different patient information) or labeled incompletely missing the required patient unique identifiers (patient's name and date of birth or medical record number).
- Specimen was received Cytology laboratory received empty
- Specimen was received with an attached needle
- Specimen was submitted in a glass container.
- Specimen was submitted in greater than 500 mL volume. Due to limited amount of refrigerated storage space, cytology laboratory will accept up to 500 mL of fluid.
- Sputum was received unfixed. If a concurrent sputum microbiology culture is required, two (2) separate specimens must be obtained and submitted to the laboratory.
- Specimen from a patient suspected to have Creutzfeldt-Jakob Syndrome, (CJD).
- Outside slides submitted for consultation are broken beyond repair.
- Rejected specimens require an incident report to be completed on the UCH patient safety website: RL Solutions. The report must be submitted within 24-hours of discovery of the problem.
- When rejecting an unacceptable specimen, laboratory staff will contact the submitting physician, or designee in the clinic, via secure chat/ phone/ or email to report the identified problem (e.g. specimen collection, transport issue, labeling) so the specimen can be properly re-submitted or recollected.
- All rejected unacceptable specimens are recorded in the "Rejected Specimens" logbook. A copy of the original request form and specimen rejection form are kept in the logbook, including information for the contacted person, date of the notification, and the disposition of the unacceptable specimen (method of returning the specimen to the provider).
- The general supervisor periodically reviews the "Rejected Specimens" logbook to track any trends in recurring errors and/or submitting clinicians needing additional guidance on specimen submission.

SPECIMEN DEFICIENCIES

- For unclear test orders received (using non-specific terms), cytology staff will make an effort contact the submitting provider via secure chat/phone/email to clarify orders.
- The submitting physician or designee must correct the problem in order for cytology laboratory to accept the specimen for processing.
- Examples of specimen deficiencies include, but is not limited to:
 - Specimen was received without corresponding request order for testing (may be printed from Epic)



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- A request order form was received without the corresponding specimen (a request for the specimen may be placed with Clinical Laboratory, for shared samples)
- Specimen received in unsealed container from which the specimen leaked out
- Specimens received without indication of specimen site and laterality with orders indicating different sampling sites. Cytopathology specimens, especially non-gynecologic samples should be labeled on the specimen container with specimen site, laterality, and date of collection.
- Specimen container and/or order missing date of collection
- Specimen deficiencies will be reported via RL Solutions UCH patient safety website.
- Due to the fragile nature of fresh cellular material, cytology laboratory will not attempt to recover for processing fresh specimens that are over 7 days old, or frozen specimens.
- For sub-optimal specimens, exp. specimens received leaking from the primary collection container but sealed in the secondary container (specimen biohazard bag), cytology laboratory will make an effort to recover as much of the specimen as possible. Specimen deficiency will be recorded via “Leaked” Retrieval Flag in CoPath, LIS
- Cytology laboratory personnel will consult with the Technical Director, Cytopathologist, or Cytology Supervisor regarding unacceptable or sub-optimal specimens not covered by the above list. An appropriate comment for the specimen processing will be entered into the laboratory LIS at accessioning.