

NAPLES PATHOLOGY ASSOCIATES CLIENT SERVICES MANUAL

Naples Pathology Associates
1110 Pine Ridge Rd, Unit #306
Naples, FL 34108

rev 08/2024





TABLE OF CONTENTS

- 1- Test Orders Accepted at NPA
- 2- Introduction to Naples Pathology Associates
 - 2-1 Specimen Submission Requirements
 - 2-2 Specimen Pickup
 - Order Supplies, Requisitions or Forms
 - Specimen Shipping Information
 - Specimen Pick Up Log/Courier Manifest
 - NPA Contact Information
 - Request an email encryption link
- 3- Specimen Submission Requirements Chart
 - 3-1 Histology
 - 3-3 Cytology
 - 3-6 Advanced Studies
- 4- Specimen Collection Procedures
 - 4-1 Routine Histology (tissue specimens)
 - Breast and Axilla Submission Instructions
 - 4-2 Frozen Section
 - Lymphoma Protocol
 - Direct Immunofluorescence (DIF)
 - Gout Crystal Examination
 - 4-3 Muscle Biopsy
 - Corneal Donor Tissue
 - 4-4 Non-Gynecologic Cytology
 - Fine Needle Aspiration (FNA)
 - Direct Smear
 - 4-5 CSF (Cerebral Spinal Fluid) Cytology
 - Pleural or Ascitic Fluid
 - Sputum
 - Urine cytology
 - 4-6 Gynecologic Cytology
 - 4-7 ThinPrep® Pap Test Specimen Collection
 - 4-9 ThinPrep® Lubricant Compatibility List
 - 4-10 ThinPrep® collection – Brush/spatula device protocol
 - 4-11 Rovers® Cervex-Brush® Combi device
 - 4-12 ThinPrep® collection - Broom device protocol
 - 4-13 Conventional Pap Smear
- 5- Specimen Collection
 - OneSwab
 - UroSwab
 - NasoSwab
- 6- Test Menus
 - 6-1 OneSwab Test Menu
 - 6-2 UroSwab Test Menu
 - 6-3 NasoSwab Test Menu



Test Orders Accepted at NPA

Histology

Routine H&E (Permanent Section)/Biopsy
 Frozen Section
 Lymphoma Protocol
 Direct Immunofluorescence (DIF)
 Gout Crystal Examination
 Corneal Donor Tissue
 BIA-ALCL Protocol
 Gross Examination only (stone, foreign body)

Advanced Studies

Afirma
 B-Cell
 Biotheranostics CancerTYPE ID
 BRAF
 Castle Biosciences (DiffDx, DecisionDX)
 Melanoma, SCC, Tissue Cypher)
 Consultation on Outside Case
 FISH-Test Other
 Flow Cytometry
 Foundation One
 Her2 Fish
 Her2 IHC
 HNPCC / Lynch Syndrome
 HPV Genotyping on Tissue
 IHC'S
 Mammaprint
 Microsatellite Instability (MSI)
 Mismatch Repair Gene (MMR)
 Oncotype Dx
 Osteomyelitis Protocol
 Solicited Consultation
 Special Stains
 Stone Analysis
 T-Cell

Non-Gynecologic Cytology

Fine Needle Aspiration (FNA)
 Direct Smear
 Cerebral Spinal Fluid (CSF)
 Pleural or Ascitic Fluid
 Sputum
 Urine Cytology

Gynecologic Cytology

Conventional Pap Smear
 Liquid-based Pap Test – ThinPrep®
 Molecular Testing for Infectious Disease
 HPV Screen
 HPV Genotyping
 Chlamydia
 Gonorrhea
 Trichomonas
 Herpes Simplex Virus (HSV)
 *OneSwab – Gynecologic

Molecular Testing for Infectious Disease (Other)

*Nasoswab
 *OneSwab – Other
 Intestinal Pathogen Panel
 Skin & Soft Tissue Infectious
 *UroSwab

*See individual test menu breakdowns at end



CLIENT SERVICES MANUAL

The purpose of this manual is to provide our clients with guidelines for the submission of specimens to the Naples Pathology Associates laboratory (NPA). Proper identification and appropriate collection of specimens is critical to good patient care and accuracy of results. Please call the lab at 239-263-1777 if you have questions about how to submit a specimen.

SUBMISSION REQUIREMENTS FOR ALL SPECIMENS

Please follow the instructions below to avoid unnecessary delays in processing the specimen:

1. **Specimen Labeling:** Every specimen container must be labeled with at least two patient identifiers. Preferred identifiers: Patient name and DOB. A requisition label containing the unique requisition number is also acceptable if the patient's name is written on the label.
2. **NPA requisition:** ***Patient identifying information on the requisition must match the information on the specimen container.*** The site listed on the specimen container must match the specimen site listed on the requisition. Make sure to enter the ICD-10 code and date of specimen collection. Clearly mark the test(s) requested.
In addition:
 - For breast specimen: Enter time the tissue was removed from the patient and time tissue was placed in formalin.
 - For ThinPrep specimens: Indicate on the NPA requisition: Pap or No Pap.
3. **Clinical History:** Pertinent clinical history is very important for the pathologist's interpretation of the specimen and final ICD-10 classification.
4. **Demographic and Insurance Information:** Include patient demographics and insurance information with requisition or write the information on the NPA requisition.
5. **Courtesy Copy of NPA Report:** If a courtesy copy of the final NPA report is requested to be sent to an outside physician, the following information must be provided for the physician:
 - Full name (First and Last)
 - NPI Number and Credentials
 - Location Name
 - Location Address
 - Office Phone Number
 - Office Fax Number

NOTE: If the above information is not provided NPA cannot process the courtesy copy request.

6. **Place specimen in a biohazard bag** with the paperwork in the outside pocket. All specimens on the same patient can be placed in the same bag.

REQUEST FOR SPECIMEN PICK UP**FROZEN SECTION or other immediate pickup:**

1. **Please call NPA at 239-263-1777** to add the procedure to our frozen schedule (preferably at least 1 day in advance).
2. **To coordinate transportation of the specimen, please call Mail Station Courier at 239-436-3910 (preferably at least 1 day in advance)** - Inform the dispatcher that the specimen will be a frozen section or fresh specimen. Depending on your location, Mail Station will provide day-of specimen pick up call-in instructions.

ROUTINE: please call 239-263-1777 (NPA) – Request a routine specimen pickup. State if the specimen will be in a lockbox instead of in the office. Naples Pathology sends a courier to pick up specimens from our client offices Monday – Friday during business hours.

SUPPLIES, REQUISITIONS, AND FORMS

Laboratory supplies can be ordered by phone or by faxing a Laboratory Supply Request Form to NPA. The Laboratory Supply Form, requisitions, and other forms are available on our website, www.naplespathology.com, in the Client Resources section.

SPECIMEN SHIPPING VIA UPS

NPA provides shipping boxes and pre-paid UPS Clinical Pack bags for offices outside of our courier pick up area. Place the bagged specimens and reqs in an NPA shipping box, and then put the shipping box in the pre-addressed Clinical Pak. Our mailing address is: Naples Pathology Associates, 1110 Pine Ridge Rd, Unit 306, Naples, FL 34108.

SPECIMEN PICK UP LOG / COURIER MANIFEST (available upon request)

Records the patient's name and number of specimens for each patient that is being sent to NPA. One copy of the manifest stays at office, the other accompanies the specimens to NPA.

CONTACT US

Emails Containing Patient Information Must Be Encrypted: If you wish to email patient information to NPA and your office does not have encryption available, NPA can send you an encryption link to upload the file.

<p>LABORATORY *For Technical Questions, Patient Results, & Supply Requests* 239-263-1777 Phone 239-263-6983 Fax</p> <p>*For Specimen Pick-Up* 239-263-1777 Routine Specimen Pick Up 239-436-3910 Frozen Section/STAT Pickup: Request a Frozen pickup (see full instructions above)</p> <p>*For Client Services & Billing Related Questions* Director of Sales and Marketing: Regis Bernardi 716-913-8556 rbernardi@naplespathology.com</p>	<p>BILLING OFFICE *Customer Service (8:00am-4:30pm Mon-Fri EST)* 866-512-6639 Phone 954-656-6439 Fax</p> <p>*Online Bill Pay* www.mrapay.com Mail payments to: Naples Pathology Associates P.O. Box 166324 Miami FL 33116</p>
---	---

SPECIMEN SUBMISSION CHART
Naples Pathology Associates

For specimen collection instructions, see Client Services Manual

NPA routine pickup: 239-263-1777 Immediate pickup (e.g. frozen section, lymphoma): 239-436-3910

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
HISTOLOGY	ROUTINE HISTOLOGY (Permanent Section) <i>TAT: 1 business day Breast or fatty tissue: 2 days Bone: possibly > 2 days</i>	Biopsy	Formalin	Room Temp / Routine pick up <i>(Next day pick up OK)</i>	
		Excision	Formalin	Room Temp / Routine pick up <i>(Next day pick up OK)</i>	<i>Provide previous NPA biopsy accession number, or a complete copy of the outside pathology report</i>
		BREAST TISSUE, Biopsy or Resection	Formalin – <u>Enter tissue removal and fixation times on requisition</u>	Room Temp / Routine same day pick up	<i>Provide previous NPA biopsy accession number or a complete copy of outside pathology report.</i>
	FROZEN SECTION <i>TAT: Approx 30 min after receipt</i>	Fresh Tissue (no formalin)	Saline or saline-soaked gauze	Room Temp / Call NPA & Mail Station for frozen specimen schedule & coordination of specimen pick up	
	LYMPHOMA PROTOCOL <i>TAT: 1-2 days</i>	Lymph node (LN) fresh specimen	Saline or saline-soaked gauze; RPMI for LN or LN aspirate also acceptable	Room Temp /Refrigerate if in RPMI Call for immediate pick up	
BIA-ALCL (Breast Implant Associated Anaplastic Large Cell Lymphoma) <i>TAT-1-2 days</i>	Capsule tissue-fresh; Fluid, if available, in RPMI	Submit using Lymphoma Protocol, write "R/O BIA-ALCL" on req	Room Temp /Refrigerate if in RPMI Call for immediate pick up		

SPECIMEN SUBMISSION CHART
Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
HISTOLOGY	<p align="center">CORNEAL DONOR TISSUE</p> <p align="center"><i>TAT: 1-2 days</i></p>	<p>Corneal donor tissue / Patient corneal button</p>	<p>Formalin</p> <p>1. Submit a requisition with the patient (transplant recipient) demographic information and insurance information. For each specimen letter on the requisition, specify whether it is Donor tissue or Patient corneal button.</p> <p>2. Label donor specimen as "DONOR" tissue and with patient name and DOB. Label patient's removed tissue as "PATIENT" tissue, with name and DOB.</p>	<p>Room Temp / Routine Pick up</p>	<p>If available, add donor cornea serial number in the clinical description.</p>
	<p align="center">DIF (Direct Immunofluorescence)</p> <p align="center"><i>TAT: 7 days</i></p>	<p>Biopsy</p>	<p><u>Prefer 2 specimens :</u> Peri-lesional – Michel's solution Lesional – Formalin</p>	<p>Room Temp or Refrigerated; Routine pick up</p>	

SPECIMEN SUBMISSION CHART

Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
CYTOLOGY	GYN CYTOLOGY (Pap Test only)	Cervical, endocervical, vaginal Liquid -based Pap Test (ThinPrep®)	ThinPrep	Room Temp / Routine pickup	<i>HPV HR or HPV genotyping, chlamydia, gonorrhea, trichomonas, or HSV can be added to a ThinPrep pap specimen for up to 42 days.</i> <i>Tests other than the above can be added if specimen received within 9 days of collection.</i>
		Conventional	Specimen smear on labeled glass slide, preserved with cytology spray fixative	Room Temp / Routine pickup	<i>Conventional pap smears are a suboptimal method to evaluate cervical and/or Gyn cytology specimens. The ThinPrep Liquid Based Pap Test is the optimal and preferred method.</i>
	TAT: 3-5 days				
	THINPREP PAP with HPV HR, HPV genotyping, Chlamydia, Gonorrhea, Trichomonas, HSV	Cervical, vaginal, endocervical	ThinPrep	Room Temp / Routine pickup	<i>HPV, chlamydia, gonorrhea, trichomonas, or HSV can be added for up to 42 days to a ThinPrep specimen</i>
TAT: 5-7 days					
THINPREP PAP WITH ONESWAB® for Infectious Disease Testing	Urogenital	ThinPrep (for Pap) + OneSwab (with swab inside)	Room Temp / Routine pickup. Same day pickup preferable for TAT.	<i>Prefer receipt of OneSwab within 5 days, however can attempt testing as long as the specimen DNA is intact.</i> <i>Additional tests can be ordered for up to 30 days after stabilization at reference lab</i>	
TAT: 5-7 days					

SPECIMEN SUBMISSION CHART
Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
CYTOLOGY	INFECTIOUS DISEASE TESTING ONLY (NO PAP) <i>(Molecular Testing by PCR)</i>	Skin	OneSwab <i>(with swab submitted)</i>	Room Temp / Routine same day pickup preferable for TAT.	<i>Prefer receipt of OneSwab within 5 days, however can attempt testing as long as the specimen DNA is intact.</i> <i>ThinPrep must be received at reference lab within 9 days.</i> <i>Additional tests can be ordered for up to 30 days after stabilization at reference lab</i>
		Urogenital	OneSwab (preferred); or ThinPrep with "No Pap" marked on requisition Note: Use OneSwab for AV Panel	Room Temp / Routine same day pickup preferable for TAT.	
		HPV screen or HPV genotyping no initial screen	Use ThinPrep if no other tests ordered. Otherwise use OneSwab <i>(submitted with swab)</i>	Room Temp / Routine same day pickup <u>REQUIRED</u> if OneSwab	
		Urine	UroSwab <i>(submitted with swab)</i>	Room Temp / Routine same day pickup preferable for TAT.	
		Respiratory	NasoSwab <i>(submitted with swab)</i>	Room Temp / Routine same day pickup preferable for TAT.	
	TAT: 3-5 days				<i>Specimen viable for 5 days in UroSwab or NasoSwab</i> <i>Additional tests can be ordered for up to 30 days once stabilized at reference lab</i>

SPECIMEN SUBMISSION CHART
Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
CYTOLOGY	NON-GYN CYTOLOGY TAT: 1 day	Fine needle aspirate (FNA) -or- Cyst contents aspirate	First Pass: 2 direct smears (1 fixed, 1 air dried). Remaining fluid from first pass in CytoLyt. Second, third and any additional passes should be submitted in CytoLyt; RPMI if flow cytometry is ordered	CytoLyt: Room Temp / Routine same day/next day pickup. RPMI: Refrigerate / Same day pickup	<i>Specimen for flow cytometry must be received same day as collection</i> <i>Specimen in CytoLyt for cytology is stable up to 8 days</i>
			Fresh specimen- <u>remove needle</u> before transport to NPA	Refrigerate / Call for immediate pickup	
		Lymph node FNA	CytoLyt- cytology only (RPMI is acceptable) Flow cytometry - RPMI	CytoLyt: Room Temp / Routine same day/next day pickup. RPMI: Refrigerate / Same day pickup	<i>Specimen for flow cytometry must be received same day as collection</i> <i>Specimen in CytoLyt for cytology only is stable up to 8 days</i>
		Body Fluid (CSF, pleural, synovial)	Fresh; or RPMI if flow ordered	Refrigerate / Routine same day pickup	<i>CSF minimum volume for cytology - 1 ml; additional 1 ml minimum required for flow</i>
		Sputum	Clean, dry container, no fixative	REFRIGERATE / Routine same day pickup	
		Voided urine or bladder wash	Fresh	Refrigerate / Routine same day pickup	<i>Cytology, recommended vol: 30 ml</i>

SPECIMEN SUBMISSION CHART

Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
ADVANCED STUDIES	AFIRMA <i>TAT: 14 days</i>	Thyroid FNA	Submit Afirma Collection Tube with CytoLyt FNA specimen	Room Temp if same day pickup / Routine pickup <i>(Refrigerate if next day pickup)</i>	
	BIOETHERANOSTICS CancerTYPE ID <i>TAT: 7 days</i>	Cancer of unknown origin	Clinician can write an order to NPA to initiate the test -OR- Clinician can order directly from BioTher. BioTher then sends a request for tissue to NPA.	NA	
	CASTLE DecisionDx-Melanoma <i>TAT: 9-14 days</i>	Melanoma diagnosis	Clinician orders the test directly from Castle BioSci. Castle sends request for tissue to NPA.	NA	<i>Option for standing order available</i>
	CASTLE TissueCypher Assay <i>TAT: 9-14 days</i>	Barrett's Esophagus	Clinician orders the test directly from Castle BioSci. Castle sends request for tissue to NPA.	N/A	<i>Option for standing order available</i>
	FLOW CYTOMETRY <i>TAT: 1 day</i>	CSF, Pleural Fluid	Submit fresh or in RPMI	Refrigerate CSF-call for immediate pickup	<i>Specimen for flow must be received on the same day as collection.</i>
		Peripheral blood	Lavender top tube	Refrigerate / Routine pickup	<i>Minimum volume 2 ml; more if very low WBC</i>
		Lymph node/ Tissue, BIA-ALCL	Submit fresh or in RPMI	Room temp/Refrigerate if in RPMI Call for immediate pickup	

SPECIMEN SUBMISSION CHART
Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
ADVANCED STUDIES	FOUNDATION ONE		NPA must receive a written request from clinician*	NA	* Strongly recommend that the physician's office call pt insurance before ordering to confirm that patient's policy will cover the test.
	GOUT CRYSTALS TAT: 1 day	Tissue	<u>Do not submit in formalin or saline:</u> Submit in empty sterile container -or- 100% alcohol	Room Temp / Routine same day pickup	
		Synovial Fluid	Remove needle and transport in the syringe to NPA	Room Temp / Routine same day pickup	
	HPV GENOTYPING ON TISSUE TAT: 5 days	Head and Neck (oropharyngeal) Cancer	Written order by clinician on a block already at NPA		Evidence of HPV infection needed prior to sendout for HPV genotyping.
		Condyloma Accuminatum	Written order by clinician on a block already at NPA		No evidence of HPV infection needed prior to sendout
	IRON, QUANTITATIVE TAT: 3-9 days	Liver biopsy	Formalin	Room temp / Routine pickup	
	MAMMAPRINT TAT: 5-10days	Breast cancer	Written order by clinician to NPA -or- Clinician orders directly from Agendia & Agendia will request tissue from NPA	NA	
	MSI - Microsatellite Instability -or- MMR - Mismatch Repair gene -or- HNPCC / Lynch Syndrome TAT: 5-7 days	MMR by IHC: Colon or rectal tumor preferred MSI by PCR: colon tumor preferred + peripheral blood in EDTA (lav top); *can be performed on adenomatous polyp	Formalin	Room Temp/ Routine same day pickup	* Note: Negative result on an adenomatous polyp does not rule out Lynch Syndrome

SPECIMEN SUBMISSION CHART

Naples Pathology Associates

	TEST	SPECIMEN TYPE	TRANSPORT MEDIUM / ORDER METHOD	SPECIMEN STORAGE/ PICKUP STATUS	ADDITIONAL COMMENTS
ADVANCED STUDIES	ONCOTYPE DX <i>TAT: 10 days</i>	Breast cancer	Written order by clinician to NPA - OR - Clinician orders test directly from Genomic Health. Genomic Health will request tissue from NPA.	NA	
	OSTEOMYELITIS PROTOCOL <i>TAT: >1 day</i>	Bone	Bone specimen submitted in formalin to NPA. Surgery center to send separate specimen to micro lab for culture	Room Temp / Routine pickup	
	REQUEST FOR SECOND OPINION ON AN NPA DIAGNOSIS <i>TAT: 7-14 days</i>		Written request from clinician for a second opinion on an NPA diagnosis. Send patient insurance information.	NA	
	CONSULT REQUEST ON A CASE DIAGNOSED ELSEWHERE <i>TAT: 3-5 days</i>	Glass slides (original or recuts), billing, and original pathology report; blocks if indicated	Clinician requests an outside facility to send case slides and pathology report to NPA for review.	NA	<i>Slides must be sent to the NPA laboratory regardless if inpatient or outpatient.</i> <i>e.g. Clinician wants NPA to review a case to confirm diagnosis before treatment.</i>
	STONE ANALYSIS <i>TAT: 7 days</i>	Kidney stone, Gall stone	Transport in a clean dry container	Room Temp / Routine pickup	

KEY: NA - Not applicable Room Temp / RT - Room temperature Refrigerate - Refrigerate until pickup Soln - Solution TAT - Turn around time

SPECIMEN COLLECTION PROCEDURES

Naples Pathology Associates

ANATOMIC PATHOLOGY (HISTOLOGY) SPECIMEN COLLECTION

ROUTINE HISTOLOGY (e.g. BIOPSY or EXCISION)

Label the specimen container with the specimen site and at least two (2) patient identifiers, preferably patient's full name and DOB.

Tissue should be placed in 10% neutral buffered formalin fixative as soon as possible after removal from the patient in order to preserve the tissue architecture and cellular components. Ideally, the amount of formalin should be 15-20 times that of the volume of the specimen for proper fixation (i.e. - a ratio of 20:1).

For Excisions or Resections:

- Orientation of the specimen must be clearly indicated on the specimen and defined on the requisition.
- Refer to the previous NPA biopsy accession number or send a complete copy of the outside pathology report.

Specimen Viability:

Specimens that are placed in an adequate volume of formalin are preserved indefinitely at room temperature.

BREAST AND AXILLA SUBMISSION INSTRUCTIONS

Specimens for Frozen Section or Lymphoma need to be submitted fresh. All other breast and axilla specimens can be submitted in formalin.

The following instructions were developed for handling breast and axilla tissue to keep patient specimens within fixation parameters for predictive marker testing.

Surgery Center Instructions

1. Place non-frozen, non-lymphoma breast or axilla specimens into formalin as soon as possible. Be sure to place the specimen in a large enough container. There should be a 1:20 ratio of tissue to formalin by volume in the container for proper fixation to occur.
2. Record the time the specimen was removed from patient and the time the specimen was placed in formalin on the requisition.

Radiology Instructions (if applicable)

1. Personal Protective Equipment (PPE) is needed when handling specimens in formalin. Minimally, gloves should be worn. Nitrile gloves, eye protection (i.e. glasses, goggles, guard &/or shield) and a barrier garment (i.e. lab coat, apron, protective arm sleeves) are recommended.
2. Place specimen container on a formalin neutralizing pad.
3. Open specimen container, pick up specimen and allow formalin to drip into container.
4. Place the specimen on the neutralizing pad, replace the specimen container lid, and pat the specimen with paper towels to slightly dry.
5. Record the time the specimen was taken out of formalin.

6. Perform imaging.
7. Return specimen to specimen container with formalin immediately after imaging, to limit the time out of formalin.
8. Record the time the specimen was returned to formalin on the requisition.

FROZEN SECTION

Send fresh tissue for frozen section examination in saline or wrapped in saline-soaked gauze. Please call NPA at **239-263-1777** to add the procedure to our frozen schedule (preferably at least 1 day in advance). To coordinate transportation of the specimen, please call our courier service, Mail Station Courier, at **239-436-3910**. Inform the dispatcher that the specimen is for frozen section. Depending on your location, Mail Station will provide day-of specimen pickup call-in instructions.

LYMPHOMA PROTOCOL

For lymphoma protocol, send fresh tissue in saline or wrapped in saline-soaked gauze. Call our courier service (Mail Station Courier, **239-436-3910**) for immediate pickup. Upon receipt, a touch prep of the tissue will be performed to determine if flow cytometry is indicated. If so, a representative portion of the specimen, or if necessary the entire specimen, will be submitted for flow cytometry. Any remaining tissue, if present, will be processed for microscopic examination (permanent section). "Lymphoma Protocol" should be written on the requisition.

DIF (Direct Immunofluorescence)

The preferred method for Direct Immunofluorescence studies is to submit a lesional specimen in formalin and a peri-lesional specimen in Michel's solution for DIF testing. If Michel's solution is not available, send the DIF specimen in saline or saline-soaked gauze. Routine daily pickup is adequate.

GOUT CRYSTAL EXAMINATION

TISSUE

Submit fresh in a clean, empty container or in 100% alcohol. No saline or formalin.
Store specimen at room temperature, call NPA for routine same day pickup.

SYNOVIAL FLUID

Specimen can be submitted in the syringe (with needle removed) or in a clean, empty container.
Store at room temperature and call NPA for routine same day pickup.

MUSCLE BIOPSY

NPA does not accept these specimens. University of Florida Department of Pathology may accept the specimen. These instructions are provided as a reference for your convenience:

1. Prior to the procedure, contact the UF Health Pathology Laboratories Client Services Department (888-375-5227) to request a muscle biopsy kit and specimen submission instructions.
2. Ship the specimen DIRECTLY to the University of Florida (i.e., do not send it to NPA). Follow the kit directions for packing and shipping in the provided pre-paid Sat delivery FedEx envelope.
3. Call UF Client services before shipping the specimen (888-375-5227)

CORNEAL DONOR TISSUE

1. Submit a requisition with the patient (transplant recipient) demographic information and insurance information. For each specimen letter on the requisition, specify whether it is Donor tissue or Patient corneal button
2. Label donor specimen as "DONOR" tissue and with patient name and DOB
Label patient's removed tissue as PATIENT tissue, with name and DOB

NON-GYN CYTOLOGY SPECIMEN COLLECTION

(Fine Needle Aspirates, CSF, Fluids)

FINE NEEDLE ASPIRATE (FNA)

SPECIMEN REQUIREMENT:

Adequate cellular material must be for obtained for examination. Cellularity depends on the specimen site and characteristics of the lesion being aspirated. Preparation of direct smears is at the discretion of the treating physician.

SUPPLIES

- 3, 5, 10 or 20 mL syringe as appropriate
- 22 to 25 gauge needle of appropriate length
- CytoLyt solution

FNA COLLECTION:

1. Label the CytoLyt container with patient name, DOB and specimen site.
2. Procure the specimen.
3. Gently expel the FNA specimen into the CytoLyt solution, and then rinse out the syringe barrel by pulling some CytoLyt into the syringe and gently expelling back into the CytoLyt container.
4. If a core biopsy is also collected, it can be submitted either in a separate formalin container, or in the same CytoLyt container as the FNA sample.
5. Call for routine same day pick up. The specimen can remain at room temperature until transported to the lab.

DIRECT SMEAR PREPARATION

SUPPLIES:

- Frosted end glass slides
- 3% glacial acetic acid alcohol solution container for slide transport.

SMEAR PREPARATION:

1. Slides should be labeled with the patient's name and site prior to collection.
2. For a direct aspiration, apply the fluid in a thin layer across the labeled slide and immediately immerse in the glacial acetic acid alcohol.
3. For a fine needle aspiration, expel some of the syringe contents onto the slide and smear it on the slide. The simplest way is to lay a second slide on top of the first, allowing the aspirated material to provide surface tension between the two slides. Gently and quickly pull the two slides apart in a horizontal motion to distribute the material in a thin film over both slides.
4. Immediately immerse the slides into the container of 3% glacial acetic acid alcohol fixative for fixation and transport. *(cont'd next page)*
5. If material remains in the hub of the needles, flush it into the CytoLyt container. Refrigerate until transport.

CSF (CEREBRAL SPINAL FLUID) CYTOLOGY

CSF is sent fresh to NPA without fixative. Since the cellularity of CSF is usually very low, please provide as much as clinically feasible, ideally 3 – 4 ml. Submit specimen in a labeled vial and refrigerate until pickup. Indicate if flow cytometry is to be performed in addition to the cytology.

Keep refrigerated. Call for immediate pickup.

Please Note: NPA does not perform cell counts or cultures on CSF

PLEURAL OR ASCITIC FLUID CYTOLOGY

Body cavity fluid is sent fresh to NPA. Label the container with the patient's name and DOB. Indicate on the req if flow cytometry is requested as well.

Keep refrigerated. Call for routine same day pickup.

Please Note: NPA does not perform cell counts or cultures on fluids

SPUTUM CYTOLOGY SPECIMEN COLLECTION

First morning, deep cough sputum into a clean container is preferred.
Keep refrigerated. Call for routine same day pickup

Note: NPA does not perform cultures.

URINE CYTOLOGY

CYTOLOGY ONLY: Submit 20-30 ml freshly voided urine or bladder wash. For cytology only, no preservative is necessary. Keep refrigerated until pickup.

GYNECOLOGIC CYTOLOGY (PAP TEST)

Limitations of the Procedure

A Pap test is intended for screening, and as is the case for any screening test there is an inherent false negative rate. The reported incidence of false negative results for Pap testing ranges from 10-30%. For this reason repeatedly negative Pap tests performed at regular intervals are more accurate than a single, isolated, apparently normal Pap test. Many factors can contribute to a false negative result including sampling error, blood or inflammatory cells obscuring abnormal cells, or an inadequate volume of cells collected (QNS).

A QNS (quantity not sufficient) is reported when there are insufficient cells for accurate diagnosis. This could be due to pre-analytic sampling error, i.e. an insufficient number of cells collected from the cervix. For example, if the device to collect the cells from the cervix is over-rotated, some of the cells can get rubbed off and lost to collection; blood cells seen on a pap slide may be indicative of over-rotation irritation.

A QNS report could also be due to use of a lubricant that is incompatible with the ThinPrep test, or use of a pre-lubed speculum, that gums up the filter collecting the cells from the specimen container, causing it to cease collection prematurely. A list of approved lubricants is available below.

LIQUID-BASED PAP TEST COLLECTION (ThinPrep®)

SPECIMEN VIABILITY:

An appropriately collected ThinPrep specimen is viable for up to 6 weeks (42 days) at room temperature.

ANCILLARY TESTING

Ancillary testing for on a previously collected ThinPrep Pap specimen is available for up to 42 days on the following tests:

- HPV HR
 - HPV 16, 18/45 Genotyping
 - Chlamydia
 - Gonorrhea
 - Trichomonas
 - HSV-1, HSV-2
- Infectious disease testing other than the above can be added to a ThinPrep for up to 9 days after collection.

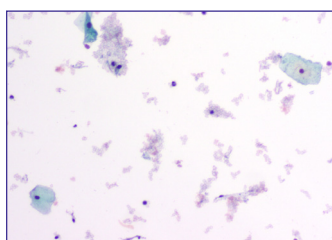
See below for:

- ThinPrep® Pap Test Specimen Collection
- ThinPrep® Lubricant Compatibility List
- ThinPrep® Collection – Spatula/Brush device protocol
- ThinPrep® Collection - Broom device protocol

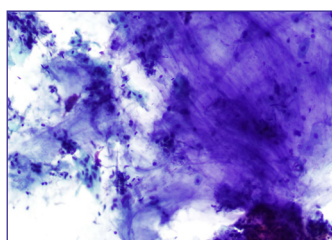
ThinPrep® Pap Test: specimen collection

Training bulletin

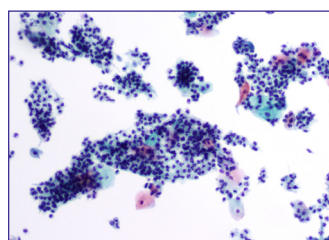
The detection of cervical cancer and its precursors as well as other gynecologic abnormalities is the primary purpose of obtaining a cervical cell sample. The following guidelines are referenced from CLSI Document GP15-A3¹ and are recommended in the collection process for obtaining a ThinPrep® Pap Test (TPPT) specimen. In general, the guidelines state that it is important to obtain a specimen that is not obscured by blood, mucus, inflammatory exudate or lubricant.



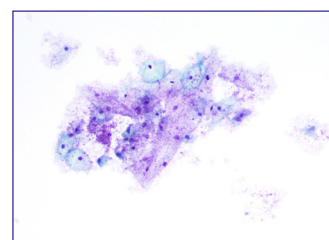
Unsatisfactory specimen
obscured by blood



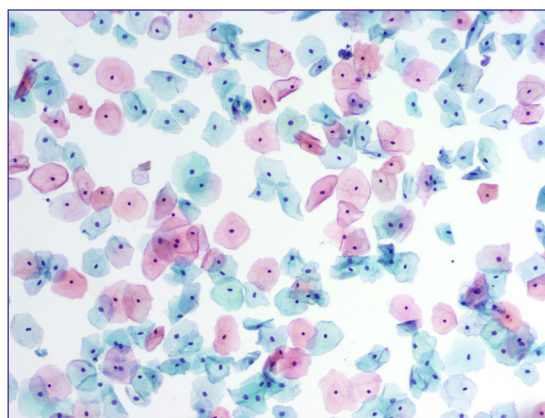
Unsatisfactory specimen
obscured by mucus



Unsatisfactory specimen
obscured by inflammation



Unsatisfactory specimen
obscured by lubricant



Satisfactory ThinPrep Pap Test specimen

Patient information

- The patient should be tested two weeks after the first day of her last menstrual period, and definitely not when she is menstruating.
Even though the TPPT reduces obscuring blood, clinical studies have demonstrated that excessive amounts of blood may still compromise the test and possibly lead to an unsatisfactory result.²
- 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 exam³.

ThinPrep[®] Pap Test: specimen collection

Training bulletin

Specimen collection preparation

- **Prepare the speculum.**

For patients without physical or physiological need for lubricant, use lukewarm water to warm and lubricate the speculum.

Water lubrication has the fewest risks to the quality of the Pap sample collected.⁴

When necessary, sparingly apply **carbomer-free** lubricant on the exterior of the speculum blades.

If lubricant is necessary due to patient discomfort or the use of a plastic speculum, sparingly apply a thin film of **carbomer-free** lubricant on the speculum's surface, avoiding the tip.

Do not use an excessive amount of lubricant jelly to lubricate the speculum.

Hologic[®] evaluated a variety of popular lubricants and found those containing carbomer or carbopol polymers (thickening agents) may interfere with obtaining a representative cervical sample or cause artifact in the alcohol-based transport medium.⁴ Hologic[®] recognizes the varying availability of different types of lubricants and recommends that, if used, any lubricant should be applied sparingly.

- **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-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.**

Specimen collection

Refer to Hologic's ThinPrep Pap Test Quick Reference Guides, Part No.s DS-05867-001 and DS-05720-001, and ThinPrep[®] Pap Test Specimen Collection Protocol Video³.

Collection device rinsing

Refer to Hologic's ThinPrep Pap Test Quick Reference Guides, Part No.s DS-05867-001 and DS-05720-001, and ThinPrep[®] Pap Test Specimen Collection Protocol Video³

hologic.com | diagnostic.solutions@hologic.com | +1.781.999.7300

1. Papanicolaou Technique Approved Guidelines (CLSI Document GP15-A3) **2.** Lee et al. Comparison of Conventional Papanicolaou Smears and a Fluid-Based, Thin-Layer System for Cervical Cancer Screening. *Ob Gyn* 1997; 90: 278-284. **3.** Saslow D, et al. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. *CA Cancer J Clin* 2002;52:342-62. **4.** Lubricant Use during Pap Sample Collection, Part No. MISC-00579 Rev. 006 **5.** Specimen Collection Protocol Video, Part No. MOV-00052-001 Rev. 002.

MISC-02720-001 Rev. 001 ©2015 Hologic, Inc. All rights reserved. Hologic, Science of Sure, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to **diagnostic.solutions@hologic.com**.

ThinPrep[®]
P A P T E S T

ThinPrep® Pap Test Lubricant Compatibility List

The use of lubricants with the ThinPrep Pap test is not recommended. However, if a lubricant is necessary the following lubricant brands are validated by Hologic, Inc. for use with the ThinPrep Pap test when used as instructed.^{1*}

	Lubricant	Manufacturer	Contains Carbomer?
Preferred†	✓ Pap Test Lubricating Jelly	Aseptic Control Products	No
	✓ Surgilube Surgical Lubricant	HR Pharmaceuticals	No
	✓ CerviLube Lubricant	Sion Brands	No

	Lubricant	Manufacturer
Not Approved‡	✗ Aquagel Lubricating Gel	Parker Laboratories, Inc.
	✗ Astroglide (Physician Formula)	BioFilm, Inc.
	✗ Astroglide (Personal Formula)	BioFilm, Inc.
	✗ HR Lubricating Jelly	HR Pharmaceuticals, Inc.
	✗ Lubricating Gel	Henry Schein
	✗ Lubricating Jelly	McKesson
	✗ MediChoice Lubricating Jelly	Owens & Minor
	✗ PDI Lubricating Jelly I and II	PDI Healthcare
	✗ PSS Select (also known as Triad)	PSS World Medical, Inc.
	✗ Rite Aid Pharmacy Lubricating Gel	Rite Aid Corp.
	✗ Allegiance	Medline Industries, Inc. (formerly Triad/H&P Industries)
	✗ Aplicare Sterile Lubricating Jelly (also known as Operand Lubricating Jelly)	Aplicare Inc./Clorox Professional
	✗ Aqua Lube Personal Lubricant	Mayer Laboratories
	✗ DynaLube Lubricating Jelly	Dynarex Corporation
	✗ E-Z Lubricating Jelly	Chester Packaging
	✗ IMCO Lubricating Jelly	Medline Industries, Inc. (formerly Triad/H&P Industries)
	✗ Lubricating Jelly	DUKAL Corporation
	✗ Lubri-Gel	Sheffield Pharmaceuticals
	✗ Maxilube Personal Lubricant	Mission Pharmacal
	✗ NovaPlus	Medline Industries, Inc. (formerly Triad/H&P Industries)
✗ Pro Advantage Lubricating Jelly	National Distribution & Contracting, Inc.	
✗ ReliaMed Lubricating Jelly	ReliaMed	

*The use of lubricants (including personal lubricants) should be avoided prior to specimen collection. Lubricants can adhere to the filter membrane and may cause poor cell transfer to the slide. If its use is unavoidable, the lubricant should be used in minimum amounts.

†Validated: Lubricants have multiple lots run through periodic testing to ensure compatibility.

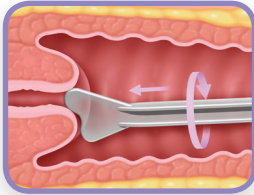
‡Not approved: Lubricants have either been tested and deemed incompatible or excluded from testing because they contain carbomer.

Reference: 1. ThinPrep 2000 System Operator's Manual. MAN-02585-001. Marlborough, MA: Hologic, Inc.; 2017

MISC-04037-001 Rev. 003 © 2020 Hologic, Inc. All rights reserved. Hologic, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks, registered trademarks, and product names are the property of their respective owners. The content in this piece is for information purposes only and is not intended to be medical advice. Information is intended for medical professionals in the U.S. and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to diagnostic.solutions@hologic.com.

Protocol: endocervical brush/spatula

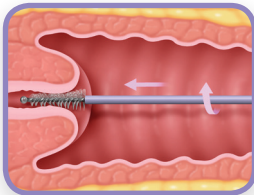
Quick reference guide



Obtain an adequate sample from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.^{1,2} Select the contoured end of the plastic spatula and rotate it 360 degrees around the entire ectocervix, while maintaining tight contact with ectocervical 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 bottom-most fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. **DO NOT OVER-ROTATE THE BRUSH.**



Rinse the brush as soon as possible in the PreservCyt Solution by rotating the device in the solution 10 times while pushing it 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 the patient's name and ID number on the vial.
Record the patient information and medical history on the cytology requisition form.

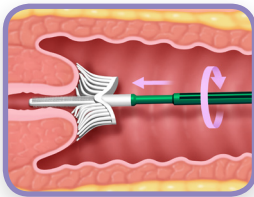


Place the vial and requisition in a specimen bag for transport to the laboratory.

Protocol: Rovers® Cervex-Brush® Combi device

Quick reference guide

Contra-indications: The Rovers Cervex-Brush Combi device should not be used during pregnancy.



Obtain an adequate sample from the cervix using a Rovers Cervex-Brush Combi device (a green, broom-like device with an integrated endocervical sampler). If desired, use lukewarm water to warm and lubricate the speculum. Sparingly apply water-soluble carbomer-free gel lubricant to the posterior blade of the speculum if necessary.^{1,2} Insert the endocervical sampler part of the device into the endocervical canal deep enough to allow the other bristles to fully contact the ectocervix. Push gently, and rotate the brush in a clockwise direction 2 times for 2 complete 360° degree turns.³



Rinse the Rovers Cervex-Brush Combi device immediately into the PreservCyt® Solution vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the brush **vigorously** to further release material. Visually inspect the Rovers Cervex-Brush Combi device to ensure that no material remains attached. Discard the collection device. **Do not leave the head of the Rovers Cervex-Brush Combi device in the vial.**



Tighten the cap of the PreservCyt Solution vial 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.

Record the patient's information and medical history on the cytology requisition form.



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

Hologic provides this Rovers Cervex-Brush Combi device protocol ("protocol") as a general informational tool only and is not an affirmative instruction or guarantee. While the information provided in this protocol may describe a particular technique or protocol, it is not intended as an endorsement and/or requirement by Hologic to utilize such technique or protocol. It is the sole responsibility of the physician to determine which specific technique and/or protocol to employ for obtaining an adequate sample. Physicians using the Rovers Cervex-Brush Combi Device must read and understand the product's Instructions for Use and comply with applicable local, state and federal rules and regulations.

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3). 2. Hologic internal study, data on file. 3. Rovers Cervex-Brush Combi, Information For Use, 2010-11.

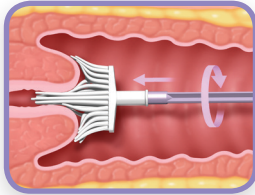
hologic.com | diagnostic.solutions@hologic.com | +1.781.999.7300

DS-05867-001 Rev. 001 © 2015 Hologic, Inc. All rights reserved. Hologic, Science of Sure, PreservCyt, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to diagnostic.solutions@hologic.com.

ThinPrep®
PAP TEST

Protocol: broom-like device

Quick reference guide



Obtain an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Apply water-soluble, carbomer-free gel lubricant sparingly to the posterior blade of the speculum if necessary.^{1,2} 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 for five complete, 360 degree turns.



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. Swirl the broom **vigorously** to further release material. Do not leave the head of the broom in the vial. 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.

Record 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.

Refer to the instructions provided with the collection device for warnings, contraindications, and limitations associated with specimen collection.

www.thinprep.com

Hologic provides this quick reference guide ("guide") as a general informational tool only and is not an affirmative instruction or guarantee. While the information provided in this guide may describe a particular technique or protocol, it is not intended as an endorsement and/or requirement by Hologic to utilize such technique or protocol. It is the sole responsibility of the laboratory to determine which specific technique and/or protocol to employ. Laboratories using ThinPrep or PreservCyt products must read and understand each product's Instructions for Use and comply with applicable local, state and federal rules and regulations.

1. Cervicovaginal Cytology Based on the Papanicolaou Technique; Approved Guideline – Third Edition (Clinical and Laboratory Standards Institute GP15-A3). 2. Hologic internal study, data on file.

hologic.com | diagnostic.solutions@hologic.com | +1.781.999.7300

DS-05867-001 Rev. 002 © 2017 Hologic, Inc. All rights reserved. Hologic, Science of Sure, PreservCyt, ThinPrep and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. All other trademarks are the property of their respective owners. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your Hologic representative or write to diagnostic.solutions@hologic.com.

ThinPrep
PAP TEST

CONVENTIONAL PAP SMEAR

NOTE: Conventional pap smears are a suboptimal method to evaluate cervical and/or Gyn cytology specimens. The ThinPrep Liquid Based Pap Test is the optimal and preferred method. NPA will accept and process Conventional Pap Smear test(s), however, medical care providers should consider performing the ThinPrep Liquid Based Pap test instead. Please contact NPA for ThinPrep supplies, submission requirements and/or questions.

1. Label the frosted end of the glass slide with the patient's name and DOB prior to sample collection. Insert the speculum (which may be slightly moistened with water or saline if necessary).
2. Rotate the spatula 360° around the circumference of the cervical os and ectocervix, maintaining firm contact with the epithelial surface. Do not smear sample onto the slide until all specimen has been collected.
3. Insert the cervical brush into the os with gentle pressure and rotate only 90° to 180° to minimize bleeding.
4. Transfer material from both sampling instruments to the slide. Spread the material collected on the spatula in a thin even layer over the glass slide with a single smooth stroke motion. Roll the brush across the glass slide by twirling the handle. Apply both samples to the slide as quickly as possible and fix immediately.
5. Note: The sample on the brush can be rolled directly over the previously smeared spatula sample, or the two samples can be applied to the slide in separate areas.
6. Immediately fix the specimen by spraying with cytologic fixative. Hold the container of spray fixative about 12" from the glass slide to avoid "blasting" the cells.
7. Transport the labeled slide(s) in a cardboard slide holder. Store at room temperature and call NPA for routine pickup.

Specimen Collection

The proper specimen collection technique is very important in identifying pathogens from DNA. Medical Diagnostic Laboratories provides the **OneSwab**[®], **UroSwab**[®], and **NasoSwab**[®] specimen collection platforms for your convenience. For women, the sequence of Pap testing in relation to other cervical or vaginal specimens does not appear to influence Pap test results or their interpretation. Therefore, when other specimens are collected for gynecological testing, the Pap test can be obtained last.

Collecting samples with **OneSwab**[®]

- Step 1. Firmly, yet gently, sample the endocervical canal with the sterile swab rotating it 360° for 10 to 30 seconds to ensure adequate sampling. When sampling a crusted over lesion, moisten the swab in sterile saline prior to taking the sample.
- Step 2. Remove the swab and place into the vial. Break the shaft at molded break point and insert into transport medium.
- Step 3. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

Collecting samples for Vaginal Group B Strep (GBS) with **OneSwab**[®]

Obtaining specimens for the diagnosis of GBS infection from both the anorectum and the distal vagina increases the sensitivity by a considerable percentage (5% to 25%) over vaginal swabbing alone. Within the genital tract, the highest isolation rates are reported from introitus and the lowest from the cervix. Pregnancy does not influence colonization.

Collecting samples of loose stool specimens with **OneSwab**[®]



- Step 1. Utilize the swab provided to obtain a sample of loose stool and insert into the vial.
- Step 2. Remove the swab and place into the vial. Break the shaft at molded break point and insert into transport medium.
- Step 3. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

Collecting samples with **UroSwab**[®]



- Step 1. Urine collection should be at least one hour between voids.
- Step 2. Have the patient collect a urine sample in a urine container.
- Step 3. Dip the sponge into the urine container.
- Step 4. Place the sponge into the vial. To prevent leakage, tightly cap the vial. Label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.

Collecting samples with **NasoSwab**[®]



- Step 1. Aseptically remove the sterile swab from package, without touching the swab head.
- Step 2. Tilt the patient's head slightly upwards. Insert the brush end downwards into the nostril all the way to the guard. Be sure to direct the swab down towards the throat and not up towards the forehead. Rotate the swab 360°.
- Step 3. Aseptically remove cap from vial.
- Step 4. Break swab at molded break point and insert into transport medium.
- Step 5. To prevent leakage, be sure the swab fits into the vial prior to capping. Tightly cap the vial and label with a minimum of two patient identifiers such as name and date of birth. For packaging and shipping instructions, please refer to MDL's catalog of services.





Test No.	Test Name
Sexually Transmitted Infections	
Leukorrhea Panel	
121	105 <i>Chlamydia trachomatis</i> (*Reflex to antibiotic resistance by Molecular Analysis)
	167 <i>Neisseria gonorrhoeae</i> (*Reflex to antibiotic resistance by Molecular Analysis)
	111 <i>Trichomonas vaginalis</i> (Reflex to metronidazole resistance)
	129 <i>Mycoplasma genitalium</i> (†Reflex to azithromycin & fluoroquinolone resistance by Pyrosequencing)
Genital Ulcer Disease Panel	
115	122 <i>Haemophilus ducreyi</i>
	126 Herpes subtype (HSV-1 & HSV-2)
	110 <i>Treponema pallidum</i> (syphilis)
739	HPV Type-Detect® 4.0 by Multiplex Real-Time PCR

Test No.	Test Name	
Vaginitis & Vaginosis		
759	Bacterial Vaginosis (BV) Panel with Lactobacillus Profiling by qPCR (<i>Atopobium vaginae</i> , BVAB1, BVAB2, BVAB3, <i>Bacteroides fragilis</i> , <i>Bifidobacterium breve</i> , <i>Megasphaera</i> Type 1 & 2, <i>Gardnerella vaginalis</i> , <i>Mobiluncus curtisii</i> , <i>M. mulieris</i> , <i>Prevotella bivia</i> , <i>Sneathia sanguinegens</i> , <i>Streptococcus anginosus</i>)	
	Aerobic Vaginitis (AV) Panel	
	153	<i>Enterococcus faecalis</i>
	141	<i>Escherichia coli</i>
	127	Group B Streptococcus (GBS)
184	<i>Staphylococcus aureus</i>	
560	Candida Vaginitis Panel	
	551	<i>Candida albicans</i>
	559	<i>Candida glabrata</i>
	566	<i>Candida krusei</i>
	558	<i>Candida parapsilosis</i>
557	<i>Candida tropicalis</i>	
134	Urogenital Mycoplasma & Ureaplasma Panel	
	129	<i>Mycoplasma genitalium</i> (†Reflex to azithromycin & fluoroquinolone resistance by Pyrosequencing)
	130	<i>Mycoplasma hominis</i>
	320	<i>Ureaplasma urealyticum</i> (*Reflex to antibiotic resistance by Molecular Analysis)

Test No.	Test Name
Pregnancy	
127	Group B Streptococcus (GBS)
137	Group B Streptococcus (GBS) Antibiotic Resistance § Only performed after positive Test #127. Only check if patient is penicillin-allergic and clindamycin/erythromycin resistance determination is required for alternate treatment.

Test No.	Test Name
150	<i>Actinomyces europaeus</i>
143	<i>Actinomyces israelii</i>
149	<i>Actinomyces turicensis</i>
125	<i>Bacteroides fragilis</i>
147	<i>Bacteroides ureolyticus</i>
581	<i>Candida albicans</i> fluconazole resistance by X-Plate Technology®
576	<i>Candida dubliniensis</i>
582	<i>Candida glabrata</i> fluconazole resistance by X-Plate Technology®
578	<i>Candida kefyr</i>
577	<i>Candida lusitanae</i>
583	<i>Candida parapsilosis</i> fluconazole resistance by X-Plate Technology®
584	<i>Candida tropicalis</i> fluconazole resistance by X-Plate Technology®
207	Cytomegalovirus (CMV) (Reflex to ganciclovir resistance by Pyrosequencing)
175	<i>Eggerthella</i> species
730	<i>Enterobacter cloacae</i>
1112	Group A Streptococcus
727	<i>Klebsiella oxytoca</i>
728	<i>Klebsiella pneumoniae</i>
136	Lymphogranuloma venereum (LGV)
124	<i>Mobiluncus mulieris</i> & <i>Mobiluncus curtisii</i>
128	<i>Molluscum contagiosum</i> virus
1118	MRSA: Methicillin Resistant and Methicillin Susceptible (MSSA) <i>Staphylococcus aureus</i> by Conventional PCR (For nasal collection, please use a <i>NasoSwab</i> ®)
1119	CA-MRSA: Community-Associated MRSA. Panton-Valentine Leukocidin (PVL) DNA§ (Type IV MRSA + #1118 Req.) [Community Associated MRSA = Type IV MRSA+ and PVL+] (For nasal collection, please use a <i>NasoSwab</i> ®)
335	<i>Mycoplasma penetrans</i>
109	<i>Neisseria gonorrhoeae</i> * and <i>Chlamydia trachomatis</i> *
362	<i>Prevotella</i> species Group 1 (<i>P. bivia</i> , <i>P. disiens</i> , <i>P. intermedia</i> , <i>P. melaninogenica</i>)
363	<i>Prevotella</i> Species Group 2 (<i>P. corporis</i> , <i>P. albensis</i>)
146	<i>Proteus mirabilis</i>
174	<i>Pseudomonas aeruginosa</i>
177	<i>Serratia marcescens</i>
151	<i>Staphylococcus saprophyticus</i>
178	<i>Ureaplasma parvum</i> (*Reflex to antibiotic resistance by Molecular Analysis)
131	Urogenital Mycoplasma Panel (<i>M. genitalium</i> † & <i>M. hominis</i>)
215	Varicella-zoster virus (VZV)

§ Reflex to fluoroquinolone resistance by Pyrosequencing

* Reflex to antibiotic resistance by Molecular Analysis

† Reflex to metronidazole resistance by Real-Time PCR



Test No.	Test Name
URINARY TRACT INFECTIONS	
176	Urinary Pathogens Antibiotic Resistance [<i>E. coli</i> , <i>K. oxytoca</i> , <i>K. pneumoniae</i> , <i>P. mirabilis</i> : amoxicillin-clavulanic acid, cephalothin (cephalexin), trimethoprim-sulfamethoxazole, nitrofurantoin, ciprofloxacin, fosfomycin. <i>E. faecalis</i> , <i>E. faecium</i> : ampicillin, nitrofurantoin, ciprofloxacin, fosfomycin, doxycycline, linezolid]***(141, 153, 154, 727, 728, or 146 Req. When panel is ordered and individual tests are not selected, all 6 will be performed and billed)
153	<i>Enterococcus faecalis</i>
154	<i>Enterococcus faecium</i>
141	<i>Escherichia coli</i>
727	<i>Klebsiella oxytoca</i>
728	<i>Klebsiella pneumoniae</i>
146	<i>Proteus mirabilis</i>
174	<i>Pseudomonas aeruginosa</i>

Test No.	Test Name
SEXUALLY TRANSMITTED DISEASES	
	Leukorrhea Panel
121	105 <i>Chlamydia trachomatis</i> (*Reflex to antibiotic resistance by Molecular Analysis) ‡
	167 <i>Neisseria gonorrhoeae</i> (*Reflex to antibiotic resistance by Molecular Analysis) ‡
	111 <i>Trichomonas vaginalis</i> (*Reflex to metronidazole resistance) ‡
	129 <i>Mycoplasma genitalium</i> (vReflex to azithromycin & fluoroquinolone resistance by Pyrosequencing)
109	<i>Neisseria gonorrhoeae</i> * and <i>Chlamydia trachomatis</i> * ‡
110	<i>Treponema pallidum</i> (syphilis)

Test No.	Test Name	Test No.	Test Name
369	<i>Acinetobacter baumannii</i>	137	Group B Streptococcus (GBS) Antibiotic Resistance by PCR** (#127 Req.) Only check if patient is penicillin-allergic and clindamycin/erythromycin resistance determination is required for alternate treatment.
150	<i>Actinomyces europaeus</i>	318	<i>Legionella pneumophila</i>
149	<i>Actinomyces turicensis</i>	136	Lymphogranuloma venereum (LGV)
222	Adenovirus	130	<i>Mycoplasma hominis</i>
147	<i>Bacteroides ureolyticus</i>	138	Polyomavirus BK
551	<i>Candida albicans</i>	139	Polyomavirus JC
576	<i>Candida dubliniensis</i>	362	<i>Prevotella</i> species Group 1 (<i>P. bivia</i> , <i>P. disiens</i> , <i>P. intermedia</i> , <i>P. melaninogenica</i>)
559	<i>Candida glabrata</i>	363	<i>Prevotella</i> Species Group 2 (<i>P. corporis</i> , <i>P. albensis</i>)
578	<i>Candida kefyr</i>	177	<i>Serratia marcescens</i>
566	<i>Candida krusei</i>	151	<i>Staphylococcus saprophyticus</i>
577	<i>Candida lusitanae</i>	575	Urogenital Candidiasis Panel (<i>C. albicans</i> , <i>C. glabrata</i> , <i>C. krusei</i> , <i>C. parapsilosis</i> , <i>C. tropicalis</i>)
558	<i>Candida parapsilosis</i>	178	<i>Ureaplasma parvum</i> (*Reflex to antibiotic resistance by Molecular Analysis)
557	<i>Candida tropicalis</i>	320	<i>Ureaplasma urealyticum</i> (*Reflex to antibiotic resistance by Molecular Analysis)
574	<i>Candida utilis</i>	131	Urogenital Mycoplasma Panel (<i>Mycoplasma genitalium</i> ^v , <i>Mycoplasma hominis</i>)
554	<i>Cryptococcus neoformans</i>	134	Urogenital Mycoplasma & Ureaplasma Panel (<i>M. genitalium</i> ^v , <i>M. hominis</i> & <i>Ureaplasma urealyticum</i> *)
207	Cytomegalovirus (CMV) (Reflex to ganciclovir resistance by Pyrosequencing)		
730	<i>Enterobacter cloacae</i>		
205	Epstein-Barr virus (EBV)		
127	Group B Streptococcus (GBS)		

‡ Applicable for adolescent females who are not candidates for pelvic exams.

Tests performed by Real-Time PCR unless otherwise indicated.

IH0023 Upd: 4.2024



Medical Diagnostic Laboratories



NasoSwab® Test Menu



Test No.	Test Name
369	<i>Acinetobacter baumannii</i>
222	Adenovirus
1101	<i>Bordetella parapertussis</i>
1102	<i>Bordetella pertussis</i> (Reflex to <i>Bordetella holmesii</i> by Real-Time PCR)
319	<i>Chlamydomphila pneumoniae</i>
1134	CombiVid® Panel [SARS-CoV-2 [COVID-19] by Real-Time Reverse Transcription PCR (CDC N1, N2, RP targets)*, Influenza A and Influenza B by Multiplex CFX rRT-PCR]
273	Coxsackie virus A & B by Pyrosequencing
1128	Enterovirus D68
1112	Group A Streptococcus
1117	<i>Haemophilus influenzae</i>
1114	Human Bocavirus
1115	Human Coronavirus (Human Coronaviruses 229E, OC43, NL-63)
1105	Human Metapneumovirus
1136	Influenza A and B detection by CFX rRT-PCR
1109	<i>Moraxella catarrhalis</i>

Test No.	Test Name
1118	MRSA: Methicillin Resistant (MRSA) and Methicillin Susceptible (MSSA) <i>Staphylococcus aureus</i> by Conventional PCR
1119	CA-MRSA: Community-Associated MRSA. Panton-Valentine Leukocidin (PVL) DNA [§] (Type IV MRSA + #1118 Req.) [Community Associated MRSA = Type IV MRSA+ and PVL+]
336	<i>Mycoplasma pneumoniae</i>
1121	<i>Neisseria meningitidis</i>
1110	Parainfluenza Viruses 1-4
174	<i>Pseudomonas aeruginosa</i>
1103	Respiratory Syncytial Virus A (RSV A)
1104	Respiratory Syncytial Virus B (RSV B)
1116	RSV A & RSV B by Multiplex Real-Time PCR
1127	Rhinovirus and Enterovirus
1131	SARS-CoV-2 [COVID-19] by Reverse Transcriptase Real-Time PCR Panel (CDC N1, N2, RP targets) This assay has been authorized by the Food and Drug Administration (FDA) for emergency use authorization (EUA). This Test is not available in NY.
1120	Severe Acute Respiratory Syndrome (SARS)
1111	<i>Streptococcus pneumoniae</i>

Tests performed by Real-Time PCR unless otherwise indicated.

Upd: 4.2024