

PCNM

Collection Guidelines

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PCNM Collection Guide

This guide provides information on Pathology Consultants of New Mexico (PCNM) services and includes routine surgical pathology, cytopathology, post-mortem examination and a variety of specialized studies that are described below. Some policies apply only to the hospital environment, and will be so identified. Complete detailed procedures are available from PCNM. If you have any questions or need further assistance please contact the appropriate staff member listed below.

Hours of Service and Personnel

Laboratory Hours and Main Phone Numbers

Hours: Regular laboratory hours are 8:00 am -12:00 pm and 1:00 pm -5:00 pm, Monday through Friday. Emergency services are available after hours by contacting the on-call pathologist.

Main numbers: (575) 622-5600 or (800) 753-7284.

On-call pathologist: A pathologist is "on-call" 24 hours a day and can be contacted at (575) 622-5600 ext. 217 or (800) 753-7284 ext. 217.

Personnel

Administration

Client Services: ext. 203

Fresh tissue specimen pickup: ext. 218

Routine specimen pickup: (575) 317-6511

Supplies: ext. 231

Reports: ext. 203

Billing: ext. 208, 225, or 204

Transcription: ext. 207

Administrator, Lisa Braggs: ext. 210 or cellular (575) 626-6957

Pathologists

George A. Atkinson, MD, FCAP., ext. 214 or cellular (575) 626-2945

Sanjay Lahiri, MD, FCAP., ext. 212 or cellular (575) 626-2946

Cytology

Cytology Lab, ext. 230

Tom Meier, SCT (ASCP), Director of Cytology, ext. 220 or cellular (575) 626-1183

John Kopcik, CT, MP (ASCP), Asst. Director of Cytology, ext. 223

or cellular (575) 626-8537

Mary Hubbard, CT, MP (ASCP), Molecular Cytologist, ext. 205

Maria Nease, Lead Cytoprep Technician, ext. 228

Inez Green, Logistics Coordinator, ext. 231

Histology

Histology Lab, ext. 218

Joanne Clark, HT (ASCP), Supervisor, ext. 221 or cellular (575) 626-0656

Michael Tyler, Lead Histotech, ext. 218

Requisition Forms and Specimen Labeling

The pathology requisition forms are designed to obtain the necessary information for processing specimens. Complete and accurate requisitions and specimen labeling are critical for ensuring positive patient identification, patient safety, and quality patient care.

All specimens must be properly identified on the containers and the requisition must provide all pertinent clinical information, including all insurance and billing information. Failure to do so may result in a delay of results or the inability to process the specimen resulting in the return of the specimen to your office.

Inconsistent or missing information on the requisition and/or specimen container may result in the specimen being rejected for testing and will be returned to the clinician's office for correction.

It is PCNMs policy that all specimens are considered to be potentially infectious and should be handled in accordance with universal precautions.

Signed Advanced Beneficiary Notice forms (ABNs) must be attached to the requisitions of Medicare patients.

Specimen Labeling Requirements

Specimen Labeling Requirements/Directions

- A minimum of two (2) patient identifiers are required on the specimen container, one of which **must** be the patient's name. Label as follows:
 1. Patient's full name (first and last, no nicknames).

2. A secondary, unique identifier such as date of birth, Social Security number or other unique identifier.
- Attach a PCNM bar code number from the requisition to the specimen container.
 - For multiple specimen containers collected from the same patient and procedure:
 1. Label with patient identifiers, as described in steps 1 and 2, above.
 2. Indicate the specimen source and/or site on each container.

Important: The two patient identifiers used on specimen containers must match those on the requisitions. Failure to do so will result in the specimen being rejected and returned to the clinician.

For clinicians that send specimens to PCNM by FedEx, UPS, or United States Postal Service: Federal Regulations Regarding the Shipping of Medical Diagnostic Specimens.

In order to facilitate transport of medical specimens while ensuring the safety of people, property and the environment, the Department of Transportation (DOT), US Postal Service, International Air Transport Association (IATA) have implemented regulations that require that specimens be properly prepared and packaged before they are shipped. Although PCNM has no enforcement of regulatory role or responsibility in your implementation of these regulations, we feel an obligation to assist our clients in ensuring that the specimens you send to PCNM meet the regulatory requirements. General answers to questions about proper shipping methods and proper shipping materials can be obtained from the Logistics Coordinator. PCNM will supply you with the proper packing and reference material to help ensure that the specimens are properly sent.

Specimens that are sent by FedEx, UPS, or United States Postal Service methods (as opposed to courier services) are strictly regulated by a number of agencies, and the penalties for non-compliance are significant. According to the regulations the “shipper” (in this case, the clinician’s office) is responsible for ensuring that the package meets the regulation requirements and that staff members who ship infectious materials have completed training and recertification in the requirements of the regulations. As the shipper of diagnostic specimens you are required to follow all relevant regulations pertaining to the proper identification and classification, packaging, labeling, and documentation of the shipment. PCNM provides the following information as a service; to be used as guidelines to assist properly trained shippers. This information does not take the place of formalized training.

SUMMARY INSTRUCTIONS

Step 1. Classify the specimen according to the Classification of Biological and Infectious Materials regulations.

Biological materials must be properly identified before packing and shipping as the requirements vary depending of the type of material being shipped.

There are three classifications of regulated biologic material: Infectious Substance-Category A, Infectious Substance-Category B, and Exempt Human Specimens.

I. Exempt human specimens are those that have a minimal likelihood of containing infectious pathogens. Nearly all the specimens (e.g. ThinPrep Pap Tests vials, PreservCyt vials, conventional Pap smears & biopsies submitted in formalin) that you send to PCNM fall in this category. The liquid in the ThinPrep vial and formalin both inactivate most infectious substances so that they no longer provide a health risk, therefore they will fall into the “exempt-human specimen” category. These qualify for an exemption from some of the infectious materials regulations and can be shipped with reduced documentation, labeling, and packaging if the specimens meet the standards for the exemption. The regulations still require a specific packing “triple packaging” procedure and proper labeling (see Summary Instructions below).

Criteria for Exempt Specimens:

1. Exempt specimens must meet the following definition: Specimens are those collected directly from humans or animals, including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluid, swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment, and prevention.

2. Exempt specimens must have minimal likelihood that the specimen contains a pathogen: A patient or animal specimen is considered exempt if there is a minimal likelihood that pathogens are present. In determining whether a patient or animal specimen has a minimal likelihood that pathogens are present, an element of professional judgement is required to determine if a substance is exempt. This judgement should be based on the known medical history, symptoms, and individual circumstances of the source, human or animal, and endemic local conditions.

If the specimen doesn't meet these two criteria, then it can not be considered exempt and must be shipped as an infectious substance as defined below. Specimens that are not transported in a ThinPrep vial or in formalin (or are not inactivated by the solutions) may not be exempt specimens depending on the exact situation as outlined in #2 above. If they are not felt to be exempt specimens then they need to be shipped as a Category A or B infectious substances and require additional shipping labels and special shipping procedures.

II. Infectious Substance- Category B (Biological Substance, Category B) specimens are infectious substances that do not meet the criteria for inclusion in Category A. They are infectious substances that are not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.

An example of this type of specimen would be blood or a specimen that is in culture media or fresh and that it is known or suspected that a Category B pathogen is likely to be present. These specimens must be packed according to the IATA Packing Instruction 650 and labeled as “UN3373-Biological Substance, Category B”.

III. Infectious Substance- Category A are infectious substances in a form that, when exposure to it occurs, is capable of causing permanent disability, or life-threatening or

fatal disease in otherwise healthy humans or animals. A list of infectious agents that fall into this category can be found in the IATA and DOT regulations. These specimens are considered dangerous goods and must be shipped in packaging that meets the Class 6.2 specifications. It will be extremely rare that this type of specimen would be sent to PCNM. If you believe you have this type of specimen, you **must** contact PCNM before shipping.

An element of professional judgement is required to classify the patient specimen. If no Category A Infectious Substances are present and a professional judgment is made that there is only a minimal likelihood that pathogens are present, the specimen may be packed according to the “Packaging for Exempt Patient Specimens” as per the regulations. If no professional judgement is made, or the specimen doesn’t meet the criteria for an exempt specimen then the specimen must be classified and packaged as “Biological Substance, Category B, UN3373”.

Step 2. Packaging for Exempt Human Specimens

In order to minimize the risk of exposure, Exempt Human Specimens shippers are required to package and mark the shipment according to the regulation’s requirements. PCNM’s primary receptacles and specimen shippers meet the requirements.

1. The packaging must consist of three components, “triple packaging”:

- i. A leakproof primary receptacle(s) (the specimen vial, container or tube).
 - ii. A leakproof secondary packaging (specimen bag-properly sealed and with biohazard labeling)
 - iii. An outer packing of adequate strength for its capacity, mass and intended usage, and with one surface having minimum dimensions of 10cm x 10cm. A sturdy outside packaging that can be capable of passing a drop test of at least 1.2 meters.
-
- a. Absorbent material must be placed between the primary receptacle and the secondary packaging.
 - b. Primary receptacles shall be packaged in secondary packaging in such a way that, under normal conditions, they can not be punctured or leak their contents into the secondary packaging. Be sure that any liquid vials are completely tightened so that they do not leak. ThinPrep vials need to be tightened so that the torque marks align to prevent leakage. Other types of vials should be securely tightened. If it is thought that there is a chance of leakage then the screw lids should be sealed with Parafilm or a waterproof tape.
 - c. For liquids, absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packing and will not compromise the integrity of the outer packaging.
 - d. When multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them. Place the multiple specimens and enough absorbent to absorb the entire contents of the

primary receptacles (specimen volume) into a large specimen transport bag, seal and place in the outer packing. Secure the secondary packaging in the outer packaging with suitable cushioning material.

2. Labeling and Documentation

For Exempt Specimens:

- Triple pack as above.
- Total volume of primary receptacle must not exceed 500ml
- Total volume per package is limited to 4L. For USPS two 500ml primary receptacles may be packed in one outer packaging for a limit of 1L
- Apply the “Exempt human specimen” label to the outer package. Do not use UN3373, Diagnostic Specimen” label as it is outdated or the “UN 3373 Biologic Substance Category B” label as it is inappropriate for these types of specimens.
- Include a packing slip, shipping manifest, or requisition in each specimen shipper between the secondary packing and outer container.
- Seal the specimen shipper with packing tape
- Check the “no” checkbox on the FedEx airbill in response to the question: “Does this shipment contain dangerous goods.

For Infectious Substance- Category B (Biological Substance, Category B)

- Triple pack similar to the above. You must use materials that meet the specifications of Packing Instruction 650 in the regulations. The primary receptacle or secondary packing must be able to withstand pressure differentials of 95kPa without leaking.
- Primary receptacle(s) must be water tight, e.g., if screw cap seal with Parafilm or similar material.
- Primary receptacle(s) must not contain more than 1L. The entire contents of the primary receptacle is considered to be the diagnostic specimen.
- Include a packing slip, shipping manifest, or requisition in each specimen shipper between the secondary packing and outer container.
- The outer packaging must not contain more than 4 L. For USPS the total volume per package is limited to 500ml.
- Apply the “UN 3373 Biologic Substance Category B” label to the package.
- Write full name of shipper and recipient on package.
- Check the “no” checkbox on the FedEx airbill in response to the question: “Does this shipment contain dangerous goods.
- Place in the FedEx Clinical pack and check the box: “Mark this box if your shipment meets the definition of Biological Substance Category B packed in compliance with IATA Packing Instruction 650” or mark the package with a “UN 3373 Diagnostic Specimen” label and label/mark “Packed in compliance with IATA packing instruction 650” on the outer package.

Requisition Information

Required Information

- Ordering clinician
- Collection date
- Patient name
- Patient Social Security number
- Patient date of birth
- Patient sex
- Pertinent clinical history or diagnostic question
- Specimen source and site
- Specific specimen information if there are multiple and different specimens from the same patient submitted with a single requisition
- ICD9 code or symptom/diagnosis
- Insurance information (complete area on the requisition or attach copies of face sheet or card(s))
- Medicare patients: attach signed ABN form to requisition

Requisitions and Supplies

Requisitions and supplies may be ordered by calling the Logistics/Supplies Coordinator at ext. 231 or by faxing the completed Supply Requisition Form to (575) 622-4795.

Clinical History and ICD-9 Coding

All pathology requests are required to have pertinent clinical history indicated in the space provided on the requisition form. ICD-9 codes may be supplied for further historical information.

Reporting

A completed surgical pathology report is usually available within one working day of **receipt** of the specimen.

Exceptions

- Large specimens requiring overnight fixation
- Bone requiring decalcification
- Cases requiring special studies or additional sections
- Cases requiring consultative assistance

Rush handling of specimens is available. Prior consultation with the pathologist on-call is required for this service.

Information on cases delayed beyond 24-48 hours can be obtained by calling client services at ext. 203 who will then transfer the call to the pathologist handling the case and who will be able to discuss it with you.

Patient requests for slides or results will be referred to the ordering clinician's office. If the ordering clinician requests slides or results to be given directly to the patient, the patient must be physically present with photo ID to receive the slides or report.

Please Note: PCNM is NOT able to send out original slides, and must make recuts. Please allow time for recuts to be made. Exceptions to this rule may be made in certain instances e.g., if pathology is not demonstrated on the recut, or by clinician

request. Sending of original slides requires consultation with the pathologist and their approval.

Surgical Pathology (Routine Procedures)

Cut off time for specimen pick-up (other than routine) is 4:00 pm

Any questions or concerns regarding tissue fixation should be directed to the Histology Lab, (575) 622-5600 or (800) 753-7284, ext. 218.

- Resected specimens should be submitted in 10% neutral buffered formalin fixative. The optimal volume ratio of fixative to specimen size is 20:1 and this ratio should be followed whenever possible. The specimen should be placed in a container large enough to hold this amount of fixative (very important). As a minimum requirement, there should be at least twice the volume of fixative as tissue. Small biopsies should be placed in at least 20.0 mL of formalin. The fixative and specimen containers are available through PCNM.
- Extremely large specimens (e.g. amputated limbs) should be placed in a large container or securely fastened plastic bag. If these specimens are not fixed, they must be double bagged, the outer being a red, appropriately labeled biohazard bag. Store the bagged specimen in a refrigerator until a courier can pick up.
- Questions arising outside of regular working hours are handled by the pathologist "on- call".

ENMMC Operating Room and/or Surgical Center Personnel

- Ensure that the correct requisition form is properly filled out (e.g., surgical pathology for tissue biopsies, cytopathology for fluids, brushings, FNAs), to include preoperative and postoperative diagnoses and clinical information as available.
- Submit the properly labeled containers of appropriate size for the specimen(s). Submit additional labels for breast biopsies.
- Generate a face sheet to accompany the specimen to the lab.
- Give the pathologist a 15-minute lead-time (or in the case of a rural location, dates must be prespecified and scheduled) when calling during normal working hours for frozen sections and be sure to contact the pathologist for any additional questions or when the situation is in any way unusual to you.
- Submit lymph node tissue fresh. Contact the pathologist on-call immediately for handling of specimen. If a pathologist is not available, or if there is a problem or delay, submit additional tissue in AZF fixative (if you have it available at your location). This is available in the frozen section room at ENMMC or at PCNM (and is provided upon request to rural locations).
- For ENMMC specimens requiring both culture and tissue analysis, contact the ENMMC clinical laboratory and be sure a microbiology requisition is also filled out.

Surgical Pathology (Special Procedures)

Frozen Sections/Intraoperative consultations (ENMMC)

- Appointments should be made in advance for frozen sections by calling PCNM between 5:00 a.m. and 5:00 p.m. (575) 622-5600 or (800) 753-7284 ext. 217. The pathologist "on-call" should be contacted at least 30 minutes in advance of the frozen section on weekends, holidays, or outside regular working hours. Frozen sections, intraoperative consultation, and FNAs outside of Roswell institutions are to be scheduled in advance and on scheduled visit days.
- Tissue for frozen section must be delivered in the fresh state with care taken to avoid the specimen drying out during transport. A completed Surgical Pathology requisition and patient face sheet must accompany the specimen.
- Upon completion of the frozen section, the pathologist will verbally contact the surgeon with the diagnosis.

Diagnostic Lymph Node Biopsies:

- All diagnostic lymph node biopsies should be promptly evaluated by a pathologist in the fresh state to ensure that the proper studies are performed. The on-call pathologist should be contacted to handle the specimen. If an infectious process is suspected, additional sterile tissue should be sent directly to the microbiology laboratory for culture. The micro lab is located at ENMMC, (575) 627-4021.
- Lymph nodes removed in a physician's office and for a suspected diagnosis of possible lymphoma should be wrapped in saline-moistened gauze and PCNM should be contacted immediately for pick up (575) 622-5600, ext. 218. Outside of Roswell, such specimens may be regarded as STAT tests and submitted to the local pathologist.

Sentinel Lymph Node Biopsy Handling Protocol

Procedural Assumptions

Sentinel lymph nodes are procured at the institutions we service using a supravital dye, rather than radioisotopes, for identification and localization. In the literature, there are controversies and variations in the way the specimen should be handled i.e., numbers of sections and levels, frozen vs. permanent sections, cytokeratin antibodies by immunohistochemistry (IHC). Frozen sections on sentinel nodes are not performed by PCNM because false-negative rates approach 25% in the literature. IHC staining is not performed; this may change if multicenter studies show any benefit and demonstrate that the information is of clinical value.

Procedure

- The container/requisition should be labeled "sentinel node" and include the location (axilla, internal mammary, lateral chest wall, etc.).
- When received (in formalin), the nodes are sectioned as close to 2 mm intervals as possible, and through the hilus of the node if this can be determined.
- A single microscopic section from each lymph node block is sufficient (there is currently insufficient data to recommend routine serial sectioning).

- If intraoperative assessment is requested, it should be done via gross assessment and performance of cytologic imprints rather than frozen section (the latter may consume significant amounts of nodal tissue).
- IHC cytokeratin staining will be performed only if suspicious cells are seen and confirmation as to epithelial origin is needed.

Rationale

In one multicenter study, occult metastases were 12 times more likely to be identified in sentinel nodes than in nonsentinel nodes. But, pathologists should resist intense analysis of such nodes if the results are going to affect clinical decision making and result in more aggressive therapy than is deemed appropriate by large clinical trials looking specifically at the effects of micrometastases. The above strategy will identify virtually all micrometastases in the 2 mm range.

Pitfalls in the diagnosis of micrometastases in sentinel lymph nodes include over-interpretation (small, tight clusters of sinus histiocytes and degenerated atypical single subcapsular histiocytes) and under-interpretation (small, cytologically bland tumor cells, rare isolated individual tumor cells, small tubules mimicking capillaries, incomplete screening of the material, poor quality sections or poor fixation).

Exceptions

If sentinel nodes are received, having been identified via radioisotopes, the specimen will be placed in formalin (if not already), stored for 24 hours prior to handling to allow for radiolabel decay, and then processed as above.

References

- Weaver, Donald L., MD, Dept. of Pathology, Univ. of Vermont College of Medicine, ASCP paper on the Diagnosis and Management of Breast Pathology, A Multimodal Approach-Sentinel Lymph Node Biopsy in Breast Cancer. Nov. 30, 2001.
- Fitzgibbons, Patrick L., MD, et al, Prognostic Factors in Breast Cancer, CAP Consensus Statement, 1999, Archives of Pathology and Laboratory Medicine, Vol. 124, July, 2000.

Skeletal Muscle Biopsies

The handling of skeletal muscle biopsies requires coordination between the surgeon, pathologist, and the University of New Mexico's neuropathology technician. It is important that the appropriate site is biopsied, with good muscle without tendon. All skeletal biopsies are sent to the UNM Neuropathology Lab for enzyme histochemistry and possible electron microscopic (EM) studies.

- The most important step is having prior notification from the surgeon that he/she is going to perform a muscle biopsy. Preferably, we should have at least two to three days prior notification. It is also important that biopsies not be obtained on a Friday as the tissue may deteriorate over a weekend after being sent to UNM.
- The submitting surgeon must supply PCNM with sufficient history, physical examination findings, appropriate laboratory studies and ancillary tests (e.g. EMG findings or others).

- Obtain the biopsy from the most appropriate site.
 1. It is important to obtain the biopsy from the muscle belly, not adjacent fascia.
 2. Obtain good longitudinal fibers; do not dissect using cautery as this creates significant artifacts. Obtain 5-6 mm x 2.5 cm of tissue.
- Once the tissue is obtained, wrap the tissue in saline-soaked gauze. Do not immerse the skeletal tissue into saline. It is important that the tissue does not dry out.
- Have the appropriate operating room (OR personnel contact PCNM to pick-up the tissue.
- This will be forwarded overnight on crushed ice to TriCore labs.

Kidney Biopsy Submission, Handling and Processing

Renal biopsies may be done with a Tru-Cut needle or a biopsy gun; with the latter, the specimens are much thinner, so a minimum of two cores should be obtained. The biopsy(s) should be received fresh, accompanied by appropriate clinical information. Ideally, the pathologist or histology supervisor should be notified *in advance* and just prior to the procedure as well, in order to be on-site with the dissecting scope to examine the core(s) and properly handle them.

Depending on the type of biopsy and clinical history, tissue will be submitted for light (LM), immunofluorescence (IF) and/or electron microscopy (EM), following the guidelines below:

Biopsy handling protocol

1. Two separate cores: Place one core in Formalin for Light and Electron Microscopy (LM and EM) studies. Place one core in Michel's fixative for Immunofluorescence (IF) studies.
2. Single core/scant material: The core should either be divided in half for Light and Immunofluorescence or submitted entirely for Light Microscopy.

All tissues from renal biopsies are sent to Nephropath in Little Rock, Arkansas for complete studies in LM, EM and IF.

Immunofluorescence Testing of Skin

Submit two samples of tissue (preferably punch biopsies no smaller than 3.0 mm or one specimen divided in half) to PCNM. Use the PCNM requisition form with appropriate clinical information and description of the lesion. One sample should be in 10% neutral buffered formalin, and the other in Michel's solution (supplies available through PCNM). Be sure the Michel's is not outdated. Call PCNM with any questions. *If the specimen is from an uninvolved site, please state such on the requisition.*

Immunohistochemistry

IHC workups will be performed as deemed appropriate by the pathologist. Specific requests for IHC by the submitting physician will be considered after contact and

discussion with a pathologist. Such work may entail delays in reporting, but provisional diagnoses will generally be rendered in the interim.

Ideally, tissue for IHC should not be over-fixed (24 hours is optimal), therefore submit it in a timely fashion. **Write the time of immersion into the fixative on the container or requisition.** IHC specimens may also require antigen retrieval methods to ensure maximal antigen recognition. Lymphoid tissues should be submitted in AZF as well as 10% NB formalin. These fixatives may be obtained through PCNM.

Special IHC oncogenic markers can be ordered and image analysis performed along with DNA and proliferation (PCNA) studies. Please contact PCNM for appropriateness to the clinical situation in cases of breast, colon, prostate, bladder and other malignancies. These studies are done on paraffin embedded tissue.

Estrogen/Progesterone Receptor

- Tissues suspected of being involved with a primary or metastatic breast carcinoma should be submitted for ER/PR/Her 2-neu (Herceptest) Assay and other markers.
- Analysis will be performed on fixed, paraffin-embedded section.

Cytopathology Procedures

Instructions for Handling Cytology Specimens

All specimens must be labeled with the patient's name, date of collection, and specimen type.

Remember that all specimens should be considered infectious and handled according to Universal Precautions.

All specimens must be properly identified and have all pertinent clinical information provided including all insurance and billing information. Failure to do so may result in a delay of lab results.

The table below summarizes the major cytology specimens and their handling. Please call the Cytology Department if the specimen is not listed or you have any questions (575) 622-5600 or (800) 753-7284, ext. 220.

Sputum	Fresh* or CytoLyt
Bronchial	Fresh* or CytoLyt
Breast Cyst Fluid	Fresh* or CytoLyt
Pleural/Peritoneal/Pelvic Fluid	Fresh* or CytoLyt
Urine/Bladder Wash	Fresh* or CytoLyt
CSF	Fresh* or CytoLyt

Bronchial/Gastric/Urinary Brushing	Cover brush with Normasol/Polysol/ Plasmalyte*
Smears	Prepare smear and immediately spray with cytology fixative
FNA-Fine Needle Aspirations	Express specimen into the provided tube of CytoLyt solution Perform needle rinse Provide 1 air-dried slide and 1 fixed slide. Follow procedure on next page
HPV testing	See detailed collection info below
CT/GC testing	See detailed collection info below
ThinPrep Pap Test	See detailed collection info below
Conventional Pap	Prepare smear and immediately spray with cytology fixative

*** Use CytoLyt Fixative only if a delay of 12-24 hours is anticipated; otherwise, refrigerate and send to the lab.**

NOTE: Cytology Specimens having multiple sites require a separate request form for each different site.

Separate specimens should be obtained for microbiology (culture) when required and submitted with a microbiology request form. Please send microbiology specimens to the appropriate lab.

Fine Needle Aspiration Collection Protocol

Use the provided CytoLyt solution for transport to PCNM.

Fine needle aspiration (FNA) with air dried smears / wet fixed smears:

1. Take one pass and express one or two drops from needle at middle of slide.
2. Place another slide over the drop and allow the drop to spread.
3. Separate the two slides. Spray cytology fixative to one slide immediately and allow the other slide to air-dry. Label the slides.
4. Make at least three to six passes trying to sample the mass thoroughly and express the specimen into the CytoLyt solution tube.
5. Rinse the needle by drawing approximately 5.0 mL of the CytoLyt fluid into the syringe and re-express back into the tube.

6. Repeat this with each needle and syringe used.
7. Label the CytoLyt tube and smears appropriately.
8. Send these to the lab along with all pertinent clinical information including level of clinical suspicion for malignant lesion and radiographic findings.

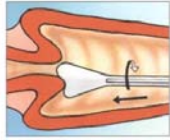
CytoLyt transport medium is an essential solution in the Cytoc ThinPrep specimen preparation system that we utilize at Pathology Consultants of New Mexico; do not substitute cytology fixatives. For replacement supplies, call PCNM at (575) 622-5600 or (800) 753-7284, press 4.

ThinPrep Pap Test

This liquid collection methodology improves specimen quality. The air-drying factor is eliminated and the processing of the sample via filtration removes much of the blood, mucus and inflammation that can obscure a sample. Then a thin, uniform layer of well-preserved cells is applied to the slide for conventional light microscopic evaluation. For replacement supplies, call PCNM at (575) 622-5600 ext. 231 or (800) 753-7284 ext. 231.

ThinPrep® Pap Test™ Quick Reference Guide

Endocervical Brush/Spatula Protocol



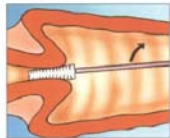
Obtain...

...an adequate sampling from the ectocervix using a *plastic* spatula.



Rinse...

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



Obtain...

...an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottom-most fibers are exposed. Slowly rotate $\frac{1}{4}$ or $\frac{1}{2}$ turn in one direction. DO NOT OVER-ROTATE.



Rinse...

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



Tighten...

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



Record...

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

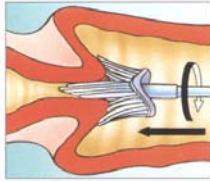


Place...

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

ThinPrep® Pap Test™ Quick Reference Guide

Broom-Like Device Protocol



Obtain...

...an adequate sampling from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.



Rinse...

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



Tighten...

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



Record...

...the patient's name and ID number on the vial.

...the patient information and medical history on the cytology requisition form.



Place...

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

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THE
ThinPrep
PAP TEST

One Vial. More Results.

Pap Test Coding Criteria

Refer to the following guide: [Pap ICD-9 Codes for Medicare, Medicaid, and All Insurances](#)

Cytology Ancillary Testing

PCNM performs several ancillary tests. Both HPV hybrid capture and CT/NG testing is available directly from the ThinPrep Pap test vial. CT/NG testing may also be performed using the appropriate type of Gen-Probe Aptima Combo 2 test kits for endocervical, vaginal or urine specimens for females. CT/NG testing may be performed for males using Gen-Probe's Unisex Swab Specimen Collection kit or Urine specimen collection kits (see the collection details below).

HPV Testing

The following table provides the details on the proper collection, handling and storage for specimens to be tested for HPV using the Digene Hybrid Capture Method.

- **This method is FDA-approved for females only. There is no sampling device approved for males.**
- **Do not use cervical brush with pregnant women.**
- **Sample collection is recommended prior to application of acetic acid or iodine if a colposcopy will be performed. Changes in pH affect the Digene assay.**
- **All specimens must be individually bagged to prevent cross-contamination**

Labeling	Refer to PCNM Specimen Labeling Requirements listed in this manual.
Handling	All specimens should be regarded as potentially infectious and handled according to Universal Precautions.
Interfering Substances	Includes, but is not limited to, acetic acid and iodine.
Sample Collection and Storage	<p>Endocervix, brushing in ThinPrep PreservCyt:</p> <ul style="list-style-type: none">• Sample: Use recommended collection methods described in the "ThinPrep Pap Quick Reference Guide" found in the PCNM Collection Guidelines handbook. Submit entire vial.• Storage: Store at 15-30C (room temperature). Sample must be received by laboratory within 90 days after collection. Do not freeze. <p>Endocervix, brushing in Digene Specimen Transport Medium (STM):</p> <ul style="list-style-type: none">• Sample:<ol style="list-style-type: none">1. Remove excess mucus from the cervical os and surrounding ectocervix using a Dacron swab. Discard swab.2. Insert brush 1-1.5 cm into the os of the cervix until the largest outer bristles of the brush touch the ectocervix. Rotate it 3 full turns in a counter-clockwise direction. DO NOT INSERT BRUSH COMPLETELY INTO THE CERVICAL CANAL.3. Remove the brush from the canal. Avoid touching the bristles to the outside of the tube or to any other object.4. Insert brush to bottom of the Transport Tube. Snap off shaft at score-line and cap tube securely.5. Submit brush with entire volume of STM (1 mL).• Storage: Refrigerate at 2-8C. Specimens may be shipped without refrigeration to a testing laboratory; however, specimens should be shipped in an insulated

	<p>container using either an overnight or 2-day delivery vendor.</p> <p>Cervical Biopsy:</p> <ul style="list-style-type: none"> • Sample: Freshly collected biopsy 2-5 mm cross-section immediately preserved in Digene Cervical Sampler vial (STM). • Storage: Store frozen at -20°C until samples can be shipped in an insulated container (maintain sample at 2-30C) for next-day delivery to the laboratory.
Sample Rejection	<p>Samples may be rejected under the following circumstances:</p> <ul style="list-style-type: none"> - Inadequate labeling. - Insufficient specimen volume. - Unsatisfactory specimen cellularity (for PreservCyt specimens) - Expired transport media

CT/NG Testing by Nucleic Acid Amplification

Gen-Probe Aptima Combo 2 Method. The following table provides the details on the proper collection, handling and storage for specimens to be tested for CT/NG for this method of testing.

VERY IMPORTANT, all CT/GC specimens must be individually bagged to prevent cross-contamination.

Collection Information	Female	Male
Labeling	Refer to PCNM Specimen Labeling Requirements listed in this manual.	Same as for female
Handling	All specimens should be regarded as potentially infectious and handled according to Universal Precautions.	Same as for female
Specimen Rejection	<p>Sample rejection criteria:</p> <ul style="list-style-type: none"> - submitted in M4 media - submitted in Digene Cervical Sampler tubes - submitted in expired transport tubes - swab or transport media is not from “ Gen-Probe Aptima Unisex Swab or Vaginal Collection Kit” - no swab in swab transport tube - two swabs in swab transport tube - urine transport tube not filled to within the “Fill Area” marked on tube. If above or below marks then it must be rejected. - urines not received at PCNM within 24 hours of collection must be rejected - inadequate labeling. Minimum requirement is patient’s name and/or PCNM requisition reference number. - unsatisfactory specimen cellularity (for PreservCyt specimens) - submitted in expired transport media 	Same as for females

Collection Information	Female	Male
<p>Sample Collection, Storage, and Transport. See details listed below.</p> <p>Important: To prevent specimen rejection. All swab and urine specimens must be collected and transported using the correct Gen-Probe Aptima Collection kit. Check for expiration dates prior to use.</p> <p>If a fresh urine is submitted, the collection time must be noted on the requisition and be received by PCNM within 24 hours of collection</p>	<p><u>C. trachomatis and N. gonorrhoeae DNA Acceptable sample types:</u></p> <p>A. Endocervix brushing in <u>ThinPrep PreservCyt Pap Vial</u> B. Endocervix swab using Aptima <u>Unisex Swab in Aptima Swab Specimen Transport Tube</u> C. Urine in <u>Aptima Urine Specimen Transport Tube</u>; or fresh if specimen can be received by PCNM within 24 hours of collection D. Vaginal Swab Specimen in using <u>Aptima Transport Tube</u></p>	<p><u>C. trachomatis and N. gonorrhoeae DNA : Acceptable sample types:</u></p> <p>A. Urethral swab using <u>Aptima Unisex Swab in Aptima Swab Specimen Transport Tube</u> B. Urine in <u>Aptima Urine Transport Tube</u>; or fresh if specimen can be received by PCNM within 24 hours of collection.</p>

Stepwise Collection Procedures For CT/NG Specimens

ThinPrep PreserveCyt Specimens

A. Endocervix, brushing in ThinPrep PreservCyt:

Collection: Use recommended collection methods described in the “ThinPrep Pap Quick Reference Guide” found in [PCNM Collection Guidelines](#) handbook. Submit entire vial.

Storage: Room temperature (15-30°C). Transport: Maintain at 15-30°C during transport. Deliver to lab within 7 days after collection. ThinPrep PreservCyt: Not Applicable for males use Aptima Unisex Swab Collection Kit as outlined below.

OR

Gen-Probe Collection Kits

Unisex Swab Collection Kit Specimens

B. Endocervix or Male Urethral swab in Aptima transport media: Collection: Use *APTIMA® Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens*. For *in vitro* diagnostic use.

Contents: Each kit contains:

One Unisex Specimen Collection Swab for Endocervical or Male Urethral Swab Specimens*

One Female Cleaning Swab*

One Tube Containing GEN-PROBE APTIMA Swab Transport Medium (2.9 mL)

Warnings And Precautions:

Use this collection kit only with the GEN-PROBE® APTIMA® Assays. Performance has not been established with other products. **Do not** apply the transport medium directly to skin or mucous membranes or take internally.

Kit Storage Requirements:

Store collection kit at room temperature (15°C to 30°C).

Specimen Collection and Handling:

1. Endocervical swab specimens

a. Remove excess mucus from the cervical os and surrounding mucosa using the cleaning swab (white shaft swab in the package with red printing). **Discard this swab.**

Note: To remove excess mucus from the cervical os, a large-tipped swab (not provided) may be used.

b. Insert the specimen collection swab (blue shaft swab in the package with the green printing) into the endocervical canal.

c. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.

d. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.

e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

f. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.

g. Re-cap the swab specimen transport tube tightly.

2. Male urethral swab specimens

a. The patient should not have urinated for at least 1 hour prior to sample collection.

b. Insert the specimen collection swab (blue shaft swab in the package with the green printing) 2 to 4 cm into the urethra.

c. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.

d. Withdraw the swab carefully.

e. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.

f. Carefully break the swab shaft against the side of the tube at the scoreline and discard the top portion of the swab shaft; use care to avoid splashing of contents.

g. Re-cap the swab specimen transport tube tightly.

Specimen Transport And Storage:

After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested.

Specimens must be assayed with the APTIMA Assays within 60 days of collection. If longer storage is needed, store at –20°C to –70°C for up to 90 days after collection.

Note: Specimens should be transported in compliance with Federal regulations for transport of etiological agents. Please refer to HHS Publication No. CDC 93-8395 or latest revision

Urine Specimens

C. APTIMA® Urine Specimen Collection Kit for Male and Female Urine Specimens

For *in vitro* diagnostic use

Warnings and Precautions:

Use this collection kit only with the GEN-PROBE® APTIMA® Assays. Performance has not been established with other products. **Do not** apply the transport medium directly to skin or mucous membranes or take internally.

Kit Storage Requirements:

Store collection kit at room temperature (15°C to 30°C).

Specimen Collection and Handling:

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup free of any preservatives. Collection of larger volumes of urine may result in specimen dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
3. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black fill lines on the urine specimen transport tube label.
4. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.

Specimen Transport and Storage:

After collection, transport the processed urine specimens in the GEN-PROBE APTIMA urine specimen transport tube at 2°C to 30°C and store at 2°C to 30°C until tested. Processed urine specimens should be assayed with the APTIMA Assay within 30 days of collection. If longer storage is needed, freeze at –20°C to –70°C for up to 90 days after collection. Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer the urine sample into the APTIMA urine specimen transport tube within 24 hours of collection. Store at 2°C to 3°C and test within 30 days of collection.

Note: Specimens should be transported in compliance with Federal regulations for transport of etiological agents. Please refer to HHS Publication No. CDC 93-8395 or latest revision

Vaginal Swab

D. APTIMA® Vaginal Swab Specimen Collection Kit

For *in vitro* diagnostic use

Intended Use:

The APTIMA Vaginal Swab Specimen Collection Kit is for use with the APTIMA Assays for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. The APTIMA Vaginal Swab Specimen Collection Kit is intended to be used for clinician and patient collection of vaginal swab specimens according to the instructions provided. Patient-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. The APTIMA Vaginal Swab Specimen Collection Kit is not for home use.

Contents:

Each kit contains:

- One individually wrapped, sterile swab
- One transport tube containing transport media (2.9 mL)
- Package of Patient Information Sheets/Patient-Collection Instructions

Warnings And Precautions:

- A. For *in vitro* diagnostic use.
- B. Do not apply the transport medium directly to skin or mucous membranes or take internally.
- C. Specimens may be infectious. Use Universal Precautions when handling specimens. Only personnel adequately trained in handling infectious materials should be permitted to handle specimens.
- D. Take care to avoid cross-contamination during the specimen handling steps. Specimens can contain extremely high levels of organisms. Ensure that specimen containers do not contact one another, and discard used materials without passing over open containers. If gloves come in contact with specimen, change gloves to avoid cross-contamination.
- E. If the contents of the transport tube are spilled at any time during the collection procedure, use a new APTIMA Vaginal Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results due to inadequate specimen volume.
- F. Maintain proper storage conditions during specimen shipping to ensure the integrity of the specimen. Specimen stability under shipping conditions other than those recommended has not been evaluated.

Specimen Collection and Storage Conditions

Vaginal swab specimens must be transported to the laboratory in the provided swab specimen transport medium and tube. Vaginal swab specimens must be transported to the laboratory at 2° to 30°C and tested within 60 days of collection.

Note: Federal requirements for packaging must be met when specimens are transported by common land and air carriers. Refer to 42 CFR, Part 72. The most current requirements may be obtained from the Centers for Disease Control and Prevention Office of Health and Safety in Atlanta, Georgia at 404-636-3883.

Instructions for vaginal swab specimen collection:

NOTE:

If using the Patient Self-Collection method, ensure that patients read the Patient Information Sheet/Patient-Collection Instructions (available with collection kit) before providing them with a collection kit.

1. Partially peel open the swab package. Do not touch the soft tip or lay the swab down. If the soft tip is touched, the swab is laid down, or the swab is dropped, use a new APTIMA Vaginal Swab Specimen Collection Kit.
2. Remove the swab.
3. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft.
4. Carefully insert the swab into the vagina about two inches past the introitus and gently rotate the swab for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab.
5. Withdraw the swab without touching the skin.
6. While holding the swab in the same hand, unscrew the cap from the tube. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new APTIMA Vaginal Swab Specimen Collection Kit.
7. Immediately place the swab into the transport tube so that the tip of the swab is visible below the tube label
8. Carefully break the swab shaft at the scoreline against the side of the tube and discard the top portion of the swab shaft. Do not spill the contents of the tube. If the contents of the tube are spilled, use a new APTIMA Vaginal Swab Specimen Collection Kit.
9. Tightly screw the cap onto the tube.

Limitations

- A. Vaginal swab sampling is not designed to replace cervical exams and endocervical samples for diagnosis of female urogenital infections. Patients may have cervicitis, urethritis, urinary tract infections, or vaginal infections due to other causes or concurrent infections with other agents.
- B. Women who have symptoms suggesting pelvic inflammatory disease (PID) should not use the patient-collected vaginal swab specimen as a replacement for a pelvic exam.
- C. The performance of vaginal swab specimen has not been evaluated in pregnant women.
- D. The performance of vaginal swab specimen has not been evaluated in teenage women less than 16 years of age.
- E. The patient-collected vaginal swab specimen application is limited to health care facilities where support/counseling is available to explain the procedures and precautions.

Vaginal Swab Specimen Performance

The assay performance characteristics of the vaginal swab specimen are provided in the appropriate APTIMA Assay package insert. The APTIMA Assay package inserts may be referenced on-line at www.gen-probe.com.

***** NOTES *****