Specimen Collection Manual

9. Specimens for Histology (Tissue) Examination

10. Autopsy Cases

11. Molecular

12. Attachments

13. References

2. Scope

The purpose of this manual is:

- to provide instruction on the collection and submission of specimens for processing;
- to help ensure that optimal specimens and information are obtained for accurate and timely diagnosis;
- to save patients the unnecessary costs of repeated tests.

Detailed information is provided regarding specimen requirements, specimen collection and labeling, and data management. If you cannot find the answer to your questions in the manual, please call the laboratory.

Tests desired by clients that are not performed at Opus Pathology are referred to qualified, licensed reference laboratories chosen for the quality of service provided including, but not limited to, accuracy, reliability, turnaround time, and range of services offered.

Opus Pathology strives to maintain a reputation for quality, innovation, and dependability, and we welcome comments and suggestions to further that effort.

3. Intended Use

This manual is distributed by marketers and client services personnel to all physician's offices, hospitals, and surgical centers utilizing Opus Pathology's laboratory services.

4. Preface

4.1 Pathology Staff

- Danielle C. Gibson, M.D., Laboratory Medical Director
- Estelle E. May, M.D., Laboratory Technical Supervisor, Clinical Consultant
- John R. Olson, M.D.
- Charles B. Bramlett, M.D.
- Joseph C. Moore, M.D.
- Albert C. Domm, M.D.
- Alan S. Boyd, M.D.
- Jeffrey Zwerner, M.D.
- Alexander Thurman, M.D.
- Melissa Chiles, MD
- Solomon Lee, DO
- Mayuko Imai, MD
- Nihar Hotchandani, MD

4.2 Phone Numbers / Hours of Operation

1. **Columbia**
   - Main Number: 931-490-1000
     1-800-388-1294
   - Laboratory Fax: 931-381-7002
   - Billing Fax: 931-388-1548

2. **Pathologist** After Hours (Ask to Have Pathologist Called)
   - 931-381-1111
3. Hours of Operation – 8am – 5:00pm central time

4.3 Laboratory Accreditations

1. Columbia, TN
   a. College of American Pathologists; Laboratory #2973901
   b. U.S. Department of Health and Human Services; CLIA #44D0659433
   c. State of Tennessee Department of Health; #0000002030

5. Laboratory Services

5.1 Results and Reports

1. Results of all tests are entered into the laboratory information system as they are completed.
2. The reports are generated from the laboratory information system and are sent to the client via their choice of:
   a. Courier
   b. Mail
   c. Fax
   d. Interface
3. The Client Services Department has been designed in order to give physicians, nurses, and office personnel, as well as hospital-based pathologists and laboratory personnel, a central location to call for report results and/or status.
4. Our Client Services Department is available to access specific reports and facilitate communication between our physician clients and the pathologists. Slide requests are also handled in this department.

5.2 Test Methodologies

1. Upon request, the laboratory will provide clients with a list of current test methods, including performance specifications.
2. When the laboratory changes an analytic methodology, reagents, reference ranges, or anything else which may significantly impact patient test results or their interpretation, the change is communicated and explained through the use of direct mailings or as part of the test report itself.

5.3 Special Tests, Either Performed In-House or Sent to a Referral Lab

Special tests are also available and include:

a. Cytogenetic Studies
b. Flow Cytometry
c. Fine Needle Aspiration Biopsy and Interpretation
d. Immunohistochemistry
   (Including Estrogen/Progesterone Receptors and HER-2/neu Studies)
e. Immunofluorescence
f. Stone Analysis
g. FISH Studies (Solid Tumor or Hematopathology)
h. COLOR Testing

5.4 Ordering Supplies

1. All clients will be supplied with specimen containers, fixative, bags for submitting specimen containers, and requisition forms.
2. We have a wide selection of supplies to fit each specimen requirement.
3. Complete an Opus Pathology Supply Requisition form including:
   a. Location/Clinic Name
   b. Address
   c. Phone Number
   d. Date of Order
   e. Contact Person
   f. The Amount of Each Supply Needed
4. Place the supply requisition form in the courier pick-up box or fax it to the laboratory.
5. Our policy is to fill all supply requests within 48 hours. If you need the supplies sooner, please call the laboratory and we will make every effort to meet your needs.

6. Compliance with Federal and Regulatory Agencies

6.1 Commitment

1. Opus Pathology is committed to maintaining a culture which promotes prevention, detection, and resolution of instances of conduct that do not conform to:
   a. Federal and State Laws
   b. Regulatory Agency Requirements
   c. Federal, State, and Private Payer Health Care Program Requirements
   d. The Laboratory's Ethical and Business Policies
2. As part of this commitment, physicians are notified of all requirements.
3. Opus Pathology will update physicians as to changes in the medical necessity and billing compliance requirements relating to services offered by Opus Pathology in order to protect both the physician and the laboratory.

6.2 Test Ordering and Specimen Submission

1. Federal and state statutes and regulations and hospital policy define who may order and receive the result of a laboratory test.

2. Only a person fulfilling one of the following criteria may order and/or receive the result of a laboratory test in Tennessee:
    a. A medical doctor physician, who holds the M.D. degree and who is licensed to practice medicine and surgery.
    b. An osteopathic physician (osteopath), who holds the D.O. degree and who is licensed to practice medicine and surgery.
    c. A dentist (or dental specialist, e.g., an oral surgeon) who holds the D.D.S. or D.M.D. degree and who is licensed to practice dentistry.
    d. A nurse practitioner, physician's assistant or physician extender employed by a hospital or working under the direction of a medical doctor.
    e. A chiropractic physician licensed to practice chiropractics.
    f. An optometrist licensed to practice optometry.
    g. A podiatrist licensed to practice podiatry.
3. A nurse may not order a test or receive test results (exception, the nurse may receive test results for a physician).

6.3 Specimen Rejection Policy

1. It is our policy at Opus Pathology to meet all regulatory agency guidelines and to provide the best patient care possible. To do so we must enforce the following procedures:
    a. All requisitions must have the patient's name, tissue type, and all available clinical history.
    b. All specimen containers must be labeled with the patient's name, a second unique patient identifier (e.g., date of birth, social security number, etc.) and the tissue type.
    c. All slides, smears, and frozen section specimens must be received with the patient's name and a second unique patient identifier (e.g., accession number, date of birth, social security number, etc.).
2. The above procedures must be followed, otherwise processing of the specimen may be delayed while we attempt to obtain the required information; the requisition and specimen may be returned to you for appropriate identification.
3. Additionally, specimens may be rejected when:
    a. slides are broken beyond repair.
    b. a specimen is received in a syringe with an attached needle.
    c. the names on the specimens and requisitions do not match.
    d. the specimen is submitted in expired fixative.
    e. insurances are not accepted by Opus Pathology

6.4 Verbal Orders

1. Any additional testing which is verbally requested must be followed up with a "Additional Test Order Form" within 30 working days in order to comply with regulatory requirements.

6.5 Medical Necessity and Advanced Beneficiary Notice (ABN)

1. Laboratories can submit claims to federally funded health programs only for services considered medically necessary.

2. An ICD-10 code should be submitted with all orders substantiating the medical necessity of the testing.
3. The ABN gives the patient advance notice that Medicare will not pay for the procedure.

6.6 Reportable Diseases

1. Tennessee laws require the reporting of certain diseases to public health officials.
2. Complete reporting of all communicable diseases recognized within the hospital or medical practice requires the cooperative effort of nursing personnel, laboratory personnel, and the infection control practitioner, in conjunction with the monitoring efforts of the infection control committee.
3. See attachment 1 for a listing of reportable diseases in Tennessee.

7. Overview of Cytology, Histology, and Molecular Specimens

7.1 General Information

1. Once removed from the patient, specimens must be immediately preserved to avoid deterioration.
2. See the following list for guidance in determining which section of this manual to refer to for appropriate instructions:
   a. Cytology
      - Body Fluids
      - Breast Fluids
      - Cervical/Vaginal Smears
      - CSF (Spinal Fluid)
      - Fine Needle Aspiration (FNA)
      - Sputum
      - Urine
   b. Histology
      - Breast Biopsy
      - Cervical/ECC Biopsies
      - Endometrial Biopsies
      - Gastrointestinal Biopsies
      - Prostate Biopsies
      - Vas Deferens
      - Skin Biopsies
      - Other Tissue Specimens
   c. Molecular
      - STI Testing
      - HPV Testing
      - Vaginitis Testing

7.2 Labeling

1. Always verify the identification of the patient by asking their name.
2. If glass slides are being submitted, label the slide(s) with the patient's name and a second unique identifier (e.g., date of birth, social security number, etc.).
3. Label the primary specimen container, not the lid, with the patient's first and last name, a second unique patient identifier (e.g., date of birth, social security number, etc.) and the tissue type.
4. If there are multiple specimens, place each specimen in a separate container and clearly note the specimen type/source in addition to the patient name and second patient identifier.

7.3 Requisitions

1. Each specimen submitted must be accompanied by an Opus Pathology requisition form.
2. We know that proper and timely billing of your patients is one of your concerns. In order for us to accomplish this task, we must have accurate patient information legibly written on the requisition accompanying the specimen. Please include the following:
   a. Complete patient name as it appears on the primary insurance card.
   b. Complete address of the patient.
   c. Patient's date of birth and social security number.
   d. Guarantor's name if other than the patient.
   e. Complete insurance information. A copy of the patient's insurance card(s), front and back, attached to the requisition is best.
   f. Appropriate ICD-10 Code.
   g. Patient's clinical history. This is a regulatory requirement because of the importance in aiding accurate diagnosis.
   h. Requesting physician's first and last name (circle the appropriate choice if multiple physician names appear on the requisition).
   i. Specimen type and source.
   j. Specimen collection date.
   k. The procedures or special tests desired.
3. If the above information is not complete and legible, processing of the specimen may be delayed while we contact your office by phone or fax to obtain the required information.

7.4 Specimen Packaging

1. Secure container lid so that there is no leaking and seal the container in a "biohazard bag".
2. Place the requisition in the outer pocket of the bag.

7.5 Courier Services

1. When specimens are ready to be picked up, place in the designated area for courier pick-up.
2. If your office is not on a regular pick-up schedule, call the laboratory to request a courier pick-up.

3. Call the laboratory if you have a specimen which requires immediate pick-up in order to maintain specimen integrity (such as fresh tissue). If you have prior knowledge of such needs, it is preferable to give Opus Pathology 24-hour notice of such special needs.

8. Specimens for Cytology Examination

8.1 Submitting Specimens to the Laboratory

1. All cytology specimens should be submitted to the laboratory as soon as possible after collection. Once removed from the patient, specimens should be immediately fixed in CytoLyt at 2:1 ratio (2 parts specimen to 1 part CytoLyt) to avoid deterioration. Delay in submission results in deterioration of unfixed specimens. If delay is unavoidable (more than 1 hour), please refrigerate specimens until they are picked-up.
2. All cytologic examinations are submitted on Opus Pathology requisition forms.
3. The specimens should be labeled with the patient's first and last name, a second unique patient identifier (e.g., date of birth, social security number, etc.) and the source of the specimen.
4. All cytology specimens should be submitted in CytoLyt preservative with the exception of body fluids collected in large vacuum drainage bottles and synovial fluids.
5. **Do not add Carbowax Fixative (Saccomano's Fluid) to a cytology specimen.**
6. If questions arise as to how a cytology specimen should be handled and you cannot find the answer within this manual, call the laboratory.

8.2 Body Cavity Fluids (Pleural, Peritoneal, and Pericardial)

1. Equipment Needed:
   a. Clean Container
   b. Opus Pathology Requisition
2. Perform tap.
3. If specimen is collected in large vacuum drainage bottles, it does not need to be fixed.
4. Have the specimen delivered immediately to the laboratory. If there is a delay, it should be refrigerated or a portion of CytoLyt solution (30 ml) should be added to the specimen.
5. The laboratory does not accept syringe needles. Flush the barrel of the needle into the specimen container, using the proper preservative, and dispose of the needle into a Sharps container.

8.3 Urine

1. A voided urine specimen should be obtained after the patient has been well hydrated and approximately three hours after the last void. **Do not submit the first morning void for cytology**.

2. Clean catch samples are necessary. Female patients should be instructed to spread the labia during collection. A small amount of urine is to be passed and discarded, and the remainder of the sample collected. Males should be instructed to pass and discard a small amount of urine and then collect the specimen.
3. If the patient is unable to cooperate satisfactorily, a catheterized specimen should be obtained. Method of collection should be stated on the request form. Fifty ml is a sufficient sample. **Do not submit 24 hour collection for cytology**. This is unsatisfactory because of cellular degeneration.
4. Fix the specimen at a 2:1 ratio (2 parts specimen to 1 part CytoLyt).

8.4 Sputum

1. The sample is collected in a wide mouth plastic container.
2. The preferred specimen is that produced by a deep cough as soon as the patient awakens in the morning. The patient should be asked to rinse his mouth with water before coughing. If sputum production is scanty, several coughs over a period of 2 to 3 hours may be necessary to produce a sufficient sample.
3. Add 30 ml of CytoLyt and have the specimen delivered to the laboratory as soon as collection is completed.
4. If three consecutive specimens are to be collected, all three specimens can be delivered on the third day of collection.

8.5 Cerebrospinal Fluid

1. The specimen for cytologic examination should be collected in a separate container.
2. As large a volume as possible should be submitted.
3. For cytology specimens, specimen should be submitted in CytoLyt.
4. Any portion of the specimen collected for cultures or clinical testing should be collected fresh, refrigerated, and sent to appropriate clinical laboratory.

8.6 Breast Fluids

1. Material may be obtained either from secretions expressed from the nipple or by aspiration of cystic lesions.
2. **Nipple Secretions**
   a. Equipment:
      - Glass Slides (Available from the Laboratory)
      - 95% Alcohol or Spray Fixative
   b. Express material from nipple by gentle compression of the areolar area between thumb and finger.
   c. Material is expressed directly onto the glass slide and gently spread over its surface.
   d. The slide is immediately spray fixed.
   e. Do not allow drying to occur.
   f. If secretion appears when pressure is applied to a particular area, it is advisable to note this on the request form and prepare a specially identified slide from this material. This may be helpful in guiding future biopsy.

g. Cellularity tends to increase with each expression and 4-6 slides should be made.

8.7 Cyst Aspirations

1. Most breast cyst fluids do not need cytologic examination.
2. Submit the cyst fluid if:
   - the cyst is recurrent.
   - the fluid appears bloody (brownish fluid suggestive of old bleeding, not fresh blood due to the procedure).
   - the patient is postmenopausal and not on hormonal replacement therapy.
3. Add CytoLyt to specimen (2:1 ratio – 2 parts specimen to 1 part CytoLyt).

8.8 Fine Needle Aspiration (FNA) Biopsy

1. Clinicians should have experience to perform FNA's in their offices. Lack of experience often results in inadequate or insufficient specimens.
2. Fine needle aspiration of palpable lesions and fat aspiration for the detection of amyloid are offered by Opus Pathology physicians who have subspecialty training and expertise in these areas. To obtain more information or to schedule an FNA call the laboratory. Patients having FNA's performed at a hospital by Opus Pathology physicians will incur hospital charges.
3. Equipment:
   a. Glass Slides
   b. 22, 25 or 27 Gauge Needles
   c. Aspiration Gun and Syringe to Fit in Gun
   d. Alcohol Swabs
   e. Cotton 4 x 4 Gauze Pads
   f. Spray Fixative
4. The lesion is localized by palpation. The lesion must be easily palpable to obtain an adequate specimen.
5. A needle can be used alone or attached to a syringe, which can be attached to aspiration gun if desired.
6. Inspire air into syringe to ensure adequate suction, if using a syringe. Leave a small amount of air in syringe before aspiration.
7. Localize and stabilize the lesion with one hand. Clean skin with alcohol swab.
8. Insert needle into lesion with opposite hand and apply suction.
9. Move the needle rapidly back and forth in the lesion while changing the direction of the needle. Continue until material is evident in the needle hub.
10. Release suction before withdrawing the needle.
11. Withdraw needle and have patient or assistant apply pressure to puncture site with cotton gauze.
12. Prepare smears by placing a small drop of material near the labeled end and smearing with another slide.
13. Prepare both fixed and unfixed smears from each pass.
    a. Fixed smears must be immediately spray fixed.
    b. Unfixed smears are air-dried.

c. Material remaining in the needle hub after preparation of the smears can be rinsed into a container of CytoLyt labeled with the patient's name.

14. Repeat aspiration 3 times to ensure that an adequate specimen has been obtained.
15. Label slides with the patient's first and last name, whether fixed or air-dried, and the site of specimen (e.g., left breast).
16. Complete a Opus Pathology cytology requisition form. Indicate that the specimen is an FNA and specify the site aspirated, the clinical impression, and all pertinent clinical history.

8.9 Cytology Specimen Reference Chart

Specimen	Fixative Agent	Special Instructions
Brushings, Bronchial and Gastric	Cut unsheathed brush off and submit in Cytolyt or Preservcyt	
Washings	Add CytoLyt 2:1 ratio	2 parts specimen:1 part CytoLyt
Urine	Add CytoLyt 2:1 ratio	2 parts specimen:1 part CytoLyt
Sputum	Early morning collection, 3 consecutive mornings (may be collected in same container). Add CytoLyt 2:1 ratio	2 parts specimen:1 part CytoLyt
Cerebrospinal Fluid	Add CytoLyt 2:1 ratio	2 parts specimen:1 part CytoLyt
Fine Needle Aspiration	Make two smears per pass. Spray one immediately with fixative and let other smear air-dry.	Needle may be rinsed in Cytolyt and submitted for ThinPrep and cell block processing.

8.10 ThinPrep Pap Test

1. Patient Guidelines
   a. Clinicians should have experience to perform FNA's in their offices. Lack of experience often results in inadequate or insufficient specimens.
   b. 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.
   c. The patient should not use vaginal medication, vaginal contraceptives, vaginal creams, vaginal jellies, or douches during the 48 hours before the exam.
   d. The patient should refrain from intercourse 48 hours prior to the exam

2. Collection Guidelines – Endocervical brush/spatula
    a. 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).
    b. 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. Select the contoured end of the plastic spatula and rotate it 360 degrees around the entire ectocervix, while maintaining tight contact with ectocervical surface.
    c. Rinse the spatula as quickly as possible into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times.
    d. 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.
    e. 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.
    f. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
3. Collection Guidelines – Broom-like Device
    a. 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. 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
    b. 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.
    c. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
4. Storage Guidelines
    a. Store PreservCyt Solution without cytologic samples at 15°C to 30°C (59°F to 86°F). Do not use PreservCyt Solution beyond the expiration date marked on the vial.

9. Specimens for Histology (Tissue) Examination

9.1 Submitting Specimens to the Laboratory

1. Tissue specimens submitted to the laboratory must meet certain requirements before they will be accepted for examination. If you have questions about the collection of histology specimens not answered in this manual, please call the laboratory.

2. All specimens are to be placed in containers with lids tightly secured to prevent leaking.
3. The containers (not the lids) are to be labeled with the patient's first and last name, a second unique patient identifier (e.g., date of birth, social security number, etc.) and specimen source.
4. Multiple specimens should be placed in separate containers with each source clearly identified in addition to the patient's name and a second patient identifier.
5. Most tissue specimens are submitted in formalin, which contains formaldehyde. Use caution when handling, as formaldehyde is toxic if inhaled or swallowed, and can be irritating to the eyes, respiratory system, and skin; there is a risk of serious damage to the eyes. It also has possible carcinogenic potential.
6. A formalin warning label must be attached to the container. Most containers are pre-labeled by the factory before use. If a pre-labeled container is not used, please identify the solution on the specimen container (e.g., formalin, glutaraldehyde, saline, etc.).

9.2 Routine Specimen Requisition Slips

1. Routine specimens must be accompanied by a Opus Pathology requisition form.
2. The requisition must be completed as outlined previously, including the following information:
   a. to the degree known, any preoperative and postoperative diagnoses.
   b. pertinent clinical information.
   c. the specimen source, listed numerically if multiple specimens are submitted.

9.3 Routine Tissue Fixation and Transport to the Laboratory

1. Place routine tissue specimens in a properly labeled container that contains 10% formalin solution.
2. The size of the container should be proportionate to the size of the specimen, so that the formalin:tissue ratio is approximately 20:1.
3. Place the specimen in a biohazard bag and place the requisition in the pouch of the bag.
4. Notify the laboratory of the need for a pick-up, if your clinic is not on a regular pick-up schedule.

9.4 Intra-Operative Tissue Consultations (Frozen Sections)

1. Call the laboratory to notify the pathologist when services are needed.
2. Label the specimen containers as described above.
3. Complete a Opus Pathology requisition as previously instructed, including the following information:
   a. clinical history/preoperative diagnosis.
   b. tissue removed; listed in numerical order if multiple.
   c. any special instructions/information.

9.5 Bone Marrow

1. Aspirate 10.0 ml of bone marrow into the first syringe, which is to be used for bone marrow smears, clot section, flow cytometry, and cytogenetics. If additional bone marrow is required for special studies, such as additional flow cytometry,

cytogenetics, FISH and culture, then employ a second syringe to obtain the larger amounts of bone marrow.

2. Submit the aspirate for morphologic evaluation in a purple top (EDTA) tube, and smears will be prepared at our lab. Be sure to clearly label the tube as "aspirate", so it is not confused with a tube of peripheral blood.
3. An EDTA (purple top) tube of peripheral blood should always be simultaneously submitted, or alternatively, 2 unstained peripheral smears and the results of a recent CBC are to be submitted. Be sure to clearly label the tube as "peripheral blood".
4. Bone marrow core biopsies are to be submitted in formalin.

9.6 Bone Marrow Aspirate for Cytogenetic Studies

1. Preferred Method of Collection:
   a. Collect sample in syringe and quickly but gently discharge into two sodium heparin green top tubes.
2. If aspirate is suboptimal (clotted, small sample, marrow is packed), also submit:
   a. Bone marrow core biopsy: One or more trephine needle samples (10 mm) collected in sterile transport medium. Note that the specimen is for cytogenetics along with name and source.
   b. Peripheral blood: 3-6 ml in sodium heparin green top vacuum tube. Note that the specimen is for cytogenetics, along with "peripheral blood" and patient name.
3. Sterile transport medium may be obtained from Opus Pathology.
4. Complete the Opus Pathology requisition, including clinical data and diagnostic information.
5. Maintain specimen at room temperature and call Opus Pathology for immediate pick-up of specimen. Opus Pathology will forward specimen to the appropriate laboratory.

9.7 Bone Marrow Aspirate for Flow Cytometry

1. Bone marrow aspirate is collected in a sodium heparin tube (green top) and immediately mixed well. Do NOT use lithium sodium tubes. An EDTA tube (purple top) may also be submitted.
2. Store bone marrow sample at 20º to 30º C (room temperature). **Do not refrigerate.**
3. If RPMI solution is available, 1-2 ml of the aspirate sample can be added to the RPMI at the time of the procedure.
4. Specimens must be received in the laboratory as quickly as possible after collection. Call for a special STAT pick-up. Monday-Friday. Specimens must be picked up by 5:00 p.m.

9.8 Stone (Calculus) Analysis

1. Air-dry the stone and place in a clean, dry container (such as a sterile urine container). Stones transported in liquid or bound up in tape interfere with and delay analysis, compromising results.
2. Label as instructed and submit with completed requisition.
3. Opus Pathology will forward specimen to the appropriate laboratory.

9.9 Specific Specimen Requirements

1. The following specimens should be received fresh and require **immediate** processing. Contact the laboratory for instructions.
   a. *Diagnostic Lymph Node Biopsies* – must be received fresh.
   b. *Breast Biopsies* – must be received fresh for frozen section study; otherwise, place in formalin. The time that the specimen was removed from the patient and the time that it was placed in formalin must be documented on the requisition.
   c. *Products of Conception* – submit a portion fresh in sterile saline if cytogenetic testing is needed; otherwise, place in formalin.
   d. *Tissue Biopsies for Immunofluorescence* – must be received fresh in saline, or immediately placed in Michel's transport solution.
   e. *Tissue for Electron Microscopy* – must be received fresh in saline or immediately placed in 2% glutaraldehyde (tissue fragments must be 1 mm or smaller).

9.10 Muscle and Nerve Biopsies

1. Fresh muscle should be divided into three portions: approximately half for histochemistry, half for routine paraffin-embedded light microscopy, and a few small pieces for electron microscopy.
2. For histochemistry, the specimen should be sent to Vanderbilt Pathology Laboratory Services (VPLS) in the fresh state. The following guide should be followed.
   a. The muscle specimen must be transported to VPLS **within four hours** of removal from the patient. The specimen should be carefully wrapped in a saline-moistened (not soaked or wet but only moist) gauze. The specimen in the moist gauze should be placed inside a plastic Petri dish, securely closed with tape, and sent on regular ice (not dry ice). The shipping container should be marked to indicate that this is perishable material.
3. For routine microscopy, muscle is placed in 10% buffered formalin and sealed for shipping.
4. For electron microscopy, 3-6 small (1 mm cube) pieces are placed in 2% glutaraldehyde and sealed for shipping. Any commercial or "routine" fixative for EM is used; if this is not available, please notify VPLS and EM fixative will be provided for you.
5. For nerve biopsies a small portion of fresh nerve is placed in glutaraldehyde for electron microscopy as described above. The remainder is pinned on a small wooden blade or stick, placed in buffered formalin in a small screw-top bottle, and sealed for shipping.

Contact Information:

VUMC Neuropathology
1161 21st Avenue South
C-2318 MCN
Nashville, TN 37232-2561
615-322-3998

Questions regarding account and shipping information should be addressed to **Tom Peters**, 615-936-0510 or 1-800-551-5227, extension 4.

Technical questions should be directed to the Division of Neuropathology, 615-322-3998 or 1-800-551-5227, extension 8

9.11 Electron Microscopy

1. Applies to brain biopsy, cardiac biopsy, endocrine tumors, kidney biopsy, muscle biopsy, nerve biopsy, and needle aspiration cytology.
2. A major application of electron microscopy is to define tumor classification, when light microscopy is equivocal and when proper therapy and prognosis depend on accurate diagnosis.
3. The specimen should consist of fresh unfixed tissue.
4. The specimen must be submitted fresh in normal saline or immediately placed in glutaraldehyde (within two minutes after removal from the patient).
5. The sample should be minced into cubes 1 mm or less and placed in a container of glutaraldehyde of sufficient quantity to cover the specimen entirely.

9.12 Histology Specimen Reference Chart

Specimen	Fixative Agent	Special Instructions
Routine Pathology	10% buffered formalin.	Place specimen and requisition to appropriate area for pick up and document required information in appropriate log book.
Frozen Section	No fixative; saline to keep specimen moist.	Call the laboratory 15 minutes before frozen section is to be performed. Take specimen immediately to Pathology with requisition.
Tagged Specimen	Frozen Section – no fixative. Permanent – 10% buffered formalin.	Note the tag locations on the requisition. Follow appropriate protocol.
Stat Gram Stain Culture	Culture tube (taken in the OR if possible).	Place specimen in plastic bag and forward to laboratory.
Breast Needle Localization	Frozen Section – no fixative. Permanent – 10% buffered formalin.	Follow appropriate protocol.
Breast Sentinel Node Biopsy	Frozen Section – no fixative. Permanent – 10% buffered formalin.	Follow appropriate protocol.
Lymphoma Study	Do not immerse in formalin.	Call Pathology and take labeled specimen and requisition immediately to Pathology.
Testicular Study	Call Pathology	Call Pathology and take labeled specimen and requisition immediately to Pathology.
Nerve Biopsy	Call Pathology	Call Pathology 24 hours in advance of procedure.
Muscle Biopsy	Call Pathology	Call Pathology 24 hours in advance of procedure.
Liver Biopsy for Quantitative Iron Study	No fixative.	Place labeled specimen in iron-free container and forward to Pathology immediately along with requisition.

10. Autopsy Cases

10.1 General Information

1. The on-call pathologist for Opus Pathology (931-490-1000) arranges autopsies on patients in the hospital system to be performed by Forensic Medical Nashville (850 R. S. Gass Boulevard, Nashville, TN 37216; phone 615-743-1800; Fax 615-743-1890).

2. See ‘Attachment 2’ for the following:
    a. Who is authorized to give permission for an autopsy.
    b. The types of autopsies performed by Tennessee law.
    c. Details regarding Medical Examiner cases.

11. Molecular

11.1 Submitting Specimens to the Laboratory

1. All molecular specimens should be submitted to the laboratory as soon as possible after collection.
2. All molecular examinations are submitted on Opus Pathology requisition forms.
3. If questions arise as to how a molecular specimen should be handled and you cannot find the answer within this manual, call the laboratory.

11.2 Aptima Multitest Swab Collection Guidelines

1. General Guidelines
    a Use the provided swab only. Failure to use the provided swab may invalidate the test results.
    b Do not apply the Specimen 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 pathogens. Ensure that specimen containers do not contact one another, and discard used materials without passing over the 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 Multitest Swab Specimen Collection Kit. Failure to use a new kit may invalidate the test results.
    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.
    g Do not use the kit after its expiration date to collect specimens. Note: Hazard communication information for labeling of globally marketed products reflects the US and EU Safety Data Sheets (SDS) classifications. For hazard communication information specific to your region, refer to the region specific SDS on the Safety Data Sheet Library at www.hologicsds.com
2. Kit Storage Requirements
    a. Store collection kit at room temperature (15°C to 30°C).
3. Vaginal Swab Specimen Collection and Handling
    a. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
    b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.

c. Carefully insert the swab into the vagina about 2 inches (5 cm) past the introitus and gently rotate the swab clockwise for 10 to 30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin.
d. 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 Multitest Swab Specimen Collection Kit.
e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
f. Carefully break the swab shaft at the score line against the side of the tube.
g. Immediately discard the top portion of the swab shaft. 8. Tightly screw the cap onto the tube.

4. Penile Meatal Swab Specimen
   a. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
   b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
   c. Roll the swab clockwise on the tip of the penis, outside the opening of the penis (hole through which urine is passed). It is not necessary to put the swab inside the opening of the penis. Make sure to roll the swab all the way around the opening of the penis to get the best sample. Ensure the swab does not touch any other area of the skin.
   d. 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 Multitest Swab Specimen Collection Kit.
   e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
   f. Carefully break the swab shaft at the score line against the side of the tube.
   g. Immediately discard the top portion of the swab shaft.
   h. Tightly screw the cap onto the tube.
5. Lesion Swab Specimen Collection and Handling
   a. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection kit.
   b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
   c. If needed, expose the base of the lesion to access fluid.
   d. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion.
   e. 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 Multitest Swab Specimen Collection kit.
   f. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
   g. Carefully break the swab shaft at the score line against the side of the tube.

h. Discard the top portion of the swab shaft.
i. Tightly screw the cap onto the tube.

6. Rectal Swab Specimens Collection and Handling
   a. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
   b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
   c. Carefully insert the swab into the rectum about 1-2 inches (3-5 cm) past the anal margin and gently rotate the swab clockwise for 5 to 10 seconds. Withdraw the swab without touching the skin.
   d. 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 Multitest Swab Specimen Collection Kit.
   e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
   f. Carefully break the swab shaft at the score line against the side of the tube.
   g. Immediately discard the top portion of the swab shaft.
   h. Tightly screw the cap onto the tube.
7. Throat Swab Specimens Collection and Handling
   a. Partially peel open the swab package. Remove the swab. 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 Multitest Swab Specimen Collection Kit.
   b. Hold the swab, placing your thumb and forefinger in the middle of the swab shaft covering the score line. Do not hold the swab shaft below the score line.
   c. Carefully insert the swab into the throat ensuring contact with bilateral tonsils (if present) and the posterior pharyngeal wall, then withdraw the swab without touching the inside of the cheeks or tongue.
   d. 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 Multitest Swab Specimen Collection Kit.
   e. Immediately place the swab into the transport tube so that the score line is at the top of the tube.
   f. Carefully break the swab shaft at the score line against the side of the tube.
   g. Immediately discard the top portion of the swab shaft.
   h. Tightly screw the cap onto the tube.
8. Specimen Transportation and Storage
   a. Multitest swab specimens must be transported to the laboratory in the provided swab specimen transport medium and tube.
   b. Refer to the appropriate Aptima assay for proper specimen storage conditions. Note: Specimens must be shipped in accordance with applicable national and international regulations.

11.3 Urine Specimen Collection Guidelines

1. General Guidelines
   a. Do not apply the transport medium directly to skin or mucous membranes or take internally.
2. Kit Storage Requirements
   a. Store collection kit at room temperature (15°C to 30°C).
3. Specimen Collection and Handling
   a. The patient should not have urinated for at least 1 hour prior to specimen collection.
   b. 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 rRNA target dilution that may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen.
   c. 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.
   d. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.
4. Specimen Transportation and Storage
   a. After collection, transport the processed urine specimens in the Aptima urine specimen transport tube at 2°C to 30°C and store at 2°C to 30°C until tested.
   b. Processed urine specimens should be assayed with the Aptima assay within 30 days of collection. If longer storage is needed, refer to the appropriate Aptima assay package insert.
   c. 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 30°C and test within 30 days of collection.

11.4 HPV Testing

1. Usage
   a. To screen women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy. The results of this test are not intended to prevent women from proceeding to colposcopy.
   b. In women 30 years and older, the Aptima HPV assay can be used with cervical cytology to adjunctively screen to assess the presence or absence of high-risk HPV types. This information, together with the physician’s assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management.
2. Approved Specimens for HPV Testing
   a. Clinician-collection PreservCyt Solution liquid Pap specimens with broom-type or cytobrush/spatula collection devices.

3. Approved Collection Kits
    a. Hologic Broom Type
    b. Hologic cytobrush/spatula
4. Expiration Dates
    a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility. Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
    b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
    a. Transport the ThinPrep liquid cytology specimens at 2°C to 30°C.
    b. Specimens should be transferred to an Aptima Specimen Transfer tube within 105 days of collection. Specimens will be transferred at Opus Pathology.
    c. Prior to transfer, ThinPrep liquid cytology specimens should be stored at 2°C to 30°C, with no more than 30 days at temperatures above 8°C.
    d. ThinPrep liquid cytology specimens transferred to an Aptima Specimen Transfer tube may be stored at 2°C to 30°C for up to 60 days.
    e. If longer storage is needed, the ThinPrep liquid cytology specimen or the ThinPrep liquid cytology specimen diluted into the Aptima Specimen Transfer tube may be stored at -20°C to -70°C for up to 24 months.

11.5 Chlamydia Trachomatis and/or Neisseria Gonorrhoeae Testing (CT/GC Assay)

1. Usage
    a. Tests for Chlamydia Trachomatis and/or Neisseria Gonnorhoeae in symptomatic and non-symptomatic patients.
    b. The performance of the test has not been evaluated in adolescents less than 14 years of age.
2. Approved Specimens for CT/GC Testing
    a. Clinician-collected endocervical, vaginal, throat, rectal, and male urethral swab specimens.
    b. Female and male urine specimens.
    c. Clinician-collection PreservCyt Solution liquid Pap specimens.
3. Approved Collection Kits
    a. Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens.
    b. Aptima Urine Collection Kit for Male and Female Urine Specimens.
    c. Aptima Multitest Swab Specimen Collection Kit for Vaginal, Throat, and Rectal Swab Specimens.
    d. ThinPrep Vial for Clinician-collected Pap specimen.
4. Expiration Dates
    a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility. Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the

package insert, are valid for testing even if the expiration date on the collection tube has passed.

b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.

5. Specimen Storage Before Testing:
   a. Urogenital Swab Specimens
      - 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 Combo 2 assay within 60 days of collection. If longer storage is needed, freeze urogenital specimens in the swab specimen transport tube within 7 days of collection at -20°C to -70°C to allow testing up to 12 months after collection (see *Specimen Stability Studies*).

   b. Extragenital Swab Specimens (Throat and Rectal)
      - After collection, transport and store the swab in the swab specimen transport tube between 4°C and 30°C, or -20°C and -70°C until tested. Specimens must be assayed with the Aptima Combo 2 assay within 60 days of collection (see *Extragenital Specimen Handling and Stability Study)*.

   c. Urine Specimens:
      - Maintain urine specimen at 2°C to 30°C after collection and transfer to the Aptima urine specimen transport tube within 24 hours of collection. Transport to the lab in the primary collection container or the transport tube at 2°C to 30°C. Store at 2°C to 30°C and test the processed urine specimens with the Aptima Combo 2 assay within 30 days of collection.
      - If longer storage is needed, freeze urine specimens in the Aptima urine specimen transport tube within 7 days of collection at -20°C to -70°C to allow testing up to 12 months after collection (see *Specimen Stability Studies*).

   d. PreservCyt Solution Liquid Pap Specimens:
      - PreservCyt Solution liquid Pap specimens intended for CT and/or GC testing must be processed for cytology and/or transferred to an Aptima Specimen Transfer tube at Opus Pathology within 30 days of collection when stored at 2°C to 30°C (see *Specimen Stability Studies*).
      - Once the PreservCyt solution liquid pap specimen is transferred to the Aptima specimen transfer tube, the specimen must be assayed with the Aptima Combo 2 assay within 30 days when stored at 2°C to 8°C, or 14 days when stored at 15°C to 30°C. If longer storage is needed, freeze specimen within 7 days of transfer to the Aptima specimen transfer tube at -20°C to -70°C to allow testing up to 12 months after transfer (see *Specimen Stability Studies*).

11.6 Bacterial Vaginosis Testing (BV Assay)

1. Usage
   a. The BV test is intended to aid in the diagnosis of BV using clinician-collected and patient-collected vaginal swab specimens from females with a clinical presentation consistent with vaginitis and/or vaginosis.

b. The performance of the test has not been evaluated in adolescents less than 14 years of age.

2. Approved specimens for BV Testing
   a. Clinician-collected vaginal swab specimens.
3. Approved collection kits
   a. Aptima Multitest Swab Specimen Collection Kit.
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration is expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. After collection, swab specimens in transport tubes can be stored at 2ºC to 30ºC for up to 30 days. If longer storage is needed, specimens may be stored at -20°C or -70°C for an additional 60 days.

11.7 Vulvovaginal Candidiasis and Trichomoniasis (CV/TV Assay)

1. Usage
   a. The CV/TV test detects and discriminates RNA markers from *Candida* species group (*C. albicans, C. tropicalis, C. parapsilosis, C. dubliniensis*), *Candida glabrata, and Trichomonas vaginalis* in clinician-collected and vaginal swab specimens from symptomatic females.
   b. The performance of the test has not been evaluated in adolescents less than 14 years of age.
2. Approved Specimens for CV/TV Testing
   a. Clinician-collected vaginal swabs.
3. Approved Collection Kits
   a. Aptima Multitest Swab Specimen Collection Kit for Vaginal Swab Specimens.
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. Swab Specimens
      - After collection, swab specimens in transport tubes can be stored at 2ºC to 30ºC for up to 30 days.
      - If longer storage is needed, swab specimens in transport tubes can be stored at -20ºC or -70ºC for an additional 60 days.

11.8 Trichomonas Vaginalis

1. Usage
   a. The Trichomonas vaginalis tests for the detection of ribosomal RNA (rRNA) from *Trichomonas vaginalis* to aid in the diagnosis of trichomoniasis from symptomatic or asymptomatic women.
   b. Performance has not been evaluated in women less than 14 years of age.
2. Approved specimens for Trichomonas Vaginalis Testing
   a. Clinician-collected endocervical and vaginal swab specimens
   b. Clinician-collection PreservCyt Solution liquid Pap specimens
3. Approved Collection Kits
   a. Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens.
   b. Aptima Multitest Swab Specimen Collection Kit for Vaginal, Throat, and Rectal Swab Specimens.
   c. ThinPrep Vial for Clinician-collected Pap specimen
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. Swab Specimens
      - After collection, transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested.
      - Assay specimens within 60 days of collection. If longer storage is needed, freeze the specimen transport tube at ≤ –20°C for up to 24 months.
   b. Specimens Collected in PreservCyt Solution
      - Transport and store the PreservCyt Solution specimen at 2°C to 30°C for up to 30 days.
      - Specimens collected in PreservCyt Solution must be transferred into an Aptima specimen transfer tube according to the instructions in the Aptima Specimen Transfer kit package insert.
      - After transfer to an Aptima specimen transfer tube, specimens may be stored an additional 14 days at 15°C to 30°C or 30 days at 2°C to 8°C.
      - If longer storage is needed, the PreservCyt Solution specimen or the PreservCyt Solution liquid Pap specimen diluted into the specimen transfer tube may be stored at ≤ –20°C for up to 24 months after transfer.

11.9 Mycoplasma genitalium (M.gen Assay)

1. Usage
   a. The Mycoplasma genitalium test is for the detection of ribosomal RNA (rRNA) from *Mycoplasma genitalium*. It is intended for use as an aid in the

diagnosis of *M. genitalium* urogenital infections in male and female patients suspected of *M. genitalium* infection.

b. The performance of the test has not been evaluated in adolescents less than 15 years of age.

2. Approved Specimens
   a. Clinician-collected vaginal swab specimens (in a clinical setting).
   b. Clinician collected endocervical swab specimens.
   c. Female and male urine specimens.
   d. Clinician-collected male urethral swab specimens.
3. Approved Collection Kits
   a. Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens.
   b. Aptima Urine Collection Kit for Male and Female Urine Specimens.
   c. Aptima Multitest Swab Specimen Collection Kit.
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration is expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. Swab Specimens
      - After collection, swab specimens in transport tubes can be stored at 2ºC to 30ºC for up to 60 days.
      - If longer storage is needed, swab specimens in transport tubes can be stored at -20°C or -70°C for up to an additional 90 days.
   b. Urine Specimens
      - Before urine specimens can be tested, urine must be transferred to an Aptima urine transport tube in accordance with the instructions in the urine collection kit package insert.
      - After collection, urine specimens in the primary collection container can be stored at 2ºC to 30ºC for up to 24 hours before urine is transferred to the transport tube.
      - Processed urine in the transport tube can be stored at 2ºC to 30ºC for up to 30 days (after transfer).
      - If longer storage is needed, processed urine in the transport tube can be stored at -20°C or -70°C for up to an additional 90 days (after transfer).

11.10 Herpes Simplex Viruses1&2 (HSV 1&2 Assay)

1. Usage
   a. The HSV 1 & 2 test is intended for use as an aid in the diagnosis of HSV-1 and/or HSV-2 infections in symptomatic male and female patients.

b. The Aptima HSV 1 & 2 test is not intended for use with cerebrospinal fluid or for prenatal screening.
c. The Aptima HSV 1 & 2 assay does not distinguish between infectious and non-infectious HSV-1 and HSV.

2. Approved specimens for HSV 1&2
   a. Clinician-collected swab specimens from anogenital lesions placed in the STM.
3. Approved collection kits
   a. Aptima Multitest Swab Specimen Collection Kit (for STM).
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. Specimens collected in the Aptima Multitest Swab Specimen Collection Kit (STM)
      - Transport and store the specimen in the Aptima Multitest Swab Transport Media (STM) at 2°C to 30°C until tested. Specimens must be tested with the Aptima HSV 1 & 2 assay within 36 days of collection. Specimens stored at -20°C to -70°C for up to 36 days may also be tested with the Aptima HSV 1 & 2 assay.
      - Aptima swab specimens may be frozen and thawed up to 3 times prior to testing.

11.11 HPV 16/18 Genotype Testing (GT HPV)

1. Usage
   a. The Aptima HPV 16 18/45 genotype assay is an *in vitro* nucleic acid amplification test for the qualitative detection of E6/E7 viral messenger RNA (mRNA) of human papillomavirus (HPV) types 16, 18, and 45 in cervical specimens from women with Aptima HPV assay positive results.
   b. In women 21 years and older with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results.
   c. In women 30 years and older, the Aptima HPV 16 18/45 genotype assay can be used to test samples from women with Aptima HPV assay positive results. The assay results will be used in combination with cervical cytology to assess the presence or absence of high-risk HPV genotypes 16, 18, and/or 45.
2. Approved Specimens for HPV Testing
   a. Clinician-collected PreservCyt Solution liquid Pap specimens with broom-type or cytobrush/spatula collection devices.
3. Approved Collection Kits
   a. Hologic Broom Type
   b. Hologic cytobrush/spatula

4. Expiration Dates
    a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
    b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
    a. Transport the ThinPrep liquid cytology specimens at 2°C to 30°C.
    b. Specimens should be transferred to an Aptima Specimen Transfer tube within 105 days of collection. Specimens will be transferred at Opus Pathology.
    c. Prior to transfer, ThinPrep liquid cytology specimens should be stored at 2°C to 30°C, with no more than 30 days at temperatures above 8°C.
    d. ThinPrep liquid cytology specimens transferred to an Aptima Specimen Transfer tube may be stored at 2°C to 30°C for up to 60 days.
    e. If longer storage is needed, the ThinPrep liquid cytology specimen or the ThinPrep liquid cytology specimen diluted into the Aptima Specimen Transfer tube may be stored at -20°C to -70°C for up to 24 months.

11.12 Panels

1. Client Ordering Panel Suggestion
    a. STI Symptomatic Panel: CT/NG, Trichomonas, Mycoplasma Genitalium
    b. STI Asymptomatic Panel: CT/NG, Trichomonas
    c. Vaginitis Panel: Bacterial Vaginosis, Candida species, Candida Glabratum, Trichomonas Vaginalis
    d. Vaginitis PLUS STI Panel: Bacterial Vaginosis, Candida species, Candida Glabratum, Trichomonas Vaginalis, CT/NG, Mycoplasma Genitalium
2. Collection Guidelines for Panels

Test	**Collection Kit**
HPV Only	ThinPrep (PreservCyt)
CT/NG	ThinPrep (PreservCyt), Aptima Multitest Swab, or Urine Swab
HSV 1&2	Aptima Multitest Swab
Trich Only	ThinPrep (PreservCyt), Aptima Multitest Swab
M. Gen Only	Aptima Multitest Swab or Urine Swab
STI Panel Symptomatic	Aptima Multitest Swab
STI Panel Asymptomatic	Aptima Multitest Swab

Vaginitis Panel	Aptima Multitest Swab
Vaginitis Panel PLUS STI Panel	Aptima Multitest Swab (2 samples)

11.13 GBS Testing

1. Usage
   a. The GBS assay is an automated qualitative in vitro diagnostic test utilizing real-time PCR for detection of Group B Streptococcus DNA from antepartum women following 18-24 hours incubation.
2. Approved specimens for GBS Testing
   a. Clinician-collected vaginal/rectal swabs according to standard technique.
3. Approved Collection Kits
   a. Flocked swab, immediately placed into a non-nutritive media (Liquid Stuart's or Amies)
4. Expiration Dates
   a. Expiration dates listed on the collection kits pertain to the collection site and not the testing facility. Samples collected any time prior to the expiration date of the collection kit, and transported and stored in accordance with the package insert, are valid for testing even if the expiration date on the collection tube has passed.
   b. If the expiration date is before the date of collection, the testing is invalid and another sample must be taken.
5. Specimen Storage Before Testing:
   a. After collection, swabs can be stored at 15°C to 30°C for up to 48 hours. Samples must be received at laboratory within 48 hours.

12. Attachments

12.1 Attachment 1

1. The list of reportable diseases in Tennessee is below. Labs reporting outbreak events or conditions not listed below but of public health significance should immediately contact TDH Communicable and Environmental Disease Services at (615)741-7247 or 1-800-404-3006.
   a. Requires immediate telephonic notification (24 hours a day, 7 days a week), followed by a written report using form PH-1600 within 1 week.
      - Anthrax (*Bacillus anthracis*)
      - Botulism-Foodborne (*Clostridium botulinum)*
      - Botulism-Wound (*Clostridium botulinum*)
      - *Burkholderia mallei*
      - Disease Clusters or Outbreaks (e.g., foodborne, waterborne, healthcare, etc.)

- Influenza A Virus: Novel
- Measles virus
- Middle East Respiratory Syndrome Coronavirus (MERS-CoV)
- *Neisseria Meningitis*
- Rabies Virus: Animal, Human
- Ricin Toxin
- *Staphylococcus aureus* Enterotoxin B-producing (pulmonary)
- Variola Virus (Orthopox Virus)
- Viral Hemorrhagic Fever Viruses (including Ebola, Lassa, Marburg)

b. Requires immediate telephonic notification (next business day), followed by a written report using the PH-1600 within 1 week.

- *Bordetella pertussis*
- Brucellosis (*Brucella Species*)
- *Candida auris* (includes rule-out)
- Chikungunya Virus
- Colistin-resistant Gram Negative Bacteria
- *Coxiella burnetii*
- Diptheria (*Corynebacterium diphtheriae, ulcerans*)
- Equine Encephalitis Viruses: Eastern, Venezuelan
- *Francisella tularensis*
- *Haemophilus influenzae*
- Hepatitis A virus
- Meningitis – Other Bacterial
- Mumps Virus
- *Mycobacterium tuberculosis* complex (*M. tuberculosis, M. bovis, M. canettii, M. africanum, M. microti*)
- Poliovirus
- Rubella Virus
- *Salmonella*: Typhi
- *Staphylococcus aureus*: Vancomycin Non-Sensitive – All Forms
- *Streptococcus pyogenes*: Invasive Disease
- Syphilis (*Treponema pallidum*): Congenital
- Yellow Fever Virus
- *Yersinia: pestis*
- Zika Virus

c. **Category 3** – requires reporting via fax within 24 hours

- Coronavirus disease (COVID-19) caused by SARS-CoV-2

d. **Category 2 –** requires written report using form PH-1600 within 1 week.

- *Acinetobacter* Species, Carbapenem-Resistant
- *Anaplasma phagocytophilum* species
- *Babesia* species
- *Borrelia burgdorferi*
- California/LaCrosse Serogroup Viruses
- *Campylobacter* species
- *Chlamydia trachomatis*
- *Clostridium botulinum* – Infant
- *Clostridium difficile*
- *Clostridium tetani*
- Cryptosporidiosis (*Cryptosporidium* Species)
- Cyclosporiasis (*Cyclospora* Species)
- Dengue Virus
- *Ehrlichia* Species
- *Enterobacteriaceae*, Carbapenem-Resistant
- *Enterococcus* Species: Vancomycin-Resistant Invasive Disease
- *Escherichia coli*, Extended Spectrum Beta Lactamase [ESBL] Producing
- *Escherichia coli*: Shiga Toxin-Producing
- Hepatitis B Virus
- Hepatitis C Virus
- Human Immunodeficiency Virus
- *Klebsiella* Species: Extended Spectrum Beta Lactamase-Producing
- Legionellosis (*Legionella* Species)
- Listeriosis (*Listeria* Species)
- *Mycobacterium leprae*
- *Mycobacterium* Nontuberculosis Species (Extrapulmonary Only)
- *Neisseria gonorrhoeae*
- *Plasmodium* Species
- *Rickettsia* Species (Other Than *R. typhus*)
- St. Louis Encephalitis Virus
- *Salmonella*: Other Than *S. typhi*
- Shigellosis (*Shigella* Species)
- *Staphylococcus aureus*: Methicillin-Resistant Invasive Disease, Toxin-Producing (TSST-1)
- *Streptococcus agalactiae* Invasive Disease
- *Streptococcus pneumoniae* Invasive Disease
- *Streptococcus pyogenes*: Toxin-Producing
- *Trypanosoma cruzi*
- *Vibrio cholerae* Species
- West Nile Virus Infections

e. **Category 4**: Laboratories and physicians are required to report all blood lead tests. Levels ≥5µg/dl should be reported within 1 week. Levels <5µg/dl should be reported within 1 month. See www.tn.gov for additional information.
   - Lead blood levels

12.2 Attachment 2

1. Permission for Autopsy
   a. All autopsies are performed by Forensic Medical Management, PLC, Nashville, TN.
   b. Tennessee law summary: An autopsy may be performed on the body of a dead person, if written permission is granted by the next of kin who assumes custody of the body for purpose of burial, such as the surviving spouse, the father, the mother, a child, a guardian, next of kin, or in the absence of any of the foregoing, such governmental agencies as charged by law with the responsibility for burial.
   c. Persons granting permission for an autopsy must sign a permit in the presence of medical staff.
   d. Permission for an autopsy may be granted as follows:

2. Autopsies Performed
   a. Tennessee Law Provisions: Three types of autopsies are ordinarily permitted.
      - Medical Examiner's Autopsy – certain types of death must be investigated by an autopsy (see below).
      - Sudden Infant Death Syndrome – a parent or guardian of an infant (two years of age or younger) who may have died from SIDS must be offered by the County Medical Examiner the opportunity of having an autopsy performed on the dead infant's body (see below).
      - All Other Autopsies – persons who die and who do not fit the criteria for Tennessee Statutory Autopsies (the preceding two types) may have an autopsy.

3. Medical Examiner Cases
   a. Tennessee law mandates that certain deaths be reported to the County Medical Examiner.
   b. The following types of cases are to be reported to the county Medical Examiner in order that jurisdiction of these cases might be established.
      - Death when not under the care of a physician for a potentially fatal illness. Generally, "care of a physician" is defined as an ongoing physician-patient relationship where the physician has treated the deceased. This treatment does not necessarily have any defined time restrictions.
      - Death of a person when the attending physician, or his or her representative, is unavailable to sign the death certificate (for example, an out of state physician or a physician on vacation).
      - Death occurring suddenly when in apparent good health when the cause of death has not been established by medical treatment.

- Death from violence of any type. All gunshot wounds, stab wounds, blunt trauma, fall related deaths, fire deaths, drowning, and motor vehicle collisions, regardless of the time elapsed from onset of incident to the time of death (for example, if a person is shot with injury to the spinal column resulting in paraplegia and then develops a urinary tract infection and sepsis at a later date, the death can be traced back to the injury and this is a reportable Medical Examiner case).
- Death related to an overdose of illegal drugs, alcohol or legal medications (including natural or herbal remedies).
- All deaths of children without a clear underlying natural cause of death. Any injuries in a child should alert you to contact the state Medical Examiner's office for consultation, even when there is a natural disease present. Sudden infant death syndrome (SIDS) is a diagnosis of exclusion requiring a complete autopsy, and all suspected SIDS deaths must be reported to the Medical Examiner.
- Death occurring in a prison or of a prisoner.
- Death occurring on the job or related to employment.
- Death believed to present a public health hazard.
- Death of a patient during or as a result of a diagnostic or therapeutic procedure; a medication error; or adverse, allergic, or toxic reaction to a therapeutic agent.
- Death of a nursing home or extended care resident when abuse, neglect, or overmedication is strongly suspected or confirmed as contributing to death.
- Death of a fetus greater than 20 weeks gestation and the death is related to an act of violence, maternal substance abuse, or an accident.
- Death of a person from any cause when their identity is unknown or unclear.
- Death when cremation of the remains is to be performed.

c. Tennessee State Law does not contain the "24 hour rule". In other words, the death of any patient admitted to the hospital in the 24 hours preceding death does not have to be reported to the Medical Examiner unless the death satisfies the criteria outlined above. Also, the above criteria should serve as a guideline.

13. References

1. Clinical and Laboratory Standards Institute. Viral Culture; Approved Guidelines. CLSI document M41-A [ISBN 1562386239] Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898, USA 2006