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MEET OUR PATHOLOGISTS

All of our pathologists are Board certified in Anatomic and Clinical Pathology by the American Board of Pathology. We are licensed in 18 states.

| Robert Haas, MD | Anatomic Pathology  
|                 | Clinical Pathology  
|                 | Cytopathology       |

Robert Haas, MD has been with MetroPath since 2005. He is a graduate of Duke University. He received his MD degree from Case Western Reserve University School of Medicine, Cleveland, Ohio, followed by his residency in Anatomic and Surgical Pathology at Stanford University, and completed his Cytopathology fellowship at the University of California, San Francisco. Dr. Haas is Board certified in Anatomic and Clinical Pathology (2004) and Cytopathology (2005) by the American Board of Pathology.

| Mary Kenny-Moynihan, MD | Anatomic Pathology  
|                         | Clinical Pathology  |

Mary Kenny-Moynihan, MD has been with MetroPath since 2001 and is the Medical Director for MetroPath’s independent laboratory. She graduated from the University of Dublin, Trinity College School of Medicine, Dublin, Ireland with an MD degree. She completed her residency in Anatomic and Clinical Pathology at Emory University, Atlanta, Georgia during which time she served as a visiting scientist in the Papillomavirus Division at the Centers for Disease Control and Prevention in Atlanta, Georgia. She has authored numerous peer-reviewed papers in gynecologic pathology. Dr. Kenny-Moynihan is Board certified in Anatomic and Clinical Pathology (1993) by the American Board of Pathology.

| Mirna Knight, DO, PhD | Anatomic Pathology  
|                      | Clinical Pathology  
|                      | Molecular Pathology |

Mirna Knight, DO, PhD has been with MetroPath since 2006. She received her PhD in Molecular Biology from the University of Zagreb in Croatia in conjunction with the Burnham Institute in La Jolla, CA, and her DO degree from the University of Kansas Medicine and Biosciences followed by a fellowship and residency in Anatomic and Clinical Pathology at the Mayo Clinic. She has done extensive research and published numerous papers related to Molecular Biology. Dr. Knight is Board certified in Anatomic and Clinical Pathology (2005) by the American Board of Pathology.

| Derek Konopka, MD | Anatomic Pathology  
|                  | Clinical Pathology |

Derek Konopka, MD has been with MetroPath since 1985. He is a graduate of the University of Michigan Medical School in Ann Arbor where he received his MD degree. He completed his residency in Anatomic and Clinical Pathology at the University of Colorado and Surgical Pathology at Stanford University, California. He has served as director of Surgical Pathology for the St. Anthony Hospital Systems since 1987, and is currently chairman of the Pathology Department. Dr. Konopka is Board certified in Anatomic and Clinical Pathology (1984) by the American Board of Pathology.
Stephen Worth, MD has been with MetroPath since 2002. He is a graduate of Grinnell College, Grinnell, Iowa and received his MD degree from the University of Wisconsin Medical School in Madison. He completed his residency in Anatomic and Clinical Pathology at the University of Iowa, and his Surgical Pathology fellowship at the University of California, San Francisco. He currently serves as Medical Director for the laboratories at St. Anthony Hospital, St. Anthony North Health Campus, and Avista Adventist Hospital. Dr. Worth is Board certified in Anatomic and Clinical Pathology (1998) by the American Board of Pathology.

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Bryan Coffing, MD has been with MetroPath since 2011. He is a graduate of Dartmouth College, Hanover, NH and received his MD degree from Dartmouth Medical School in Lebanon, NH. He completed his residency in Anatomic and Clinical Pathology and fellowship in Hematopathology at the University of Michigan Health System, Ann Arbor, and his fellowship in Dermatopathology at Dartmouth-Hitchcock Medical Center. He currently serves as Medical Director for the laboratory at Summit Medical Center. Dr. Coffing is Board certified in Anatomic and Clinical Pathology (2009), Hematopathology (2010), and Dermatopathology (2011) by the American Board of Pathology.
➤ HISTORY:

Metropolitan Pathologists, PC is Denver's oldest independent anatomic pathology laboratory. We offer comprehensive cytology, surgical pathology, and molecular pathology testing. Our clients include doctors' practices, medical offices, hospitals, other labs in and around Denver and outlying states that select us to complete specific testing for their clients.

Our pathologists diagnose disease in all areas of the body and alert healthcare providers so that patients may receive immediate and appropriate care.

At MetroPath, you and your patients are our number one priority. We strive for the highest rate of accuracy, aided by innovative diagnostic technology, to deliver the best care and service in the industry. We seek to establish an environment of trust and confidence that reflects genuine concern for patient well-being. We offer:

• A wide variety of testing in state-of-the-art lab facilities
• A skilled team of pathologists who average 16 years' experience
• Accurate, efficient, and reliable tests and results
• 24-hour turnaround time on tissue studies, biopsies, and non-gyn/FNA specimens
• ThinPrep® and SurePath™ Pap tests with 2-day turnaround time
• Electronic ordering and reporting including web access
• In-house billing, insurance filing, and support systems
• Exceptional standard of customer service
• Regional courier services
• Overnight air delivery of specimens and results

➤ MISSION STATEMENT:

Building trust with every patient, providing excellence with every test

➤ CERTIFICATION:

Metropolitan Pathologists, PC is certified or accredited by the following agencies:

• Clinical Laboratory Improvement Amendments (CLIA)
• College of American Pathologists (CAP)
• American Society of Clinical Pathologists (ASCP): certifies Cytotechnologists, Histotechnologists, Molecular Pathology Medical Technologists
The College of American Pathologists

certifies that the laboratory named below

Metropolitan Pathologists PC
Laboratory
Lakewood, Colorado
Mary B. Kenny-Moynihan, MD

LAP Number: 7175660
AU-ID: 1371515
CLIA Number: 06D0512490

has met all applicable standards for accreditation and
is hereby accredited by the College of American Pathologists’
Laboratory Accreditation Program. Reinspection should occur prior
to March 15, 2016 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership,
or location and assumes that all interim requirements are met.

Chair, Commission on Laboratory Accreditation

President, College of American Pathologists
If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

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FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER. PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
Metropolitan Pathologists, PC provides this collection procedure booklet for our clients which describes proper procedures for collecting, labeling, fixing, submitting, and transporting laboratory specimens to our laboratory. This manual is effective for two years unless procedures or methodologies change.

Our vision to set new standards in care and service is guided by six pathologists, each certified by the American Board of Pathology with an average of 16 years’ experience in their respective fields, as well as an exceptional management team.

A talented administrative staff provides critical daily support services, including scheduling, updates, and claims resolution to ensure a smooth, hassle-free experience for each and every patient.

As a collaborative team, we remain dedicated to investigation, diagnosis, and discovery of disease in the human body.

Information and awareness are keys to sustained good health. We want all of our clients and patients to be informed about our testing protocols and health-related issues. We invite you to learn more about our specific tests and diagnoses by visiting our website: www.metropath.com in addition to accessing a number of Web sites that will serve as critical resources for medical professionals and patients.

If you have questions, or would like additional information, please contact us.
CYTOLOGY

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ACCEPTABILITY OF GYN CYTOLOGY SPECIMENS

To maintain specimen integrity and quality, specimens will **NOT** be accepted for the following reasons:

- Lack of two patient identifiers on specimen container or slide(s)
- No name on requisition form
- Name on requisition form does not match name on vial or slide
- No specimen received with requisition form
- No requisition form received with specimen
- Name illegible or missing first/last name
- Slide received broken beyond repair
- Name written on cardboard holder or adhesive tape (conventional slides)
- Vial is expired according to expiration date

If a specimen is determined to be unacceptable, a rejection report will be issued with the reason for rejection and sent back to the client along with the specimen.

The following guidelines are to assist in proper specimen preparation:

- Label all specimen containers with two patient identifiers: First and last name, DOB, requisition sticker with number, hospital number, Social Security Number, clinic patient ID number, or unique random number.
- The requisition form must include the patient’s name, gender, birth date, specimen site, test requested, date and time of collection, person ordering test, and any other pertinent clinical information.
- All information should be printed clearly and the name spelling should match exactly on the requisition form, the specimen container, and patient information sheet, if included.
GYN CYTOLOGY REVIEW POLICY/HIGH RISK CRITERIA

➢ Cytology Slide Review Policy:

• All negative cytology cases from patients considered to be “high risk” are reviewed in our Quality Control Program by a supervisory qualified cytotechnologist.

• Other negative cases are randomly selected for QC review by the computer system for a total minimum case review of 10% or more.

• All abnormal cases are reviewed and signed out by a pathologist.

• All unsatisfactory cases are reviewed by a supervisory qualified cytotechnologist.

➢ High Risk Patient Criteria:

• Any patient who has not had a Pap test for more than 6 years.

• Any previous abnormal Pap test (ASC-US and above) that is now negative but has not had two consecutive negative Pap tests indicated by the clinician.

• Any patient suspected of having a sexually transmitted disease, provided the clinician supplies the information.

• Any patient who has had sexual relations with multiple partners, based on clinical information.

• Any patient who has any clinical evidence of an abnormality or history of cancer other than Basal Cell Carcinoma or other non-pertinent Carcinoma.

• Abnormal bleeding.

• All unsatisfactory Pap tests except acellular specimens.
CERVICAL / VAGINAL PAP TEST CELL COLLECTION

PURPOSE: Screening and interpretation of primary or metastatic neoplasms; genital infections such as Herpesvirus, Human Papilloma Virus, Trichomonas vaginalis

Turnaround Time: 2 business days after receipt in the lab

REFERENCE RANGE: Negative to abnormal consistent with malignant neoplasm.

RESPONSIBLE PERSONS: Nursing personnel, Cytology, Pathologists and Physician

POLICY: Slides/vial must be labeled with patient's first and last name and one other identifier such as date of birth, requisition form number, hospital number, Social Security number, patient ID number, or unique random number. It is required that specimens be properly fixed to be accepted. Endocervical brush and cervical scrape are recommended. All information must be completed on requisition form. The date of collection, date of birth and LMP (if applicable) are required.

GENERAL: Failure to obtain adequate ectocervical, endocervical, or vaginal cell population is suboptimal for evaluation. Use of lubricating jelly on the vaginal speculum will interfere with cytologic examination. If transferring specimen to slide(s), SPECIMENS MUST NOT BE SMEARED OR SCRUBBED ONTO THE SLIDE.
GUIDELINES FOR PATIENT PREPARATION OF PAP TESTING

The following guidelines are referenced from CLSI Document GP15-A2 and the Hologic ThinPrep® Pap Test™ (TPPT) Specimen Training Bulletin. In general, the guidelines state that it is important to obtain a specimen that is not obscured by blood, mucus, inflammatory exudate, or lubricant.

➤ Patient Information:

• The patient should be tested 2 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.
• The patient should not use vaginal medication; vaginal contraceptives; vaginal gels, lubricants, or douches during the 48 hours before the exam.

➤ Patient Preparation:

• Lubricant jellies should never be used to lubricate the speculum. Hold the speculum under warm running water to moisten so it can be more easily inserted.

• Remove excess mucus or other discharge that is present before taking the sample. This should be gently removed with ring forceps holding a folded gauze pad.
  The excess cervical mucus is essentially devoid of meaningful cellular material, and when present in the sample vial, may yield little or no diagnostic material.

• Remove inflammatory exudate from the cervical canal before taking the sample. Remove by placing a dry 2x2-inch piece of gauze over the cervix and peeling it away after it absorbs the exudate or by using a dry proctoswab or scopette.
  The excess inflammatory exudate is essentially devoid of diagnostic cellular material and, when present in the sample vial, may yield little or no diagnostic material.

• The cervix should not be cleaned by washing with saline or it may result in a relatively acellular specimen.

• The sample should be obtained before the application of acetic acid.
PROCEDURE FOR THINPREP® SPECIMEN COLLECTION

➢ Supplies:
  ThinPrep vial containing PreservCyt® Solution (accompanied by a cytobrush and plastic spatula or a Cervex broom)
  Requisition form
  Plastic transport bag

➢ Labeling:
  Write patient first and last name and one other identifier on outside of vial.

➢ Specimen Collection:
  (1) Open a ThinPrep vial containing PreservCyt® Solution so that it is ready for putting the specimen in as soon as it is taken.

  (2) To take a cervical sample:
    • Use the double edge end of a plastic spatula, with the longer point at the cervical os.
    • Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
    • Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.

  (3) To take an endocervical sample:
    • Use the double edge end of a plastic spatula, with the longer point at the cervical os.
    • Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
    • Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal smear. Discard.
    • Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
    • Slowly rotate the cytobrush 1/2 to one full (180-360°) revolution only. **DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.**
    • Gently remove brush without touching the vaginal surface.
    • Rinse the brush **IMMEDIATELY** (do not let it set in the vial) 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.
      - **DO NOT** scrape the cytobrush with the spatula. This action causes the cells to clump and harden when they come in contact with the solution in the vial. Discard the brush.
      - **DO NOT** put cytobrush head into the vial. It will cause a machine breakdown.
(4) If a Cervex Broom® is used to obtain the specimen:

- 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.

**NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS**

- Rinse 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. Discard the broom.
  - **DO NOT** put the Cervex Broom® into the vial. It will cause a machine breakdown.

(5) Close the vial securely to prevent leaking by making sure the black marks on the lid and vial are in alignment.

(6) Follow instructions on the ThinPrep® Pap Test™ Quick Reference Guide Protocol for taking the actual specimen (follows this procedure).

(7) If requiring the use of lubrication during sample collection:

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

- **Lubricant Gels:** If lubricant must be used due to patient discomfort or other circumstances:
  - Lubricant should be used sparingly (dime size amount) and applied only to the exterior sides of the speculum blades, avoiding contact with the tip of the speculum. (see picture at the end of this procedure)
  - When a lubricant is used in excess, it can adversely affect the Pap sample. Be aware that those lubricants containing carbomer or carbopol polymers (thickening agents) interfere with the ThinPrep Pap test when found in the sample vial.
  - If any lubricant is used, it should always be applied very sparingly (no more than a dime size amount).

➢**Fixation/Storage:**

PreservCyt® Solution: cells are preserved for 30 days at 4°C-37°C (39°F-98.6°F).
Requisition Form:
Complete the requisition form including LMP and any pertinent information that will aid in rendering an accurate evaluation.

Transport:
1. Put the vial in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

Turnaround Time: Routine: 2 business days after receipt in the lab

Result Interpretation:
Negative, infections, to abnormal consistent with malignant neoplasm

Note:
Expired vials are unacceptable for use and will be rejected for testing.

Appropriate Use of Lubricant for Pap Collection

Lubricant gels should be used sparingly.

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

Dime size amount

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MISC-00579-001 Rev. 004
Obtain...

An adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary. Select contoured end of plastic spatula and rotate it 360 degrees around the entire ectocervix while maintaining tight contact with ectocervical surface.

Rinse...

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

Obtain...

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

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.

Record...

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

Place...

The vial and requisition in a specimen bag for transport to the laboratory.
Quick Reference Guide
Broom-Like Device Protocol

Obtain...
an adequate sampling from the cervix using a broom-like device. If desired, use
lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant
sparsely applied to the posterior blade of the speculum can be used 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 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.

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

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

www.thinprep.com

PROCEDURE FOR SUREPATH™ SPECIMEN COLLECTION

➤ Supplies:
- SurePath collection vial with ethanol fixative
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name and one other identifier on outside of vial.

➤ Specimen Collection:
1. Open a SurePath vial containing ethanol fixative.
2. To take a Pap sampling using a Cervex Broom®:
   - Visualize the uterine cervix.
   - Insert the central bristles of the broom into the endocervical canal.
   - Using gentle pressure, push the broom in the direction of the cervix until the lateral bristles are splayed out over the ectocervix.
   - Rotate 5 full turns in a CLOCKWISE direction.
   - Remove the broom.
   - While holding the handle of the broom in a gloved hand, dislodge the broom head from the handle and place the head into the SurePath vial without touching the head of the device.
   - Tightly seal the cap onto the vial to prevent leakage.
3. To take a Pap sampling using a cytobrush and spatula:
   - Insert the contoured end of the plastic spatula and rotate 360° around the entire ectocervix.
   - Snap the device handle and drop the detachable head into the vial. Do NOT touch the head of the device while detaching.
   - Insert the cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate 1/2 to one full revolution in one direction. Do NOT over-rotate brush as profuse bleeding may occur.
   - Snap the device handle and drop the detachable head into the SurePath vial. Do NOT touch the head of the device while detaching.
   - Tightly seal the cap onto the vial to prevent leakage.

NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS

• Remove the broom.
• While holding the handle of the broom in a gloved hand, dislodge the broom head from the handle and place the head into the SurePath vial without touching the head of the device.
• Tightly seal the cap onto the vial to prevent leakage.
➤ Fixation/Storage:
SurePath Solution: cells are preserved for 30 days at 15°C-30°C (59°F-86°F).

☞ NOTE: After specimen vial is opened for processing, maximum storage time is 14 days.

➤ Requisition Form:
Complete the requisition form including LMP and any pertinent information that will aid in rendering an accurate evaluation.

➤ Transport:
(1) Put the vial in the plastic transport bag in the sealable partition.

(2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround Time: Routine: 2 business days after receipt in the lab

➤ Result Interpretation:
Negative, infections, to abnormal consistent with malignant neoplasm

➤ Note:
Expired vials are unacceptable for use and will be rejected.
THINPREP IMAGING SYSTEM:

- The ThinPrep® Imaging System is the first Imaging-Directed Cytology system and is used in this laboratory for all ThinPrep specimens that are eligible for Imaging.
- Metropolitan Pathologists was the first laboratory in Colorado, and the 3rd laboratory in the US, to implement this state-of-the-art equipment.
- The System improves diagnostic capability for greater accuracy by scanning every cell and cell cluster.
- FDA approved in June 2003.

ThinPrep® Imaging-Directed System

- Requires consistent reproducible slide preparation
- Uses a quantitative stain to enable nuclear measurements by computer
- Integrates a computer and human for review of every slide to ensure a more accurate result

ThinPrep® Pap Test with Imaging

- Calls attention to important fields on the slide, facilitating the review of the slide by the cytotechnologist
- Reduces False Negative Fraction
- Improves sensitivity and specificity
NON-GYN CELL COLLECTION

PURPOSE: To provide cytological studies through use of proper collection, preparation, staining and microscopic examination of cytologic specimens from a variety of body sites and procedures, i.e. bronchial washings/brushings, thoracentesis/paracentesis fluids, fine needle aspiration (FNA) of solid/cystic lesions, etc.

Turnaround Time: 24 – 48 hours (1-2 business days from when it arrives in the lab)

REFERENCE RANGE: Negative to abnormal consistent with malignant neoplasm

RESPONSIBLE PERSONS: Physician, Pathologist, and Cytologist

POLICY: Proper collection, with two patient identifiers, and prompt preparation of specimens for cytologic studies are extremely important for providing diagnostic material. This is especially true in the case of pulmonary and gastric cytology (sputum, bronchial washings, post-bronchoscopy sputums, and gastric brushings). These specimens must be processed in the laboratory as soon as possible after they are obtained from the patient. Optimally, these studies should be scheduled during the working hours (8:00 AM – 4:30 PM). Any deviation from this policy will result in preparations of diminished value because of degeneration of cell details. Most specimens that are allowed to sit overnight will be of questionable value.

GENERAL: It is realized that circumstances will arise when bronchial washings, gastric brushings, thoracentesis, paracentesis, spinal fluids, FNAs, etc., can only be obtained after regular hours or on weekends. An attempt will be made to study these specimens, but results/interpretation may be of very little value.

PROCEDURE: The technique uses to process specimens will be made by the Cytology department. For each specimen, depending on the thickness, volume, cloudiness, or other factors, one or more techniques will be used to make the preparation that will most likely show malignant cells. If the requesting physician has reason to prefer one technique to another, he/she should consult the pathologist in advance.

WARNING: WE DO NOT ACCEPT ANY SPECIMENS THAT ARE SUSPECTED OF HAVING CREUTZFELDT-JACOB DISEASE.

➢ THE FOLLOWING IS A LIST OF SPECIMENS FOR POSSIBLE REJECTION:

- Lacking two patient identifiers on specimen container/slides and requisition form
- Air drying of smears (especially genital tract, breast, or bronchial brushing)
- 24-hour sputum collection
- Sputum collections immediately after bronchograms
- 24-hour collection of drainage from any cavity
- 24-hour urine collections for cytology studies
- Specimens submitted in a plastic bag or any leaking container externally contaminated
- Specimens sent in repeatedly (i.e. X3) when first or second specimen is positive for malignancy
- Any premade slides that are broken beyond repair
- Name on specimen bottle or slide does not match name on requisition form
- Any slide/specimen bottle that is not labeled with patient first and last name
- Illegible writing
- Any specimen in a syringe with a needle attached
ANAL PAP SPECIMENS

➤ Supplies:
   ThinPrep® Vial OR Container with CytoLyt™ Solution
   Dacron™ Swab or Cytobrush
   Requisition Form
   Plastic transport bag

➤ Labeling:
   Write patient first and last name and specimen site/type on outside of container

➤ Specimen Collection:
   (1) Have the patient lie in the lateral recumbent position with knees drawn up toward the chest.
   (2) Use a water-moistened Dacron™ swab or cytobrush and insert into the anal canal approximately
       5-6 cm above the anal verge and into the rectal vault (done without direct visualization of the
       anal canal).
   (3) Using the external anal sphincter as a fulcrum, rotate the swab or cytobrush in a cone-shaped arc,
       applying pressure to the canal walls as the device is withdrawn.
   (4) Transfer the sample to the container with CytoLyt™ Solution by vigorously agitating the
       applicator in the solution. Discard applicator.
   (5) Tighten the cap securely to prevent leakage.

➤ Fixation/Storage:
   CytoLyt™ Solution: cells are preserved for 8 days at room temperature; however, it is preferable to
   process immediately.

➤ Requisition Form:
   Complete the requisition form. Specify pertinent clinical information that may aid in rendering a
   diagnosis.

➤ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form
       together and protect against potential leakage.

➤ Turnaround time:
   Routine: 24-48 hours after receipt in the lab

➤ Result Interpretation:
   Negative, or abnormal cells consistent with malignant neoplasm

☞ NOTE:
   (1) The patient should be advised to refrain from receptive anal intercourse or the use of intra-anal
       preparations before examination.
   (2) A swab or smear of the peri-anal skin will be considered an unsatisfactory sample.
   (3) Do NOT use cotton swabs on a wooden stick as the handle may break and splinter during
       collection.
BODY FLUIDS (Pleural Fluid, Peritoneal Fluid, Pericardial Fluid, other sites)

➤ **Supplies:**
- Screw-capped tubes for synovial fluid
- Container that holds 200 ml
- CytoLyte™ Solution
- Requisition form
- Plastic transport bag

➤ **Labeling:**
Write patient first and last name and specimen site/type on outside of container

➤ **Specimen Collection:**
1. Add specimen to container.
2. If large amounts of pleural or peritoneal fluid are obtained in a syringe or bottle, no CytoLyte™ is required. Submit as a fresh specimen and refrigerate.
3. CytoLyte™ Solution may be added to the specimen if cultures are not requested.
   a. Specimens requesting cultures must be collected fresh, without fixative.
   b. Split sample if needed.
4. Tighten the cap securely. **DO NOT SEND IN A SYRINGE WITH NEEDLE ATTACHED. SPECIMEN WILL BE REJECTED!**
5. For Synovial Fluid, 1-3 ml should be collected in a sterile screw-capped container. **DO NOT PUT INTO CYTOLYT SOLUTION IF CRYSTAL EVALUATION IS NEEDED.**

➤ **Fixation/Storage:**
CytoLyte™ Solution: cells are preserved for 8 days at room temperature; however, it is preferable to process immediately.

➤ **Requisition Form:**
Complete the requisition form. Specify the type of specimen and pertinent clinical information, i.e., history of malignancy, chemotherapy or radiation therapy, tentative diagnosis, history of alcohol abuse or smoker.

➤ **Transport:**
1. Place the specimen container in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ **Turnaround time:** Routine: 24-48 hours after receipt in the lab

➤ **Result Interpretation:**
Negative, inflammation, abnormal cells consistent with malignant neoplasm
BREAST NIPPLE DISCHARGE

Supplies:
ThinPrep® vial (PREFERRED METHOD)

OR:
CytoLyt™ Solution
Sterile screw-cap tube

OR:
Microscope Slides-frosted end
Cyto-Spray fixative
Slide holder
Warm saline
Cotton or gauze

Requisition form
Plastic transport bag

Labeling:
If using slides, write patient first and last name on slide(s) with pencil and if right or left breast
If using tube or ThinPrep vial, write patient name and specimen site/type on outside of container

Specimen Collection:
A. ThinPrep® Vial (PREFERRED METHOD):
   (1) Open the vial and have close to the patient.
   (2) Gently massage the nipple and then express subareolar area and nipple with thumb and forefinger.
   (3) When secretion occurs, allow pea sized drop to accumulate on the apex of the nipple.
   (4) Holding the vial next to the nipple, express the drop(s) into the vial. If a plastic spatula is available, you may use the spatula to scrape the discharge and then put into vial. Swish the spatula around in the solution in the vial to dislodge the specimen.
   (5) Securely close the lid.

B. CytoLyt™ Solution:
   (1) Put 15 ml CytoLyt™ Solution into a sterile screw capped tube and place near the patient.
   (2) Gently massage the nipple and then express subareolar area and nipple with thumb and forefinger.
   (3) When secretion occurs, allow pea sized drop to accumulate on the apex of the nipple.
(4) Holding the tube next to the nipple, express the drop(s) into the tube. If a plastic spatula is available, you may use the spatula to scrape the discharge and then put it into the tube. Swish the spatula around in the solution in the tube to dislodge the specimen.

(5) Securely close the lid.

C. Frosted-end Slides:

1. Have cyto-spray fixative near breast.
2. Soak nipple with warm saline in cotton or gauze for about 10 minutes.
3. Gently massage the nipple and then express subareolar area and nipple with thumb and forefinger.
4. When secretion occurs, allow pea sized drop to accumulate on the apex of the nipple.
5. Gently place slide against the nipple and slide across quickly.
6. Spray slide IMMEDIATELY with cyto-spray fixative while specimen is still wet.
7. Make sure the slide is dry before placing into the slide holder.

Fixation/Storage:
Cyto-spray fixative, CytoLyt™ Solution or ThinPrep® PreservCyt™ preserves the cells. It is important to get the specimen to the lab for processing immediately.

Requisition Form:
Complete the requisition form. Specify whether the site is left or right breast. Provide any history that would be helpful in rendering a diagnosis.

Transport:

1. Place the specimen container or slide holder in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

Turnaround time: Routine: 24-48 hours after receipt in the lab

Result Interpretation:
Negative, inflammation, infection, and abnormal cells consistent with malignant neoplasm
BRONCHIAL BRUSHINGS/WASHINGS

➤ Supplies:
Bronchial container with saline (for washes)
15ml-50 ml disposable centrifuge tube
CytoLyt™ Solution
Requisition form
Plastic transport bag

➤ Labeling:
Write patient first and last name and specimen site/type on outside of container

➤ Specimen Collection:
A. Bronchial Brush:
   (1) After collecting the specimen, cut the brush to 2 inches.
   (2) Immerse brush, with sheath removed, in 15ml centrifuge tube with CytoLyt™.
   (3) Do not allow brush(es) to air dry as this may render them UNSATISFACTORY for cytologic evaluation.
   (4) Close lid securely to prevent leakage.
   (5) Shake tube to dislodge cells from the brush.

B. Bronchial Washing:
   (1) Collect washings in 10-20 ml of saline and rinse needle by pulling the fluid into the needle a couple times so that any material left in the needle is dislodged into the tube.
   (2) Close lid securely to prevent leakage

➤ Fixation/Storage:
CytoLyt™ Solution: immediately preserves cells. Fresh specimens must be submitted to laboratory within 72 hours of collection; however, it is essential to process immediately.

➤ Requisition Form:
Complete the requisition form. Specify type of specimen and clinical information that would be helpful in rendering a diagnosis.

➤ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround time: Routine: 24-48 hours after receipt in the lab

➤ Result Interpretation:
Negative, infection, abnormal cells consistent with malignant neoplasm
BRONCHOALVEOLAR LAVAGE

➢ Supplies:
   Bronchial container with saline
   Requisition Form
   Plastic transport bag

➢ Labeling:
   Write patient first and last name and specimen site/type on outside of centrifuge tube

➢ Specimen Collection:
   (1) Collect specimen and put in centrifuge tube with saline.
   (2) Tighten cap securely.

➢ Fixative/Storage:
   Refrigerate specimen and submit to laboratory within 72 hours of collection; however, it is
   essential to process immediately.

➢ Requisition Form:
   Complete the requisition form. Specify pertinent clinical information that may aid in rendering a
   diagnosis.

➢ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and
       requisition form together and protect against potential leakage.

➢ Turnaround Time: Routine: 24-48 hours after receipt in the lab

➢ Result Interpretation:
   Negative, infection associated with immune-compromised patients, abnormal cells consistent
   with malignant neoplasm
CEREBROSPINAL FLUID (CSF)

WARNING: THIS LAB DOES NOT ACCEPT ANY SPECIMENS THAT ARE SUSPECTED OF HAVING CREUTZFELDT-JACOB DISEASE. ANY SUSPECTED SPECIMENS WILL BE REJECTED AND RETURNED TO ORIGINAL SENDER.

➢ Supplies:
   Sterile tube
   Requisition Form
   Plastic transport bag

➢ Labeling:
   Write patient first and last name and specimen site/type on outside of centrifuge tube

➢ Specimen Collection:
   (1) Collect fresh specimen and put in sterile tube.
   (2) Collect at least 1 ml.
   (3) Tighten the cap securely.

➢ Fixative/Storage:
   REFRIGERATE specimen! It is essential to process IMMEDIATELY!

➢ Requisition Form:
   Complete the requisition form. Specify pertinent clinical information that may aid in rendering a diagnosis.

➢ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➢ Turnaround Time: 24 hours after receipt in the lab

➢ Result Interpretation:
   Absence of abnormal findings to inflammation and cellular changes conclusive for malignant neoplasm
CYST FLUID (Breast Cyst Fluid, Ovarian Cyst Fluid, Hydrocele Fluid, Other Sites)

➤ Supplies:
   Needle and syringe for aspiration  
   Centrifuge tube with CytoLyt™ Solution OR ThinPrep® Vial  
   Requisition Form  
   Plastic transport bag

➤ Labeling:
   Write patient first and last name and specimen site/type on outside of container

➤ Specimen Collection:
   (1) Aspirate sample with a 25-gauge needle (the smaller the needle, the less blood there will be in the sample).
   (2) Rinse the syringe and needle into a tube containing CytoLyt™ Solution or a ThinPrep® vial by pulling the solution into the syringe several times so that any material left in the needle is dislodged into the tube.
   (3) Discard the syringe in the biohazard container. **DO NOT SEND IN A SYRINGE WITH THE NEEDLE ATTACHED. SPECIMEN WILL BE REJECTED!**
   (4) If aspirating more than one location, each specimen must be aspirated into separate tubes and marked with the specific locations.
   (5) Tighten the cap securely.

➤ Fixative/Storage:
   Cells are preserved in the CytoLyt™ Solution for 8 days but should be sent for processing immediately.

➤ Requisition Form:
   Complete the requisition form. Specify pertinent clinical information that may aid in rendering a diagnosis.

➤ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround Time: Routine: 24-48 hours after receipt in the lab

➤ Result Interpretation:
   Negative inflammation, abnormal cells consistent with malignant neoplasm
FINE NEEDLE ASPIRATION

➢ Supplies:
  - Needle and syringe for aspiration
  - Centrifuge tube with CytoLyt™ Solution
  - Frosted-end microscope slides
  - Slide holders
  - Cytospray fixative (if making slides on location)
  - Requisition Form
  - Plastic transport bag

➢ Labeling:
  - Write patient first and last name and specimen site/type on outside of centrifuge tube and on
    slides if using the slides

➢ Specimen Collection:
  A. Thyroid Aspiration:
     (1) Aspirate sample with a 25-gauge needle (the smaller the needle, the less blood there will be in the sample).
     (2) Rinse the syringe and needle into a tube containing CytoLyt™ Solution by pulling the solution into the syringe several times so that any material left in the needle is dislodged into the tube.
     (3) Discard the syringe in the biohazard container. **DO NOT SEND IN A SYRINGE WITH THE NEEDLE ATTACHED. SPECIMEN WILL BE REJECTED!**
     (4) If aspirating more than one location, each specimen must be aspirated into separate tubes and marked with the specific locations.
     (5) Tighten the cap securely.
        a. If slides are made on location by the attending personnel, each pass should have one fixed and one air dried slide:
           i. Label each air-dried slide as such.
           ii. Label other slide(s) and spray with cyto-spray fixative IMMEDIATELY, while specimen is still wet.
        b. If slides are sent through the mail:
           i. Make one air-dried slide for each pass and label as such.
           ii. Aspirate the specimen into a tube containing CytoLyt™ Solution.
           iii. If multiple locations or nodules are aspirated, each specimen must be aspirated into separate tubes and marked with the specific locations.
           iv. Pull the solution into the syringe several times so that any material left in the needle is dislodged into the tube.
           v. Discard the syringe in the biohazard container.
           vi. If a culture is requested, it must be ordered separately since it is not an automatic part of this procedure and must be collected fresh, without fixative.
B. Breast and Other Sites:

1. Aspirate sample with a 22 gauge needle.
2. Rinse the syringe and needle into a tube containing CytoLyt™ Solution by pulling the solution into the syringe several times so that any material left in the needle is dislodged into the tube.
3. Discard the syringe in the biohazard container. **DO NOT SEND IN A SYRINGE WITH THE NEEDLE ATTACHED. SPECIMEN WILL BE REJECTED!**
4. Tighten the cap securely.
   a. If slides are made on location by the attending personnel:
      i. Make at least two slides and fix immediately with cyto-spray fixative IMMEDIATELY, while the specimen is still wet.
   b. If sending specimen through the mail:
      i. Aspirate the specimen into a tube containing CytoLyt™ Solution. Pull the solution into the syringe several times so that any material left in the needle is dislodged into the tube.
      ii. Discard the syringe in the biohazard container.
      iii. If a culture is requested, it must be ordered separately since it is not an automatic part of this procedure and must be collected fresh, without fixative.

**For any lymph node specimen or sample suspicious of lymphoma (i.e. history of lymphoma), separate core biopsy specimens into RPMI (if available) or saline for FLOW Cytometry.**

➤ Fixative/Storage:

1. If making slides, immediately spray with cyto-spray fixative. Allow slides to dry before placing in the slide holder.
2. Cells are preserved in the CytoLyt™ Solution for 8 days but should be sent for processing immediately.

➤ Requisition Form:

Complete the requisition form. Specify pertinent clinical information that may aid in rendering a diagnosis.

➤ Transport:

1. Place the specimen container in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround Time: 24-48 hours after receipt in the lab

➤ Result Interpretation:

Negative inflammatory processes and some infectious diseases, to abnormal cells consistent with malignant neoplasm
GASTROINTESTINAL TRACT BRUSHINGS AND WASHINGS

➢ Supplies:
- Container with CytoLyt™ Solution (for brushes)
- Container with saline (for washes)
- Requisition form
- Plastic transport bag

➢ Labeling:
- Write patient first and last name and specimen site/type on outside of container

➢ Specimen Collection:
  1. GI Wash – Put specimen in the container with saline.
  2. GI Brush – After collecting the specimen, cut the brush to 2 inches and immerse the brush, with sheath removed, into container with CytoLyt™ Solution.
  3. Do not allow brush to air dry as this may render them UNSATISFACTORY for cytologic evaluation.
  4. Tighten the lid securely to prevent leakage.
  5. Shake the tube to dislodge cells from the brush.

➢ Fixation/Storage:
- CytoLyt™ Solution: cells are preserved for 8 days at room temperature; however, specimen should be sent for processing immediately.

➢ Requisition Form:
- Complete the requisition form and include clinical information that would aid in rendering a diagnosis.

➢ Transport:
  1. Place the specimen container in the plastic transport bag in the sealable partition.
  2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➢ Turnaround time: Routine: 24-48 hours after receipt in the lab

➢ Result Interpretation:
- Negative, reactive processes, abnormal cells consistent with malignant neoplasm

➢ Note:
- The specimen will be considered to be non-diagnostic if epithelium is not present in the specimen or if the specimen is contaminated with food or barium sulfate.
**ORAL COLLECTION**

➢ **Supplies:**
   Container with CytoLyt™ Solution OR ThinPrep® vial
   Spatula or tongue depressor
   Requisition form
   Plastic transport bag

➢ **Labeling:**
   Write patient first and last name and specimen site/type on slide(s) with a pencil

➢ **Specimen Collection:**
   (1) Scrape the lesion with a spatula or tongue depressor.
   (2) Swish the spatula around in the CytoLyt™ Solution in the vial to dislodge the cells.
   (3) Tighten the cap securely to prevent leakage.

➢ **Fixation/Storage:**
   CytoLyt™ Solution: cells are preserved for 8 days at room temperature; however, specimen should be sent for processing immediately.

➢ **Requisition Form:**
   Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➢ **Transport:**
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together.

➢ **Turnaround time:** Routine: 24-48 hours after receipt in the lab

➢ **Result Interpretation:**
   Negative, inflammation, infection, abnormal cells consistent with malignant neoplasm
PNEUMOCYSTIS JIROVECI (CARINII)

➢ Supplies:
   Container with saline
   Requisition form
   Plastic transport bag

➢ Labeling:
   Write patient first and last name and specimen site/type on outside of container

➢ Specimen Collection:
   (1) Obtain 2-3 ml of induced sputum, bronchial washing, or bronchial lavage and put into the container of saline.
   (2) Tighten the lid securely to prevent leakage.

➢ Fixation/Storage:
   Refrigerate specimen and submit to laboratory within 72 hours of collection; however, specimen should be sent for processing immediately.

➢ Requisition Form:
   Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➢ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➢ Turnaround time: 24 hours after receipt in the lab

➢ Result Interpretation:
   No pneumocystis identified, to Pneumocystis Jiroveci (carinii) pneumonia

➢ Note:
   Test includes methenamine-silver stain and is performed in the Histology Department
SPUTUM

➤ Supplies:
  Screw-top container (may add ~ 5 ml saline)
  Requisition form
  Plastic transport bag

➤ Labeling:
  Write patient first and last name and specimen site/type on outside of container

➤ Specimen Collection:
  (1) Instruct patient to rinse mouth with water upon rising in the morning.
  (2) Expectorate a deep cough specimen (not saliva or nasal aspirates) into the cup containing saline.
  (3) Tighten the lid securely to prevent leakage.

➤ Fixation/Storage:
  Refrigerate specimen and submit to laboratory within 72 hours of collection; however, specimen should be sent for processing immediately.

➤ Requisition Form:
  Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➤ Transport:
  (1) Place the specimen container in the plastic transport bag in the sealable partition.
  (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround time: 24-48 hours after receipt in the lab

➤ Result Interpretation:
  Negative, infection including Herpes virus, abnormal cells consistent with malignant neoplasm

➤ Note:
  When a pulmonary lesion is suspected, a complete sputum series (3-5 consecutive first morning sputum specimens) should be examined. Special stains will be performed when appropriate.
TZANCK SCRAPINGS (Herpes)

➢ Supplies:
   Cyto-Spray fixative
   Plastic spatula
   Frosted-end microscope slides
   Slide holders
   Requisition form
   Plastic transport bag

➢ Labeling:
   Write patient first and last name and specimen site/type on outside of container

➢ Specimen Collection:
   (1) Remove the crust dome from the lesion with the plastic spatula by scraping the ulceration.
   (2) Smear specimen on a clean labeled slide and spray with cyto-spray fixative IMMEDIATELY, while specimen is still wet.
   (3) Make sure the slides are dry before placing into the slide holder.

➢ Fixation/Storage:
   Cyto-spray fixative: cells are preserved indefinitely at temperature; however, specimen should be sent for processing immediately.

➢ Requisition Form:
   Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➢ Transport:
   (1) Place the slide holder in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➢ Turnaround time: 24-48 hours after receipt in the lab

➢ Result Interpretation:
   Negative or positive for Herpes virus
URINE

➤ Supplies:
- Urine cup
- Screw top container with CytoLyt™ Solution
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name and specimen site/type on outside of container

➤ Specimen Collection:

A. Voided Urine:
   1. Make sure patient is well hydrated.
   2. Have patient void (clean midstream catch) into a urine cup.
   3. After the urine is collected, carefully pour the urine from the specimen cup into the blue cap urine container that is pre-filled with CytoLyt™ Solution.
   4. Tighten the lid securely to prevent leakage (turn another ¼ inch after you hear the audible click).

B. Upper Urinary Tract Lesions:
   1. For a ureteral lesion, catheterize the ureter to a point just below the level of the lesion.
   2. Collect the urine into the container with CytoLyt™ Solution.
   3. Tighten the lid securely to prevent leakage.

➤ Fixation/Storage:
CytoLyt™ Solution: cells are preserved; however, specimen should be refrigerated and sent for processing immediately.

➤ Requisition Form:
Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➤ Transport:
   1. Place the specimen container in the plastic transport bag in the sealable partition.
   2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround time: 24-48 hours after receipt in the lab

➤ Result Interpretation:
Negative, inflammation, infection such as polyomavirus, cellular changes conclusive for malignant neoplasm

➤ Note:
Do not mix voided urine with bladder washings.
Specimen will be rejected if it is the first morning voided, 24-hour collection, or drainage bag
URINE FOR CYTOMEGALIC INCLUSION DISEASE

➤**Supplies:**
  - Screw top container with CytoLyt™ Solution
  - Requisition form
  - Plastic transport bag

➤**Labeling:**
  - Write patient first and last name and specimen site/type on outside of container

➤**Specimen Collection:**
  1. Place second morning clean catch voided specimen in container with CytoLyt™ Solution.
  2. Tighten the lid securely to prevent leakage.

➤**Fixation/Storage:**
  - CytoLyt™ Solution: cells are preserved; however, specimen should be sent for processing immediately.

➤**Requisition Form:**
  - Complete the requisition form and include specimen source and clinical information that would aid in rendering a diagnosis.

➤**Transport:**
  1. Place the specimen container in the plastic transport bag in the sealable partition.
  2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤**Turnaround time:** 24-48 hours after receipt in the lab

➤**Result Interpretation:**
  - No viral inclusion bodies seen, to positive for cytomegalovirus infection (CMV)

➤**Note:**
  - Urine cytology is not the most sensitive test for the diagnosis of CMV.
URINE – UroVysion FISH (FLUORESCENT IN SITU HYBRIDIZATION)

☞ **Intended Use:**
The UroVysion Bladder Cancer Kit is designed to detect aneuploidy for chromosomes 3, 7, 17, and loss of the 9p21 locus via fluorescence in situ hybridization (FISH) in urine specimens from persons with hematuria suspected of having bladder cancer. Results are intended for use in conjunction with, and not in lieu of, current standard diagnostic procedures, as an aid for initial diagnosis of bladder carcinoma in patients with hematuria, and subsequent monitoring for tumor recurrence in patients previously diagnosed with bladder cancer.

➣ **Supplies:**
- Urine cup
- UroVysion FISH kit
- Requisition Form

➣ **Labeling:**
Write patient first and last name and specimen site/type on outside of specimen container

➣ **Specimen Collection:**
1. Use a urine cup to collect the urine specimen. The patient should use the clean-catch method to collect the urine specimen into the sterile cup. There should be a minimum of 33 ml of collected urine and no more than 60 ml.
2. After the urine is collected, carefully pour the urine from the specimen cup into the blue cap urine container that is pre-filled with CytoLyt™ Solution. The ratio of urine to CytoLyt™ Solution should be 2:1 (e.g. 30 ml urine: 15 ml CytoLyt™ Solution).
3. Tightly secure the blue cap on the specimen cup to prevent leakage (turn another ¼ inch after you hear the audible click).

➣ **Fixation/Storage:**
Store between 4°C and 30°C (39°F - 86°F). Specimen must be processed within 72 hours and should be placed on ice packs.

➣ **Requisition Form:**
Complete the requisition form including specimen origin.

➣ **Transport:**
1. Place the specimen container and absorbent pads in the biohazard bag and requisition form in front pocket.
2. If shipping, place in the collection kit box that is included and send in a shipping box with ice packs.

➣ **Turnaround time:** 1 week after receipt in the lab

➣ **Result Interpretation:**
Normal to abnormal for chromosomal analysis indicative of Urothelial Carcinoma
### MOLECULAR PATHOLOGY

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ACCEPTABILITY OF MOLECULAR PATHOLOGY SPECIMENS

To maintain specimen quality and integrity, specimens will NOT be accepted under the following circumstances:

- Lack of two patient identifiers (one identifier being patient first and last name) on specimen transport vial/tube, ThinPrep® vial, Cervical Sampler, SurePath™ vial, Aptima Unisex swab, Aptima Unisex Urine specimen tube, Aptima Vaginal swab, BD Affirm Vaginosis collection tube, UTM swab
- No name on requisition form
- Name on requisition form does not match name on specimen
- Name illegible or missing first/last name
- No specimen received with requisition form
- No requisition form received with specimen
- Inappropriate collection or storage of specimens
- Expired transport media or expired specimens beyond their stability
- Leaky specimen will not be tested for Molecular tests

If a specimen is determined to be unacceptable, a rejection report will be issued to client with the reason for the rejection.

The following guidelines are to assist in proper specimen preparation:

- Label all specimen containers with two patient identifiers: First and last name, DOB, requisition sticker with number, clinic patient ID number.
- The requisition form must include the patient’s name, gender, birth date, specimen site, test requested, date and time of collection, name and address of person ordering test, and any other pertinent clinical information.
- All information should be printed clearly and the name spelling should match exactly on the requisition form and the specimen.
BACTERIAL VAGINOSIS ORGANISMS TESTING
Gardnerella vaginalis, Atopobium vaginae, Lactobacillus species, Mobiluncus mulieris, Mobiluncus curtisii, Ureaplasma urealyticum, Mycoplasma hominis and Candida species

➤ Specimens:
The specimens validated for these tests include ThinPrep® and UTM swab.

➤ Supplies:
ThinPrep® vial with PreservCyt® Solution or…
Universal Viral Transport (UTM) swab (Female)
Requisition form
Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on outside of collection container. Do not use vial or swab after expiration date printed on vial/swab.

➤ Specimen Collection:

A. ThinPrep Vial:
   (1) Open a ThinPrep vial containing PreservCyt® Solution so that the vial is ready for the specimen as soon as it is taken.
   (2) To take a cervical sample with the cytobrush/spatula:
      a. Use the double edge end of a plastic spatula, with the longer point at the cervical os.
      b. Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
      c. Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.
      d. Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
      e. Slowly rotate the cytobrush ½ to one full revolution (180°-360°) only.
         **DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.**
      f. Gently remove brush without touching the vaginal surface.
      g. Rinse the brush immediately (do not let it set in the vial) in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.
      h. Tightly seal the cap onto the vial to prevent leakage.
      i. Label specimen vial with patient name and second patient identifier.
   (3) To take a cervical sample with the Cervex broom:
      a. 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.
NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS.

b. Rinse 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. Discard the broom.
c. Tightly seal the cap onto the vial to prevent leakage.
d. Label specimen vial with patient name and second patient identifier.

B. UTM Swab:
   (1) Collect specimen with one swab.
   (2) Aseptically remove cap from vial.
   (3) Insert swab into the vial with medium.
   (4) Break swab shaft by bending it against the vial wall evenly at the pre-scored line.
   (5) Replace cap on vial and close tightly.
   (6) Label specimen tube with the patient name and second patient identifier.

➤ Fixation/Storage:
   • ThinPrep PreservCyt® Solution: Cells are preserved for 30 days at 4°-37°C (39°F-98.6°F).
   • UTM: For best recovery, keep UTM refrigerated at 2°-8°C (35.6°-46.4°F) until pick-up. Specimen is kept refrigerated for 7 days.

➤ Requisition Form:
   Complete the requisition form and include specimen site and pertinent clinical information.

➤ Transport:
   (1) Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect requisition from potential leakage.
   (3) UTM specimens should be refrigerated until pick-up.

➤ Turnaround Time: 2-3 days after specimen arrives in the lab.

➤ Result Interpretation:
   Negative or positive for each organism.

➤ Notes:
   • Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
   • UTM swabs are viable for 7 days from collection when refrigerated.
   • UTM specimens that do not have the swab in the media will be rejected.
CERVICAL DNA DTEX TEST [3q26 (TERC) & 5p15 (TERT) Gene Amplification]

➢ Specimens:
Cervical DNA Dtex test is designed to work in conjunction with a Pap test and/or HPV assay. The specimens acceptable for testing include ThinPrep or SurePath.

➢ Supplies:
ThinPrep® vial with PreservCyt® Solution or…
SurePath vial
Requisition form
Plastic transport bag

➢ Labeling:
Write patient first and last name as well as one additional patient identifier, or attach patient label, to outside of collection container.

➢ Additional Information:
This test may be ordered as a verbal add-on test to existing specimens that have not been discarded. Please call Client Relations at 303-592-7284 if you wish to add-on this assay.

➢ Specimen Collection:
A. ThinPrep Vial:
(1) Open a ThinPrep vial containing PreservCyt® Solution so that the vial is ready for the specimen as soon as it is taken.
(2) To take a cervical sample with the cytobrush/spatula:
   a. Use the double edge end of a plastic spatula, with the longer point at the cervical os.
   b. Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
   c. Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.
   d. Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
   e. Slowly rotate the cytobrush ½ to one full revolution (180°-360°) only.
      DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.
   f. Gently remove brush without touching the vaginal surface.
   g. Rinse the brush immediately (do not let it set in the vial) in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the vial wall.
      Swirl the brush vigorously to further release material. Discard the brush.
   h. Tightly seal the cap onto the vial to prevent leakage.
   i. Label specimen vial with patient name and second patient identifier.
(3) To take a cervical sample with the Cervex broom:
a. 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.

**NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS.**

b. Rinse 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. Discard the broom.

c. Tightly seal the cap onto the vial to prevent leakage.

d. Label specimen vial with patient name and second patient identifier.

B. **SurePath Vial:**

1. Open a SurePath vial containing ethanol fixative.
2. If using a Cervex Broom®:
   a. Visualize the uterine cervix. Insert the central bristles of the broom into the endocervical canal.
   b. Using gentle pressure, push the broom in the direction of the cervix until the lateral bristles are splayed out over the ectocervix.
   c. Rotate 5 full turns in a CLOCKWISE direction.

**NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS**

d. Remove the broom.

e. While holding the handle of the broom in a gloved hand, dislodge the broom head from the handle and place the HEAD into the SurePath vial without touching the head of the device.

f. Tightly seal the cap onto the vial to prevent leakage.

g. Label specimen vial with patient name and second patient identifier.

3. If using a cytobrush and spatula:
   a. Insert the contoured end of the plastic spatula and rotate 360° around the entire ectocervix.
   b. Snap the device handle and drop the detached head into the vial. Do NOT touch the head of the device while detaching.
   c. Insert the cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ½ to one full revolution (180°-360°) in one direction. Do NOT over-rotate brush as profuse bleeding may occur.
   d. Snap the device handle and drop the detached head into the SurePath vial. Do NOT touch the head of the device while detaching.
   e. Tightly seal the cap onto the vial to prevent leakage.
   f. Label specimen vial with patient name and second patient identifier.
➢ Fixation/Storage:
Inappropriate collection or storage of specimens may result in nucleic acid alteration, which may affect testing sensitivity.
• ThinPrep PreservCyt® Solution: Cells are preserved for 30 days at 4°-37°C (39°F-98.6°F).
• SurePath Solution: Cells are preserved for 30 days at 15°-30°C (59°F-86°F). After processing, specimen is good for 14 days at 15°-30°C (59°-86°F).

➢ Requisition Form:
Complete the requisition form and include specimen site and clinical information that would aid in rendering a diagnosis, including previous Pap test and HPV results.

➢ Transport:
(1) Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
(2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together yet protect requisition from potential leakage.

➢ Turnaround Time:
7-9 days after specimen arrives in the lab.

➢ Result Interpretation:
Negative or positive for amplification of chromosomal regions 3q26 and 5p15. The possibility for insufficient test results may be seen.

➢ Note:
• Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
• Expired vials are unacceptable for use and will be rejected.
CHLAMYDIA TRACHOMATIS (CT), NEISSERIA GONORRHOEAE (NG) AND TRICHOMONAS VAGINALIS (TV) TESTING

➤ Specimens:
The specimens validated for testing include ThinPrep, SurePath, Aptima Unisex urine, Aptima Unisex swab, Aptima Vaginal swab, and female UTM swab.

➤ Supplies:
- ThinPrep® vial with PreservCyt® Solution or…
- SurePath vial or…
- Aptima Swab Collection Device (Female or Male) or…
- Aptima Urine Collection Device (Female or Male for CT/NG testing only) or…
- Aptima Vaginal Swab Collection Device (Female) or …
- Aptima Specimen Transport Tube (green label) or…
- Universal Transport Media (UTM) (Female)
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on outside of collection container. Do not use labels on the outside of Aptima tubes as they do not fit inside instrument well. Do not use vials or tubes after expiration date printed on vial/tube.

➤ Specimen Collection:
A. ThinPrep Vial:
   1. Open a ThinPrep vial containing PreservCyt® Solution so that the vial is ready for the specimen as soon as it is taken.
   2. To take a cervical sample with the cytobrush/spatula:
      a. Use the double edge end of a plastic spatula, with the longer point at the cervical os.
      b. Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
      c. Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.
      d. Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
      e. Slowly rotate the cytobrush ½ to one full revolution (180°-360°) only.
         **DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.**
      f. Gently remove brush without touching the vaginal surface.
      g. Rinse the brush immediately (do not let it set in the vial) in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.
      h. Tightly seal the cap onto the vial to prevent leakage.
i. Label specimen vial with patient name and second patient identifier.

(3) To take a cervical sample with the Cervex broom:
   a. 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. **NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS.**
   b. Rinse 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. Discard the broom.
   c. Tightly seal the cap onto the vial to prevent leakage.
   d. Label specimen vial with patient name and second patient identifier.

B. SurePath Vial:
   (1) Open a SurePath vial containing ethanol fixative.
   (2) If using a Cervex Broom®:
       a. Visualize the uterine cervix. Insert the central bristles of the broom into the endocervical canal.
       b. Using gentle pressure, push the broom in the direction of the cervix until the lateral bristles are splayed out over the ectocervix.
       c. Rotate 5 full turns in a CLOCKWISE direction. **NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS**
       d. Remove the broom.
       e. While holding the handle of the broom in a gloved hand, dislodge the broom head from the handle and place the HEAD into the SurePath vial without touching the head of the device.
       f. Tightly seal the cap onto the vial to prevent leakage.
       g. Label specimen vial with patient name and second patient identifier.
   (3) If using a cytobrush and spatula:
       a. Insert the contoured end of the plastic spatula and rotate 360° around the entire ectocervix.
       b. Snap the device handle and drop the detached head into the vial. Do **NOT** touch the head of the device while detaching.
       c. Insert the cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ½ to one full revolution (180°-360°) in one direction. Do **NOT** over-rotate brush as profuse bleeding may occur.
       d. Snap the device handle and drop the detached head into the SurePath vial. Do **NOT** touch the head of the device while detaching.
       e. Tightly seal the cap onto the vial to prevent leakage.
       f. Label specimen vial with patient name and second patient identifier.
C. Aptima Swab Female Endocervical Collection:
   (1) Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (WHITE shaft in package with red printing). To remove excess mucus from the cervical os, a large-tipped swab (not provided) may be used. **DISCARD WHITE SHAFT SWAB AFTER CLEANING.**
   (2) Insert specimen collection swab (BLUE shaft swab in package with green printing) into endocervical canal.
   (3) Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
   (4) Withdraw swab carefully; avoid any contact with vaginal mucosa.
   (5) Remove cap from swab specimen transport tube and immediately place BLUE specimen collection swab into specimen transport tube.
   (6) Carefully break swab shaft at score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
   (7) Re-cap swab specimen transport tube tightly.
   (8) Label specimen swab with the patient name and second patient identifier.

D. Aptima Swab Male Urethral Collection:
   **Patient should not have urinated for at least 1 hour prior to specimen collection.**
   (1) Insert specimen collection swab (BLUE shaft swab in package with green printing) 2 to 4 cm into urethra.
   (2) Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.
   (3) Withdraw swab carefully.
   (4) Remove cap from swab specimen transport tube and immediately place BLUE specimen collection swab into specimen transport tube.
   (5) Carefully break swab shaft at score-line and discard the top portion of the swab shaft; use care to avoid splashing of contents.
   (6) Re-cap swab specimen transport tube tightly.
   (7) Label specimen swab with the patient name and second patient identifier.

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

F. Aptima Vaginal Self-Collection (Female)

Ensure that patients read the Patient Collection Instructions before providing them with a collection kit.

(1) 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 Vaginal Swab Specimen Collection Kit.

(2) 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.

(3) Carefully insert the swab into the vagina about 2 inches (5 cm) 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 and then withdraw the swab without touching the skin.

(4) 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.

(5) Immediately place the swab into the transport tube so that the score line is at the top of the tube.

(6) Carefully break the swab shaft at the score line against the side of the tube.

(7) Immediately discard the top portion of the swab shaft.

(8) Tightly screw the cap onto the tube.

(9) Label specimen tube with the patient name and second patient identifier.

G. ThinPrep or SurePath Aliquot:

(1) If the entire ThinPrep vial cannot be sent due to multiple testing requests:
   a. The CT/NG/TV sample can be pulled off before or after cytology processing of specimen.
   b. To prevent contamination, work under a hood or in a low airflow area. Wear a mask to avoid unnecessary contamination from oral flora while sampling.
   c. Vortex (preferred) or shake the sample for 5 seconds.
   d. With a clean pipette, remove 2.0 ml (1.5 ml minimum) of the well-mixed PreservCyt® Solution immediately before settling occurs.
   e. Place in a clean 2.0 ml (preferred size) transport tube with screw top. **DO NOT** use snap cap tubes.
      
      **NOTE:** If Aptima Specimen Transportation tube (green label) is available, place exactly 1.0 ml of well-mixed PreservCyt® fluid in tube. Make sure use of Aptima tube is before expiration date.
   f. Label specimen tube with the patient name and second patient identifier.

H. UTM Swab:

(1) Collect specimen with one swab.

(2) Aseptically remove cap from vial.
(3) Insert swab into the vial with medium.
(4) Break swab shaft by bending it against the vial wall evenly at the pre-scored line.
(5) Replace cap on vial and close tightly.
(6) Label specimen tube with the patient name and second patient identifier.

➤**Fixation/Storage:**

<table>
<thead>
<tr>
<th>Media</th>
<th>Room Temp (15°-30°C)</th>
<th>Refrigerated (2°-8°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ThinPrep</td>
<td>30 days</td>
<td>XX</td>
</tr>
<tr>
<td>SurePath</td>
<td>30 days *</td>
<td>XX</td>
</tr>
<tr>
<td>Aptima Swab</td>
<td>7 days</td>
<td>XX</td>
</tr>
<tr>
<td>Aptima Urine Tube</td>
<td>7 days</td>
<td>XX</td>
</tr>
<tr>
<td>Aptima Vaginal Swab</td>
<td>7 days</td>
<td>XX</td>
</tr>
<tr>
<td>UTM Swab</td>
<td>XX</td>
<td>7 days</td>
</tr>
<tr>
<td>Specimen Transport</td>
<td>See Media and storage temperatures above.</td>
<td></td>
</tr>
<tr>
<td>Tube/Aliquots</td>
<td></td>
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</tr>
</tbody>
</table>

*NOTE: After SurePath processing, specimen is good for 14 days at room temperature. Inappropriate collection or storage of specimens may result in nucleic acid alteration which may affect testing sensitivity.

➤**Requisition Form:**

Complete the requisition form and include specimen site and clinical information that would aid in rendering a diagnosis.

➤**Transport:**

(1) Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
(2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect requisition against potential leakage.

➤**Turnaround Time:** 1-2 days after specimen arrives in the lab

➤**Result Interpretation:**

Negative or positive for Chlamydia trachomatis, Negative or positive for Neisseria gonorrhoeae and Negative or positive for Trichomonas vaginalis. The possibility of equivocal results may be seen.

➤**Notes:**

• Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
• Expired vials or tubes are unacceptable for use and will be rejected.
• Aptima swab specimens that do not have the blue swab in the tube will be rejected. If the white swab, or the blue and white swab together, are in the Aptima tube, the specimen will be rejected.
• Aptima urine specimens that are filled above or below the black indicator lines on the Aptima tube will be rejected.
• UTM swab specimens that do not have the swab in the tube will be rejected.
Collection for Endocervical Swab Specimens

1. Remove excess mucus from cervical os and surrounding mucosa using cleaning swab (white shaft swab in package with red printing). **Discard this swab.**
   A large-tipped cleaning swab (not provided) may be used to remove excess mucus.
2. Insert specimen collection swab (blue shaft swab in package with green printing) into endocervical canal.
3. Gently rotate swab clockwise for 10 to 30 seconds in endocervical canal to ensure adequate sampling.
4. Withdraw swab carefully; avoid any contact with vaginal mucosa.
5. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
6. Carefully break swab shaft at scoreline; use care to avoid splashing contents.
7. Re-cap swab specimen transport tube tightly.

Collection for Male Urethral Swab Specimens

**Patient should not have urinated for at least 1 hour prior to specimen collection.**

1. Insert specimen collection swab (blue shaft swab in package with green printing) 2 to 4 cm into urethra.
2. Gently rotate swab clockwise for 2 to 3 seconds in urethra to ensure adequate sampling.
3. Withdraw swab carefully.
4. Remove cap from swab specimen transport tube and immediately place specimen collection swab into specimen transport tube.
5. Carefully break swab shaft at scoreline; use care to avoid splashing contents.
6. Re-cap swab specimen transport tube tightly.

Specimen Transport and Storage

After collection, transport and store swab in swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed with the APTIMA Assay for CT and/or GC within 60 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 90 days after collection.
Collection for Male and Female Urine Specimens

Patient should not have urinated for at least 1 hour prior to specimen collection.

1. Direct patient to provide first-catch urine (approximately 20 to 30 mL of initial urine stream) into 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 labial area prior to providing specimen.

2. Remove cap from urine specimen transport tube and transfer 2 mL of urine into urine specimen transport tube using disposable pipette provided. The correct volume of urine has been added when fluid level is between black fill lines on urine specimen transport tube label.

3. Re-cap urine specimen transport tube tightly. This is now known as the “processed urine specimen.”

Specimen Transport and Storage

1. After collection, transport and store the processed urine specimens in the APTIMA urine specimen transport tube at 2°C to 30°C until tested. Processed urine specimens should be assayed with the APTIMA Assay for CT and/or GC within 30 days of collection. If longer storage is needed, freeze at -20°C to -70°C for up to 90 days after collection.

2. Urine samples that are still in the primary collection container must be transported to the lab at 2°C to 30°C. Transfer urine sample into APTIMA urine specimen transport tube within 24 hours of collection. Store at 2°C to 30°C and test within 30 days of collection.
GROUP B STREPTOCOCCUS TESTING (Pregnancy Screening)
Including Reflex Susceptibilities if Penicillin Allergic

➤ Specimens:
Screening for GBS colonization in antepartum women between 35 to 37 weeks gestation using vaginal/rectal swab specimens.

➤ Supplies:
- Liquid Amies Culture Swab or…
- Modified Stuarts Culture Swab (No Wooden Swabs Accepted)
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on culture tube, or attach patient label to outside of culture tube. Do not use culture swab after expiration date printed on tube.

➤ Specimen Collection:
A. Vaginal-Anorectal Sample Collection:
Combination sampling of the two sites is preferred but Vaginal only or Anorectal only swabs are acceptable.
(1) Do NOT use speculum or lubricant on patient for collection.
(2) Remove swab from sterile packaging and swab the lower vagina (vaginal introitus) in a circular motion. Cervical swabs are not recommended.
(3) Swab rectum by inserting swab through the anal sphincter. **NOTE: Always follow the front to back technique; VAGINA FOLLOWED BY RECTUM. A single swab may be used or two different swabs.**
(4) Remove the cap from the transport tube and place swab into the transport tube and snap shut to prevent drying out.
(5) Label the culture swab with patient name and second patient identifier. Include the date the sample was collected and penicillin allergy status.

➤ Fixation/Storage:
The total time between sample collection and delivery to lab should be no more than 5 days at room temperature 20°-25°C. Inappropriate storage of specimens may result in damage to the organism that may affect testing.

➤ Requisition Form:
Complete the requisition form and include Labor and Delivery hospital of choice for faxing of additional results.
Please mark whether the patient is allergic to Penicillin in the case that susceptibilities may be run if indicated.

➤ **Transport:**
(1) Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
(2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together.
(3) Specimens can be transported at room temperature.

➤ **Turnaround Time:**
2-3 days after specimen arrives in the lab for screen and 4-5 additional days for susceptibilities.

➤ **Result Interpretation:**
Negative or positive for Group B Streptococcus.
Sensitive to resistant for antibiotic susceptibilities to drugs.

➤ **GBS Results for Patients in Labor:**
After hours/weekends, call 303-592-7284; option 1

➤ **Notes:**
- Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
- Expired culture swabs are unacceptable for use and will be rejected.
- Culture tubes that have no swab will be rejected.
HERPES SIMPLEX VIRUS TYPES 1 & 2 (HSV) TESTING

➤ Specimens:
The specimens validated for testing include ThinPrep and unisex mucocutaneous UTM swab.

➤ Supplies:
ThinPrep® vial with PreservCyt® Solution or…
Universal Viral Transport (UTM) swab (Female or Male)
Requisition form
Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on outside of collection container. Do not use vial or swab after expiration date printed on vial/swab.

➤ Specimen Collection:
A. ThinPrep Vial:
   (1) Open a ThinPrep vial containing PreservCyt® Solution so that the vial is ready for the specimen as soon as it is taken.
   (2) To take a cervical sample with the cytobrush/spatula:
      a. Use the double edge end of a plastic spatula, with the longer point at the cervical os.
      b. Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
      c. Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.
      d. Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
      e. Slowly rotate the cytobrush ½ to one full revolution (180°-360°) only.
         **DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.**
      f. Gently remove brush without touching the vaginal surface.
      g. Rinse the brush immediately (do not let it set in the vial) in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.
      h. Tightly seal the cap onto the vial to prevent leakage.
      i. Label specimen vial with patient name and second patient identifier.
   (3) To take a cervical sample with the Cervex broom:
      a. 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.
         **NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS.**
b. Rinse 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. Discard the broom.
c. Tightly seal the cap onto the vial to prevent leakage.
d. Label specimen vial with patient name and second patient identifier.

B. UTM Swab:
(1) Collect specimen with one swab.
(2) Aseptically remove cap from vial.
(3) Insert swab into the vial with medium.
(4) Break swab shaft by bending it against the vial wall evenly at the pre-scored line.
(5) Replace cap on vial and close tightly.
(6) Label specimen tube with the patient name and second patient identifier.

➤ Fixation/Storage:
• ThinPrep PreservCyt® Solution: Cells are preserved for 30 days at 4°-37°C (39°F-98.6°F).
• UTM: For best recovery, keep UTM refrigerated at 2°-8°C (35.6°-46.4°F) until pick-up. Specimen is kept refrigerated for 7 days.

➤ Requisition Form:
Complete the requisition form and include specimen site and clinical information.

➤ Transport:
(1) Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
(2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect requisition from potential leakage.
(3) For best recovery, UTM specimens need to remain refrigerated until pick-up.

➤ Turnaround Time: 2-3 days after specimen arrives in the lab.

➤ Result Interpretation:
Negative or positive for Herpes Simplex 1 and Herpes Simplex 2.

➤ Note:
• Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
• UTM swabs are viable for 7 days from collection when refrigerated.
• UTM specimens that do not have the swab in the media will be rejected.
HUMAN PAPILLOMAVIRUS (HPV) TESTING
HPV Reflex, HPV DNA Co-Test and High Risk 16/18 Genotyping

➤ Specimens:
The specimens validated for testing include ThinPrep and SurePath.

➤ Supplies:
- ThinPrep® vial with PreservCyt® Solution or…
- SurePath vial
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on outside of container. Do not use vial after expiration date printed on vial.

➤ Specimen Collection:
A. ThinPrep Vial:
1. Open a ThinPrep vial containing PreservCyt® Solution so that the vial is ready for the specimen as soon as it is taken.
2. To take a cervical sample with the cytobrush/spatula:
   a. Use the double edge end of a plastic spatula, with the longer point at the cervical os.
   b. Rotate around the ectocervix, placing special emphasis on the squamo-columnar junction.
   c. Rinse material in the vial by vigorously swirling the spatula 10 times. Discard or use other end for taking a vaginal sample. Discard.
   d. Using the cytobrush, gently insert the brush into the endocervical canal past the squamo-columnar junction, leaving the last two rows of bristles exposed.
   e. Slowly rotate the cytobrush ½ to one full revolution (180°-360°) only. **DO NOT OVER-ROTATE AS PROFUSE BLEEDING MAY OCCUR.**
   f. Gently remove brush without touching the vaginal surface.
   g. Rinse the brush immediately (do not let it set in the vial) in the PreservCyt® Solution by rotating the device in the solution 10 times while pushing against the vial wall. Swirl the brush vigorously to further release material. Discard the brush.
   h. Tightly seal the cap onto the vial to prevent leakage.
   i. Label specimen vial with patient name and second patient identifier.

3. To take a cervical sample with the Cervex broom:
   a. 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.
NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS.

b. Rinse 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. Discard the broom.
c. Tightly seal the cap onto the vial to prevent leakage.
d. Label specimen vial with patient name and second patient identifier.

B. SurePath Vial:
   
(1) Open a SurePath vial containing ethanol fixative.
(2) If using a Cervex Broom®:
   
a. Visualize the uterine cervix. Insert the central bristles of the broom into the endocervical canal.
b. Using gentle pressure, push the broom in the direction of the cervix until the lateral bristles are splayed out over the ectocervix.
c. Rotate 5 full turns in a CLOCKWISE direction.
   
   NOTE: DO NOT ROTATE COUNTERCLOCKWISE AS IT WILL DISLODGE THE CELLS

d. Remove the broom.
e. While holding the handle of the broom in a gloved hand, dislodge the broom head from the handle and place the HEAD into the SurePath vial without touching the head of the device.
f. Tightly seal the cap onto the vial to prevent leakage.
g. Label specimen vial with patient name and second patient identifier.

(3) If using a cytobrush and spatula:
   
a. Insert the contoured end of the plastic spatula and rotate 360° around the entire ectocervix.
b. Snap the device handle and drop the detached head into the vial. Do NOT touch the head of the device while detaching.
c. Insert the cytobrush into the endocervix until only the bottom-most bristles are exposed at the os. Slowly rotate ½ to one full revolution (180°-360°) in one direction. Do NOT over-rotate brush as profuse bleeding may occur.
d. Snap the device handle and drop the detached head into the SurePath vial. Do NOT touch the head of the device while detaching.
e. Tightly seal the cap onto the vial to prevent leakage.
f. Label specimen vial with patient name and second patient identifier.

Fixation/Storage:

- ThinPrep vials are stable at 4°-37°C (39°-98.6°F) and may be stored up to 30 days after collection.
- SurePath vials are stable at 15°-30°C (59°-86°F) and may be stored up to 30 days after collection. If specimen has been processed, storage is for 14 days.
➤ **Requisition Form:**
Complete the requisition form and include specimen site and clinical information.

➤ **Transport:**
1. Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect requisition from potential leakage.
3. Specimens can be transported at room temperature.

➤ **Turnaround Time:**
1-2 days after specimen arrives in the lab if HPV testing only or 1-2 days after cytology is resulted on reflex specimens.

➤ **Result Interpretation:**
Negative or positive for High Risk HPV for genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68.

➤ **Notes:**
- Vials that are past their expiration date will be rejected.
- A specimen will be rejected if there is less than 4 ml of specimen in the ThinPrep or SurePath vial, or if the specimen has exceeded the expiration date.
- Use of lubricating jelly on the vaginal speculum may interfere with the test results.
- Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
REFLEX TESTING FOR HPV (HIGH RISK TYPES ONLY)

Checking Requisition Form Will Over-Ride This Form


Please indicate the category(s) for reflex testing on your patients:

<table>
<thead>
<tr>
<th>High Risk HPV Only</th>
<th>HR HPV Plus 16/18</th>
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<tbody>
<tr>
<td>ASC-US</td>
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<td>ASC-H</td>
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<td>LSIL</td>
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<td>HSIL</td>
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<tr>
<td>AGUS*</td>
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<tr>
<td>HPV Only (No Pap)</td>
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</tbody>
</table>

No HPV Testing Before 21st Birthday _______

No HPV Testing Before 25th Birthday _______

Do NOT Allow HPV Testing if Previous HPV Test Was Within 12 Months _______

*(Atypical endometrial cells will not be tested)*

I request that MetroPath perform the HPV test(s) on patients with the above-indicated category(s).

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<table>
<thead>
<tr>
<th>Signature of Provider</th>
<th>Date</th>
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<tbody>
<tr>
<td>CLIENT INFORMATION</td>
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<tr>
<td>Client ID Number</td>
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<tr>
<td>Name of Provider (please print)</td>
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<td>Name of Office/Client/Practice</td>
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<td>Street Address</td>
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<td>City/State/Zip Code</td>
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</tbody>
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VAGINOSIS (BD AFFIRM™) TESTING

➤ Specimens:
BD Affirm test on vaginal fluid specimens.

➤ Supplies:
- Affirm™ VPIII Ambient Temperature Transport System
- Requisition form
- Plastic transport bag

➤ Labeling:
Write patient first and last name as well as one additional patient identifier on vial, or attach patient label to outside of collection vial. Do not use tubes after expiration date printed on vial/tube.

➤ Specimen Collection:

1. Make sure personnel collecting vaginal fluid specimens are well trained to minimize the possibility of inadequate specimens.
2. Separate swabs should be used for other tests, e.g. culture or Aptima swab samples.
3. Tear open foil pouch containing ampule. DO NOT REMOVE AMPULE LID.
4. Squeeze ampule until the pouch inside ruptures.
5. Remove cap from Sample Collection Tube (SCT) and dispense the entire contents of the ampule (3-4 drops) into the Tube.
6. Write on the tube the time the sample was collected.
7. Place the patient in position for a pelvic examination. Insert an UNLUBRICATED speculum (WITHOUT JELLY OR WATER) into the vagina to permit visualization of the posterior vaginal fornix.
8. Using the sterile swab, obtain a sample from the posterior vaginal fornix.
9. Twist or roll the swab against the vaginal wall two or three times, ensuring the entire circumference of the swab has touched the vaginal wall.
10. Swab the lateral vaginal wall while removing the swab.
11. Immediately place the swab into the Sample Collection Tube (SCT).
12. With the swab touching the BOTTOM of the collection tube, grasp the pre-scored handle of the swab just above the top of the tube and bend until the swab breaks.
13. When the swab is fully inserted into the collection tube, the score mark on the swab is approximately 1 cm above the top of the collection tube.
   NOTE: DO NOT CUT SWAB SHAFT. Shaft will break at appropriate length for testing to occur.
14. Discard the broken handle into an infectious waste container.
15. Place the cap over the exposed end of the swab and firmly press the cap onto the tube. The cap will “snap” onto the tube when it is properly seated.
Label specimen with the patient name and second patient identifier.

**Fixation/Storage:**
The total time between sample collection and proceeding with sample preparation should be no longer than 72 hours when the specimen is stored at ambient temperatures (15°C-30°C). Inappropriate storage of specimens may result in nucleic acid alteration which may affect testing.

**Requisition Form:**
Complete the requisition form and include specimen site, time specimen was collected and clinical information that would aid in rendering a diagnosis.

**Transport:**
1. Attach the bright green BV-STAT sticker with the collection date and time indicated to the outside of the specimen bag.
2. Place the tightly sealed specimen in the plastic transport bag in the sealable partition.
3. Place the requisition form in the front pocket. This will keep the specimen and requisition form together.

**Turnaround Time:**
1-2 days after specimen arrives in the lab

**Result Interpretation:**
Negative or positive for Trichomonas vaginalis, negative or positive for Gardnerella vaginalis, and negative or positive for Candida species.

**Notes:**
- Make sure the specimen is kept in a safe area where intentional or unintentional alteration of specimen (labeling changes, contamination, and temperature fluctuations) cannot take place.
- On Fridays and extended holiday weekends, due to the shortened stability of the specimen, it is required that MetroPath be called before 5:00pm and notified of the incoming specimen: 303.592.7284 (request a specimen pick-up). Arrangements will be made to pick up the specimen to ensure that the specimen integrity is not compromised.
- Affirm tube that is missing the swab will be rejected.
Acceptability of Tissue Pathology Specimens

To ensure proper and safe handling of specimens for the best quality of patient care and result reporting, tissue pathology specimens submitted to MetroPath will not be processed under the following circumstances until absolute patient identity and specimen integrity are established:

- Specimen container received without a requisition form
- Patient name on specimen container and requisition form/insurance sheet do not match
- Requisition form received without a specimen container
- Specimen is received without fixative
- Lack of two patient identifiers on specimen container

To reconcile unacceptable specimens, the client's office will be contacted by telephone/fax since rejection of a specimen may not occur. The physician's office may request that the specimen be returned to them or forwarded to a different lab.

The following guidelines are to assist in proper specimen preparation:

- Label all specimen containers with two patient identifiers: First and last name, DOB, requisition sticker with number, and/or clinic patient ID number.
- Label all specimen containers with the biopsy site or corresponding letter designation to requisition form.
- The requisition form must include the patient's name, gender, date of birth, specimen site, test requested, date and time of collection, person ordering test, and any other pertinent clinical information.
- All information should be printed clearly and the name spelling should match exactly on the requisition form and the specimen bottle.
- Clearly specify on the requisition form any special testing requests such as Chromosome Analysis for Products of Conception or Cytogenetics/Flow Cytometry.

If modification or change in patient identification is necessary, the following form is faxed to the client to provide correct information and must be signed by the provider/physician and faxed back to the lab for proper documentation:
AUTHORIZATION/LIABILITY RELEASE FORM
IRRRETRIEVABLE SPECIMEN
MISLABELED REQUISITION/MISLABELED SPECIMEN

Sent To: ___________________________  Attention: ___________________________
Fax Number: ______________________  Today’s Date: ______________________
Time Sent: _________________________  Sent By: ___________________________
Case #: ____________________________

** This specimen will not be processed until this form is completed and returned. **
An amended report will not be released until this form is completed and returned.

Issue: _________________________________________________________________

______________________________________________________________

______________________________________________________________

______________________________________________________________

I ____________________________
(HEALTHCARE PROVIDER THAT SAW PATIENT; PLEASE PRINT NAME AND TITLE)

accept full responsibility AND all liability for any potential consequences resulting from alteration of
this case. I also authorize release of results.

Signature of Healthcare Provider ___________________________  Date: __________

The information contained in this facsimile transmission is privileged, confidential, or
proprietary information intended only for the use of the individual or entity named above.
Information in this facsimile transmission may be protected by physician-patient privilege or
the privilege applicable to any laws governing proprietary information. If you received this
communication in error, please notify us immediately by telephone.

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL BACK AS SOON AS POSSIBLE.
THANK YOU.

7444 W Alaska Drive, Ste 250 • Lakewood, Colorado  80226 • 303.592.7284 • Fax 303.892.0601 • www.metropath.com
DEVICES AND SPECIMENS NOT NEEDED FOR EXAMINATION

Specimens removed during a surgical procedure are ordinarily sent to pathologists for examination. Exceptions are made by consultation with the providing physician. The following list of tissue specimens and devices do not have to be sent to the laboratory for examination at the discretion of the surgeon:

- Bunions
- Cataracts
- Hardware, tubing, implants of various types (unless requested for documentation)
- Meniscus fragments – arthroscopically removed: larger meniscus fragments may be sent for documentation, if desired
- Neonatal foreskin (adult foreskin is sent and examined microscopically)
- Skin, bone and cartilage without significant pathologic abnormality, removed as part of a cosmetic or other reconstructive procedure
- Skin, scars from revisions, unless the scar is from a burn, which rarely develop a cancer or from a previous excision of a malignancy (history should be provided and microscopic examination requested in such cases)
- Skin, soft tissue and bone removed as part of a repair or an acute traumatic injury including:
  - Debridement tissue
  - Foreign bodies (unless requested by the surgeon for documentation)
  - Foreign material
  - Nasal cartilage and bone from a nasal fracture
- Teeth, provided documentation is recorded in the medical record
BONE MARROWS

➤ Supplies:
  Bone marrow kit – may be obtained from MetroPath
  • 2 Neutral buffered formalin bottles
  • 2 green-top tubes with Sodium Heparin
  • 2 purple-top tubes with EDTA
  • 2 plastic slide holders (hold 5 slides each)
  • 2 specimen baggies – internal and external

➤ Labeling:
  Write two patient identifiers and site of biopsy on requisition form and outside of baggie

➤ Specimen Collection:
  (1) Place the bone marrow clot in formalin as soon as the specimen is removed from the patient (5 times as much fluid as the size of the clot)
  (2) Place the core biopsy in a separate container of formalin as soon as it is removed from the patient (5 times as much fluid as the size of the tissue)
  (3) Write the date and time the biopsy was taken on the requisition form so the proper steps can be taken to complete the specimen processing (i.e. proper fixation time etc.)
  (4) Write specific instructions for any special requests at the bottom section of the requisition form.

Example: Cytogenetics and/or Flow Cytometry, Gene rearrangement, etc.
IMPORTANT: Please be clear regarding the tests requested and which specimen tubes are to be used for special testing – this will expedite the process

➤ Fixation/Storage:
  Clot in one container of formalin; core biopsy in separate container of formalin. Specimen should be sent to the lab immediately for processing.

➤ Requisition Form:
  Complete the requisition form and include all clinical information that would aid in rendering a diagnosis. Include the reason for performing bone marrow (i.e. anemia, rule out MDS, lymphoma, possible leukemia).

➤ Transport:
  (1) Place the specimen container in the plastic transport bag in the sealable partition.
  (2) Place the requisition form in the front pocket or folded into the side of the box. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Turnaround Time: 24-48 hours

➤ Note:
  (1) Please include time the biopsy was taken (this is important for fixation purposes).
  (2) Include peripheral blood counts and peripheral smears, if available.
  (3) Include all appropriate ICD-9 codes for special studies.
  (4) Include two patient identifiers on all tubes, bottles, slides and requisition.
Special Instructions:
Notify Metropolitan Pathologists in advance of obtaining a frozen section biopsy so the courier is on site at the time of biopsy and a pathologist is readily available when the specimen arrives in the lab.

Supplies:
- Saline moistened gauze pad
- Plastic transport bag
- Requisition form

Labeling:
Write two patient identifiers and specimen site on the outside of the bag and on specimen label.

Specimen Collection:
1. Put specimen in a saline moistened gauze pad (DO NOT PUT IN FORMALIN).
2. Place the fresh specimen inside a specimen bag and make sure the bag is sealed to prevent leakage.

Fixation/Storage:
Do NOT fix in formalin. Send fresh specimen to the lab immediately after taking the biopsy.

Requisition Form:
- Complete the requisition form and include clinical information that would aid in rendering a diagnosis. Write “For Frozen Section” at the top of the requisition form.
- Circle the attending physician and be sure there is a correct phone number for the pathologist to call back on

Transport:
1. Place the requisition form in the outer sleeve of the specimen bag for transporting.

Turnaround Time: 20 minutes from when specimen arrives in the lab
PRODUCTS OF CONCEPTION (CHROMOSOME ANALYSIS)

➤ Supplies:
Specimen container with sterile saline or transport media (RPMI)
Specimen transport bag
Requisition form

➤ Labeling:
Write two patient identifiers on requisition form and the outside of container

➤ Specimen Collection:
1. Submit at least 0.5 to 1 cm³ sample from the fetal side of the placenta at the site of cord insertion. If possible, also obtain a 0.5 to 1.0 mm³ sample from one or two of the following tissues:
   • Gonad
   • Kidney
   • Cartilage
   • Umbilical cord
   • Membranes – such as amniotic sac
2. Place each tissue sample in a separate, tightly sealed, sterile container filled with cytogenetic transport media (provided by Colorado Genetics Lab or Metropath) or sterile saline solution.
3. Label each container with the patient’s name, a second patient identifier (such as date of birth) and type of sample.
4. Contact Metropolitan Pathologists immediately to arrange for a pick-up.

➤ Fixation/Storage:
Do NOT place specimen in formalin. Maintain specimen at room temperature. If specimen must be held overnight, please refrigerate. DO NOT FREEZE.

➤ Requisition Form:
Complete the requisition form. Write clear instructions whether or not routine Histology is required in addition to chromosome analysis. Both Histology and chromosome analysis must be clearly specified to have both tests performed.

➤ Transport:
1. Place the specimen container in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➤ Note:
1. Cytogenetic studies cannot be performed on formalin fixed tissue.
2. Paraffin embedded or formalin fixed tissue sections are accepted for FISH for chromosome Abnormalities common in pregnancy loss.
3. If routine pathology is not required, Colorado Genetics Lab may be called directly for a pickup, this expedites the process.
ROUTINE TISSUE SPECIMENS

**Supplies:** obtained from MetroPath
- 10% Neutral Buffered Formalin-filled specimen bottle(s)
- Plastic transport bag
- Requisition form

**Labeling:**
Label container and requisition with patient name (first and last) and second identifier (such as date of birth).

**Specimen Collection:**
1. As soon as the specimen is removed from the patient, place it in a specimen bottle containing 10% neutral buffered formalin (should be 5 times amount of fluid as the size of the specimen). Please do NOT place tissue biopsies in ThinPrep vials – ThinPrep fixative are different chemicals and may affect subsequent testing necessary for diagnosis.
2. Properly tighten the lid on the specimen container to prevent leakage during transport.
3. Special requests must be clearly written on the requisition form.

**Fixation/Storage:**
- 10% Neutral Buffered Formalin: preserves specimen indefinitely at room temperature

**Requisition Form:**
Complete the requisition form to include: patient identification, specimen source, clinical indication for biopsy, special requests if needed and insurance information.

**Transport:**
1. Place the specimen bottle in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

**Turnaround Time:** 24 – 48 hours from laboratory receipt

**Note:**
1. Clinic may be called for any ambiguous testing instructions, specimen integrity issues or patient identification.
2. For gross examination tissues only: follow the above protocol.
SKIN IMMUNOFLUORESCENCE

➢ Supplies:
   Specimen container with Zeus fixative can be obtained from CU Dermatopathology Consultants (see below)
   Specimen transport bag obtained from MetroPath
   Requisition form

➢ Labeling:
   Write two patient identifiers on outside of container and requisition.

➢ Specimen Collection:
   A. Immunofluorescence (punch biopsy of uninvolved and/or involved skin):
      (1) Place fresh specimen in container with Michel’s solution or Zeus fixative immediately after the specimen is obtained (DO NOT PLACE IN FORMALIN AS THIS RUINS THE IMMUNOFLUORESCENCE TEST).
      (2) Mark container for immunofluorescence “IF”.
   B. Routine Histology:
      (1) Place a specimen in a separate container with formalin.
      (2) Mark container for “Routine Histology”.

➢ Fixation/Storage:
   Place fresh tissue for immunofluorescence in Zeus fixative: good for 5 days. Use formalin ONLY if specimen is for routine Histology.

➢ Requisition Form:
   Complete the requisition form. Write clear instructions whether or not routine Histology is required in addition to immunofluorescence. In order to perform both Histology and immunofluorescence testing, the requisition form must clearly request BOTH TESTS along with two separate marked samples: one in Zeus fixative and one in formalin.

➢ Transport:
   (1) Place the specimen container in the plastic transport bag in the sealable partition.
   (2) Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

➢ Note:
   (1) If routine pathology is not required, you may contact University of Colorado Dermatopathology Consultants for direct transport.
   (2) Specimen without pathology also may be mailed to:

   CU Dermatopathology Consultants
   1999 N Fitzsimons Pkwy
   Bioscience East, Ste 120
   Aurora, CO 80045
   303.344.1022 (lab)
Supplies: obtained from MetroPath
- 10% Neutral Buffered Formalin-filled specimen bottle(s)
- Plastic transport bag
- Requisition form

Labeling:
Label container and requisition with patient name (first and last) and second identifier (such as date of birth) or clinic specific identification number.

If sending bulk specimens, please send a master log sheet with every specimen included for tracking purposes.

Specimen Collection:
1. As soon as the specimen is removed from the patient, place it in a specimen bottle containing 10% neutral buffered formalin (should be 5 times amount of fluid as the size of the specimen).
2. Properly tighten the lid on the specimen container to prevent leakage during transport.
3. Special requests must be clearly written on the requisition form.

Fixation/Storage:
- 10% Neutral Buffered Formalin: preserves specimen indefinitely at room temperature

Requisition Form:
Complete the requisition form to include: patient identification, specimen source, clinical indication for biopsy, special requests if needed.

Transport:
1. Place the specimen bottle in the plastic transport bag in the sealable partition.
2. Place the requisition form in the front pocket. This will keep the specimen and requisition form together and protect against potential leakage.

Turnaround Time: 24 – 48 hours from laboratory receipt

Note:
1. Clinic may be called for any ambiguous testing instructions, specimen integrity issues or patient identification.
COURIER INFORMATION

To call for courier service: 303.592.7284
   Toll free: 877.904.9755

When calling for courier service, provide the following information:

- Your name
- Your location
- Your address
- Your phone number
- The item(s) you would like picked up

Professionalism:
   All of our couriers are able to assist your needs. They maintain a professional attitude and appearance.

Training:
   The couriers are trained to employ universal precautions when handling potentially bio-hazardous materials. They also make sure they take great care of specimens during transport.

Interpersonal Skills:
   The couriers are trained to listen to your requests and to answer questions that are within their scope of knowledge.

Communications:
   Our couriers will communicate with you on behalf of MetroPath. They also will contact the lab immediately if there is any question or problem concerning pick-up and delivery service. They will deliver any additional paperwork or other information back to the lab that you would like delivered.
SUPPLY REQUEST FORM

Date: ___________________________
Client I.D.#: _____________________

Return Completed Form to:
☐ Courier
☐ Fax (303) 634-2515
☐ Email (supplies@metropath.com)

Clinic & Provider Name: ____________________________
Clinic Address: ____________________________________________________________________________

Ordered by: ___________________________________________ Phone #: ______________________________

MOLECULAR SUPPLIES: (Order in individual quantities unless specified by item)

_____ MetroSwab
_____ BD Affirm Vaginosis Panels
_____ Aptima Urine Collection Kit
_____ Aptima Swab Collection Kit (Endocervical & male urethral specimens)
_____ Group B Strep (GBS) (STARSWAB II)
_____ MDL OneSwab®
_____ MDL UroSwab®

CYTOLOGY SUPPLIES:

_____ ThinPrep Kit (25 vials per tray: For PAPS, Molecular Testing, Breast Discharges)
  ☐ Brushes & Spatulas - (25 each per bag) OR
  ☐ Brooms - (25 each per bag)

_____ SurePath Kit (25 vials per tray)
  ☐ Brushes & Spatulas - (25 each per bag) OR
  ☐ Brooms – (25 each per bag) OR
  ☐ Combi – (25 each per bag - SurePath ONLY)

_____ 30ml CytoLyt Solution Vials (For FNA Specimens ONLY: i.e. Thyroid, Lymph Node, Breast FNA/Cyst)(20/tray)
  Anal Pap Kits

HISTOLOGY SUPPLIES:

_____ 20ml Formalin Vials for Specimens <2cm (24 per box)
_____ 40ml Formalin Vials for Specimens >2cm (24 per box)
_____ Prostate Biopsy Kits – 6 or 12 Formalin Vials
  ☐ 6 Formalin Vials
  ☐ 12 Formalin Vials

GENERAL SUPPLIES:

_____ Specimen Bags (100 per pack)
_____ Requisition Forms (increments of 50)
_____ Patient Information Brochures (25 each unless specified)
  ☐ Pap tests _____ ☐ HPV _____
  ☐ Abnormal Pap tests _____ ☐ GBS _____
  ☐ Chlamydia _____ ☐ HSV _____
  ☐ Gonorrhea _____

_____ Other - please list ____________________________________________

7444 W. Alaska Drive, Suite 250, Lakewood, CO 80226 303-392-7284 Office 303-892-0601 Fax v.6 10/13/2014
Metropolitan Pathologists is proud to have its own in-house billing service where individual care and attention can be given to all patients and specifically to those patients who have unusual or special needs. We will bill all insurance companies or the patient for services according to information provided on the requisition form that accompanies the specimen. The following is requested:

- Fill out all demographic patient information as requested on the requisition form.
- Fill in date of service.
- Circle or write in physician’s name.
- Verify with patient that insurance information (plan name, group number, identification [SSN if required]), and guarantor’s name if different than patient, is correct.
- Attach a copy of the insurance card, front and back.
- Send supplemental insurance information, if applicable.
- Write diagnosis code and any pertinent medical information.
- Inform the Medicare patient if a test may not be covered. If the Medicare patient is having an annual routine Pap test (V76.2), make sure she signs the Advance Beneficiary Notice (ABN) on the back of the requisition form. If the physician determines that the patient is at high risk (V15.89) for developing cervical cancer based on her medical history or the Pap test is diagnostic (must have valid ICD-9 codes and ICD-10 codes after October 1st), she does not need to sign the ABN. Routine HPV and CT/NG testing are non-covered services and need signed ABN. To review the Medicare Guidelines for screening Pap tests, visit the CMS website: [http://www.cms.hhs.gov](http://www.cms.hhs.gov). ICD-9 codes are also listed that cover diagnostic Pap tests.
- The patient will be responsible only for co-pays, co-insurance, deductibles, and/or non-covered services as determined by their insurance carrier’s Explanation of Benefits. Payment plans can be arranged for those individuals requiring extra payment time.

If you have questions regarding billing issues, contact: 303.592.7284

Janine Thaut, Revenue Services Manager
Leandra Rumburg, Certified Coder
Kathy Hamilton, Certified Coder
Jayne Camp, Data Entry Supervisor
ONLINE WEB ACCESS

The MetroPath Online Lab access will allow the user to view summary results of MetroPath cases for a particular practice or physician. It is possible to cut and paste the results into a practice management system. The online access is available 24/7. There is a maintenance block on Sundays where the system may be down. The data transmitted between a web browser and our secure web server is encrypted and HIPAA compliant.

Steps for signing on:

1. Go to www.metropath.com in a web browser.
2. Click on the “Clients” link at the top of the page.
3. If presented with a security warning, accept the certificate notification.
4. Enter your user name and password. If you do not have an account setup previously, please contact your MetroPath Business Development Executive for proper account access.

Once logged in, you will have access to confidential patient reports associated with your practice. You can select your recent results, and you may also search the archive for past results. The links at the top of the page can be used to navigate to the appropriate sections you may need.

For more information, please inquire with your Business Development Executive. They can provide additional manuals for more in-depth coverage of the Online Lab application.
Welcome to the Metropolitan Pathologists Web Portal (“Portal”). Please read the following Terms and Conditions of Use (the “Terms”) carefully before using the Portal as the Terms govern your use of the Portal. Your access and use of the Portal is subject to compliance with any and all requirements, regulations, guidelines and standards of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), as well as all other applicable laws or agreements (the “Privacy and Security Laws”). These Terms may be updated by us from time to time without notice to you. By indicating “I Agree” at the bottom of the page and accessing and using the Portal, you accept and acknowledge, without limitation or qualification, that you have read the Terms and agree to comply with the Terms, any and all Privacy and Security Laws, requirements, regulations, guidelines and standards and any other applicable laws or agreements.

Limited Terms of Use of the Portal

You acknowledge and understand that the information that will be posted or accessed through the Portal is strictly confidential and contains protected patient health related information that is confidential and that compliance with any and all Privacy and Security Laws is necessary when this information is accessed and handled in any way. You must maintain compliance with any and all Privacy and Security Laws requirements, regulations, guidelines and standards while accessing, viewing, printing or downloading any and all information from the Portal. You will use the Portal for legitimate professional reasons, or, if you are a patient, for your own personal use. You may only use or download patient information contained on the Portal for the following purposes and only to the extent permissible under all applicable laws regarding the privacy of patient information: (i) for treatment of those patients under your care; (ii) to conduct your business operations; and (iii) to comply with the laws that govern health care.

You will only access information on the Portal to review patient records when you are permitted by the Privacy and Security Laws, as well as all other applicable laws or agreements, have the requisite patient’s consent, or other appropriate authorization to do so. By accessing a patient’s record, you are affirmatively representing at the time of each access that you are permitted by such Privacy and Security Laws, have the requisite patient consent, or other authorization, to do so. By accepting these Terms, you will be bound by the following:

- I understand that information created, stored and processed in the Portal may be protected by law;
- I will protect the privacy of any and all patient information at all times;
- I will use the access granted to me for business or as the patient, personal, purposes only;
• I will only request and access information of a patient for which I have appropriate authorization to do so;
• I will search for a patient based only on the patient’s first name, last name, date of birth, address and primary insurance account number;
• I will keep my unique and individually chosen UserID and password secret and not use the UserID and password of another. I will change my password immediately if I become aware that another person has knowledge of my password;
• I will not add, modify, or otherwise alter the system or the Portal in any way;
• I will not create, download, transfer or email content through the Portal that is or may be construed as offensive or discriminatory to others;
• I will logoff the system when I am not using the Portal, when I am away from my workstation, or when I no longer have an immediate need for access to the Portal;
• I will notify Metropolitan Pathologists immediately if I am no longer employed by or affiliated with the institution or entity under which I have access to the Portal, and I understand that as a result of such notification to Metropolitan Pathologists, my access to the Portal may be immediately terminated;
• I accept full responsibility for my actions and for any actions taken on or through the Portal under my UserID and password;
• I will not attempt to gain unauthorized access to any other accounts, patient records, or to material that I do not have authorization to review. I will not use the Portal in such a manner that violates any laws (including but not limited to copyright, trademark, or other laws), for any illegal or unauthorized purpose;
• I will not pass on information obtained from the Portal to other parties unless authorized by the patient, as needed to provide patient care, or as otherwise authorized under applicable law. If I do forward information, the information will be forwarded in a secure manner in compliance with any and all Privacy and Security Laws and any other applicable law or agreement;
• I acknowledge my use of the Portal may be audited; and
• I will immediately report any inappropriate access, suspicious activity, or actual or suspected breach in security or privacy to James Gelhaar, Security Officer at (303) 592-7284 or jgelhaar@metropath.com.

Termination of Use

Metropolitan Pathologists may terminate your access to the Portal at any time, with or without cause and with or without notice to you, for any reason whatsoever.

Disclaimer and Limitation of Liability

THE SERVICES PROVIDED THROUGH AND THE INFORMATION CONTAINED ON THE PORTAL ARE PROVIDED ON AN “AS IS” AND “AS AVAILABLE” BASIS ONLY. METROPOLITAN PATHOLOGISTS MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, AS TO THE OPERATION OF THE PORTAL OR THE INFORMATION, CONTENT, MATERIALS, OR PRODUCTS INCLUDED ON THE PORTAL. YOU EXPRESSLY AGREE THAT YOUR USE OF THE PORTAL IS AT YOUR SOLE RISK. TO THE FULL EXTENT PERMISSIBLE BY APPLICABLE LAW, METROPOLITAN PATHOLOGISTS MAKES NO AND HEREBY DISCLAIMS ANY AND ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF TITLE, NON-INFRINGEMENT, MERCHANTABILITY AND FITNESS FOR A PARTICULAR USE OR PURPOSE. METROPOLITAN PATHOLOGISTS DOES NOT WARRANT THAT THE PORTAL
OR INFORMATION LOCATED ON THE PORTAL IS FREE OF VIRUSES OR OTHER HARMFUL COMPONENTS.

TO THE FULL EXTENT PERMISSIBLE BY APPLICABLE LAW, METROPOLITAN PATHOLOGISTS DISCLAIMS ANY WARRANTY THAT THE PORTAL WILL BE AVAILABLE AT ALL TIMES OR WILL OPERATE WITHOUT INTERRUPTION OR ERROR. METROPOLITAN PATHOLOGISTS MAKES NO WARRANTY AS TO THE RELIABILITY, ACCURACY, TIMELINESS, USEFULNESS, ADEQUACY, COMPLETENESS OR SUITABILITY OF THE SERVICES OR INFORMATION PROVIDED THROUGH THE PORTAL. METROPOLITAN PATHOLOGISTS WILL NOT BE LIABLE FOR ANY DAMAGES OF ANY KIND ARISING FROM THE USE OF THE PORTAL, INCLUDING, BUT NOT LIMITED TO DIRECT, INDIRECT, INCIDENTAL, PUNITIVE, AND CONSEQUENTIAL DAMAGES.

Release of Liability, Indemnification

You are solely responsible for your use of the Portal and for maintaining the confidentiality of your unique UserID and password. Any use of the Portal by your employees or agents is subject to the Terms, and you will inform your employees and agents of such Terms and their obligations to abide by them. You are responsible for the use of the Portal by your employees and agents.

In consideration for Metropolitan Pathologists permitting you to use the Portal, you expressly release and hold harmless Metropolitan Pathologists, its shareholders, officers, directors, employees, agents and affiliates from any and all claims, liabilities, demands, causes of action, costs, expenses, and damages of every kind and nature, at law, in equity, or otherwise, arising out of or in any way related to your use of the Portal, whether arising from negligence or any other acts or omissions by Metropolitan Pathologists.

In addition, you will indemnify and hold harmless Metropolitan Pathologists, its shareholders, officers, directors, agents, affiliates, and employees, against all actual and direct losses, liabilities, damages, claims, costs or expenses (including reasonable attorneys’ fees) they may suffer as the result of third party claims, demands, actions, investigations, settlements or judgments against them arising from or in connection with any breach of these Terms, or from any negligence or wrongful acts or omissions, by you or your employees or agents.

The provisions of this section entitled “Release of Liability, Indemnification” shall survive termination of this Agreement.

Applicable Law and Disputes

The Terms and your use of the Portal shall be governed by and construed in accordance with the laws of the State of Colorado, without regard to conflicts of law principles. Any dispute, controversy or claim arising out of or related to these Terms or your use of the Portal will be resolved and settled through arbitration administered by the American Arbitration Association and conducted in Denver, Colorado, United States of America. The decision of the arbitrator shall be final and binding on both parties, and final judgment may be entered upon it in any court of competent jurisdiction. The prevailing party shall be entitled to costs and reasonable attorneys’ fees arising out of such arbitration. The state or federal courts located in or serving Jefferson County, Colorado, United States of America, shall have exclusive jurisdiction and venue over any action arising out of or relating to these Terms or your use of the Portal. By indicating “I Agree” you waive any claim that a court located in or serving Jefferson County, Colorado, lacks personal jurisdiction over you, is an improper venue, or is an inconvenient forum.

Other Miscellaneous Provisions
The Terms constitute the entire and only understanding between you and Metropolitan Pathologists regarding your use of the Portal. No modification or attempted modification of the Terms by you shall be binding on Metropolitan Pathologists unless made in writing and physically signed by an authorized representative of Metropolitan Pathologists. Metropolitan Pathologists may modify the Terms at any time and will include such modifications on this Portal without notice to you. You hereby agree to those modifications and to review them as they are modified from time to time.

[Trademarks, logos, and service marks (collectively the “Trademarks”) displayed on the Portal, if any, are registered and unregistered Trademarks of Metropolitan Pathologists and others. Nothing contained on the Portal should be construed as granting, by implication, estoppel, or otherwise, any license or right to use any Trademark displayed on the Portal without the written permission of Metropolitan Pathologists or such third party that may own the Trademarks displayed on the Portal. Your use or misuse of the Trademarks displayed on the Portal, or of any other content on the Portal, except as provided in the Terms, is strictly prohibited. Metropolitan Pathologists will aggressively enforce its intellectual property rights to the fullest extent of the law.]

Notices sent to you by Metropolitan Pathologists in connection with these Terms or your use of the Portal may be delivered to you by electronic mail, or through a general notice on the Portal. You may give notice to Metropolitan Pathologists by computer message at the following address: jgelhaar@metropath.com.

The Terms are severable to the extent any term is deemed invalid, illegal or unenforceable.

Metropolitan Pathologists’ failure to enforce any provision of the Terms shall not be deemed a waiver of that or any other provision of the Terms.

The parties hereto are independent contractors of one another; nothing herein shall be deemed to create any relationship of agency, partnership or joint venture between the parties.
Signing below acknowledges that you received a copy of the MetroPath 2015 Specimen Collection Procedure handbook. Distribution of this handbook fulfills one area of laboratory requirements in meeting the mandatory checklist for College of American Pathologists (CAP) Accreditation and CLIA ’88 Regulations.

Signed: __________________________________________________________

Department/Office: ______________________________________________

Date: ___________________________________________________________