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General Information

Colorado Diagnostic Laboratory, LLC (CDL) operates as the technical processing laboratory for AmeriPath's Colorado division with Colorado Pathology Consultants, P.C., providing professional medical services. AmeriPath Colorado strives to maintain a reputation for quality, innovation, and dependability, and your comments and suggestions to further that effort are welcome.

AmeriPath's in-house testing menu is enhanced by the provision of reference laboratory testing. Qualified, licensed reference labs are selected based on a protocol that considers quality of service, reliability, turnaround time, and price.

Pathology Staff

Martin Potash, MD – *Managing Director*
Sheryl Asplund, MD - Medical Director
Lorraine Pan, MD - *Cytology Department Technical Supervisor*
Morgan Cowan, MD
Jim Hopfenbeck, MD
Stephanie J. Johnson, MD
Sarah Mengshol, MD
Thomas Neuhauser, MD
Michael Pushchak, MD
Mathew Rumery, MD
Roberto A. Taguibao, MD
Sonia G. Taguibao-Veran, MD
Steven Temple, MD

Contact Information

**Main (8 am – 5 pm).....303.899.6900 or
Toll free: 877.701.8188**

Fax.....303.899.6999

Billing Inquiries.....Toll free: 866.450.7032

Courier Pick-Up (9 am – 5 pm).....303.899.6926

Customer Service (8 am – 5 pm).....303.899.6900

Specimen Collection Information.....303.899.6900

Pathologists.....303.899.6900

Laboratory Accreditations

College of American Pathologists, Laboratory #2176504-01
Center for Medicare/Medicaid Services, CLIA #06D0511305

Test Methodologies

Current test methods and performance specifications are available upon request.

If the laboratory changes analytic methodology so that test results or their interpretations may be significantly different, the change is communicated through direct mailings, memos, or information integrated into the test report.

Changes in analytic methodology resulting in significant differences in test results or interpretations may be integrated into the test report, or communicated through direct mailings or memos.

Results and Reports

Results are distributed through a variety of mechanisms depending on client preference:

- courier
- fax
- electronic reporting
- mail

Distribution of Manual

This manual is available electronically via our website.

Consultation with a Pathologist

Clinicians are welcome to consult with a pathologist regarding patient test results. The Client Services department will facilitate communication with the appropriate pathologist.

Compliance with Federal and Regulatory Agencies

AmeriPath is fully committed to compliance with all applicable:

- Federal and state laws
- Regulatory agency requirements
- Federal, state, and private payer health care program requirements
- AmeriPath ethics and business policies

Our laboratory is committed to maintaining a culture which promotes prevention, detection, and resolution of instances of conduct that do not conform to the highest ethical standards.

Ordering Tests

Laboratory tests may be ordered by physicians or other authorized personnel as defined by applicable state laws. All orders must be accompanied by a written requisition, including "add-on" tests. A written requisition will be requested at the time a verbal order is placed, and should be submitted within 24 hours. Requisitions are retained for an appropriate time period so as to meet all regulatory requirements.

Verbal Orders

Verbal requests for additional testing must be followed up with a written requisition signed by an authorized provider (preferably within 24 hours) in order to comply with regulatory requirements. The written requisition may be faxed to **303.899.6997**. Testing will not be performed until the written requisition is received.

Medical Necessity and Advance Beneficiary Notice (ABNs)

Laboratories can submit claims to federally funded health programs only for services considered medically necessary. An ICD-10 code should be submitted with all orders substantiating the medical

necessity of the testing. Additionally, Medicare frequency rules permit screening Pap tests once every two years.

For Pap tests performed more often than established guidelines, or other tests which do not meet the federally defined criteria for medical necessity or frequency, an Advance Beneficiary Notice (ABN) must be completed. If there is reason to believe that Medicare will not pay for a test, the patient should be informed. The patient should sign an ABN (supplied separately) to indicate that he or she is responsible for the cost of the test if Medicare denies payment.

Specimen Preparation and Transport

Specimen Labeling

To avoid delays in processing and specimen rejection, please label accurately and completely. Specimens not properly identified will not be analyzed without further followup. Each primary specimen container must be labeled at the time of collection with at least two patient identifiers that must also appear on the requisition.

The patient's name (full last name, then full first name, or initial) and the source is ALWAYS required. The 2nd patient identifier may be one of the following:

- Date of birth, Social Security Number, requisition/order number, accession number, or unique random number
- Barcode labels can be used if barcode matches the unique identifiers on the printed requisition
- Place the label on the specimen container, not the container lid.

Requisitions

Specimens must be accompanied by a completed AmeriPath/Quest Diagnostics requisition. Complete information on the request form must be provided to correctly process the specimen and to avoid delays in reporting.

Please include the following:

- Complete patient name
- Patient address
- Patient's date of birth and gender
- Guarantor's name and date of birth if other than patient
- Complete insurance information (Attach a copy of patient's **CURRENT** insurance card(s), front and back, to the requisition)
- Appropriate ICD-10 code
- Patient's relevant clinical history (This is a regulatory requirement because of its importance in rendering an accurate diagnosis.)
- Requesting physician's first and last name, and address if not pre-printed on the requisition. (Circle the appropriate choice if multiple physician names appear on the requisition.)
- Specimen type and source (mark checkboxes as appropriate.) For specimen types or sources not preprinted on the requisition, write in the information needed (ex. Aptima swab, vaginal).
- Specimen collection date
- Time of collection and time placed in formalin (if appropriate).
- Special test requests

If the above information is not complete and legible, processing of the specimen may be delayed while we contact your office by phone or fax to obtain the required information. The second copy of the requisition is for your office use and may be

	<i>disposed of if not needed.</i>
Specimen Packaging	<ul style="list-style-type: none"> • Use only approved well-constructed containers and packaging materials. • Secure container lids tightly to prevent leakage, and seal the container into a biohazard bag. • Fold the requisition so that the client name is visible, and place the requisition in the outer pocket of the bag. • Please place only one patient's sample(s) in each biohazard bag.
Courier Services	Place specimens in the designated area for courier pick-up. Call 303.899.6926 to request courier service. (Please call 24 hours in advance of special needs, such as fresh tissue pick-up, whenever possible.)

Specimen Rejection Policy

Specimen submissions not meeting labeling or requisition requirements will be held and subject to further follow up, or rejection. Please see section information for specific rejection criteria.

Supplies

All clients are supplied with:

- specimen containers and collection devices
- fixative (10% formalin)
- bags for submitting specimen containers
- requisition forms

Other supplies are available as needed to fulfill specimen requirements. Supplies may be obtained from AmeriPath Client Services. Please order supplies two weeks in advance of actual need to assure availability.

- Fill out the AmeriPath Supply Requisition form with the order date and contact person.
- Indicate the amount of each supply you will need.
- Place the supply requisition form in the courier pick-up box, or fax it to 303.899.6994.

Our goal is to fill all supply requests within 48 hours.

If you need the supplies sooner, please call **303.899.6900** and speak to a Client Services Representative. We will make every effort to meet your needs.

Slide Requests

Requests to have slides sent out for a second opinion or other medical reasons should be called to **303.899.6900**. Please allow 48 hour notice for this service when possible. Give the following information to the Client Services Representative:

- Patient name
- Date of birth
- Date of service
- Name, address and phone number of the facility where slides are being referred.
- Name of physician who will be reviewing the slides

AmeriPath will send slides directly to the authorized recipient (appropriate HIPAA Authorization Form and/or physician authorization will be obtained as needed prior to releasing slides.)

CYTOPATHOLOGY

NON-GYNECOLOGICAL CYTOLOGY SPECIMENS

Specimen Submission

All non-gynecological cytology specimens should be submitted to the laboratory as soon as possible after collection. Delays could result in deterioration if the specimen is unfixed. If delay is unavoidable (more than 1 hour), please refrigerate specimens and/or add CytoLyt preservative as indicated until they are picked up (please see the applicable sub-section for appropriate handling of delayed specimen transport based on specimen type). Follow labeling protocol as outlined on page 5.

Fluid and mucoid cytology specimens are processed with the ThinPrep™ Technique. All non-gynecological cytology specimens should be submitted fresh, or with CytoLyt preservative. SurePath vials are not acceptable.

Do not add Carbowax Fixative (Saccomono Fluid) to a cytology specimen.

The laboratory does not accept syringes with needles attached. Flush the barrel of the needle into the specimen container, using the proper preservative and dispose of the needle into a sharps container.

Results for non-gynecologic specimens are available within 1-2 working days following receipt into the laboratory, depending upon special studies required.

Please call **303-899-6900** with questions concerning cytology specimen collection and handling.

Unacceptable Specimen Examples

- No or illegible patient identification on the specimen container, or the test requisition
- Mismatch between name of patient on specimen and name on test requisition
- Broken slides
- Leakage of sample during transport
- No source indicated on test requisition for Non-Gyn specimens
- Expired liquid-based preservative/vial
- Non-Gyn specimens collected in a Surepath vial
- Specimens received in a syringe with needle attached
- Cerebrospinal Fluid (CSF) from a patient with suspected Creutzfeldt-Jakob Disease (CJD)

Anorectal Cytology

Supplies	ThinPrep™ vial Collection brush Requisition
Preparation	Standard colonic preparation is not required, but the rectum should be emptied prior to sample collection. Enemas or anal insertions should not occur 24 hours prior to an anal cytology exam.
Procedure	-Lubricants interfere with processing and interpretation of the sample and should not be

	<p>used.</p> <ul style="list-style-type: none"> -Insert cytobrush 5-6 cm (2 inches) into the anal canal, past the internal sphincter, into the rectal vault. -Apply firm lateral pressure to the brush handle. -Withdraw in a firm downward spiral movement, incorporating 10-12 rotations to ensure the device has made contact with the full surface area of the transformation zone. -Place brush in ThinPrep™ preservative vial and agitate vigorously several times. -The sample must be fixed within 15 seconds to avoid drying artifact. -Label the specimen with patient's full name and 2nd identifier, as well as the source. <p>NOTE: A swab or smear of the peri-anal skin is an unsatisfactory specimen site</p>
Requisition	<ul style="list-style-type: none"> -Check Anorectal Pap on requisition. -Attach "Anal cytology Pap" sticker to the requisition (provided in the collection kit). <p>NOTE: For Anal HPV information, see pages 19-20 in the Clinical Testing section.</p>
Breast Fluids	
Material may be obtained either from secretions expressed from the nipple, or by aspiration of cystic lesions.	
Nipple Secretions	
Supplies	Glass slides, OR Vial containing preservative CytoLyt Requisition
Procedure notes	<ol style="list-style-type: none"> 1. If secretion appears when pressure is applied to a particular area, it is advisable to note this on the requisition form and prepare a specifically identified slide from this material. This may be helpful in guiding future biopsy. 2. Cellularity tends to increase with each expression and 4-6 slides should be made.
Collection Procedure	<ol style="list-style-type: none"> 1. Label glass slides with patient's first and last name, a 2nd identifier 2. Express material from nipple by gentle compression of the areolar area between thumb and forefinger directly onto glass slide. 3. Gently spread material over surface of slide. 4. Specimen may be submitted air-dried or fixed. To fix, immediately drop slide into 95% alcohol, or spray with fixative.
Breast Cyst Aspirations	
Supplies	Clean container Requisition
Procedure Notes	<ol style="list-style-type: none"> 1. Most breast cyst fluids do not need cytologic examination. 2. Submit the cyst fluid if: <ul style="list-style-type: none"> • the cyst is recurrent • the fluid appears bloody (brownish fluid suggestive of old bleeding, not fresh blood due to the procedure) • the patient is postmenopausal and not on hormone replacement therapy
Procedure	<ol style="list-style-type: none"> 1. Perform aspiration. 2. Place specimen in clean container. 3. Label the specimen with the patient's first and last name, and 2nd identifier. <p>Have specimen delivered to the laboratory immediately. If there is a delay, add an equal volume of CytoLyt, or refrigerate. Please note on the container if CytoLyt has been added.</p>
Cerebrospinal Fluid (CSF)	
Supplies	Clean container Requisition
Procedure Notes	Submit the largest volume of fluid possible. Do NOT add CytoLyt to this specimen.
Procedure	<ol style="list-style-type: none"> 1. Perform spinal tap. 2. Place sample in clean container. 3. Label the specimen with the patient's first and last name, and 2nd identifier.

	Have the specimen delivered to the laboratory immediately.
Fine Needle Aspiration (FNA) Biopsy	
Please contact the laboratory at 303.899.6900 with questions about submission of FNA biopsy slides.	
Fluids from the Body Cavity (Pleural, peritoneal, and pericardial fluids)	
Supplies	Clean container (such as a sterile urine container) Requisition
Specimen Required	10 mL (or more) of fluid obtained from an appropriately performed tap
Procedure	<ol style="list-style-type: none"> 1. Perform tap. 2. Place sample in clean container. 3. Label the specimen with the patient's first and last name, 2nd identifier, and source <p>Have specimen delivered immediately to the laboratory. If there is greater than a 24 hour delay, refrigerate the specimen until it can be transported to the laboratory.</p>
Sputum	
Supplies	Wide mouth plastic container Requisition
Procedure	<ol style="list-style-type: none"> 1. Instruct patient to collect specimen as soon as they wake up. 2. Instruct patient to rinse mouth with water, then cough deeply into container. 3. Inform patient that several coughs over a period of 2 to 3 hours may be necessary to produce a sufficient sample. 4. Label the specimen with the patient's first and last name, and 2nd identifier. 5. Have specimen delivered to the laboratory immediately. If there is a delay, add 30 mL CytoLyt solution and mix well. Please note on the container if CytoLyt has been added. 6. If three consecutive specimens are to be collected, all three specimens can be delivered on the third day of collection, provided the earlier specimens are fixed with CytoLyt.
Urine	
Supplies	Clean container Requisition
Procedure Notes	<ol style="list-style-type: none"> 1. A voided urine specimen should be obtained after the patient has been well hydrated and approximately three hours after the last void. 2. Do NOT submit the first morning void for cytology. 3. Clean catch samples are necessary. Female patients should be instructed to spread the labia during collection, then pass and discard a small amount of urine. Collect the remainder. Males should be instructed to pass and discard a small amount of urine and collect the remainder. 4. If the patient is unable to cooperate satisfactorily, a catheterized specimen should be obtained. Note the method of collection on the requisition form. 5. Do not submit 24-hour collection specimens for cytology. These are unsatisfactory due to cellular degeneration.
Collection Procedure	<ol style="list-style-type: none"> 1. Provide patient with clean container and instructions. 2. Submit approximately 50 mL of urine to ensure a sufficient sample. 3. Label the specimen with the patient's first and last name, and 2nd identifier. 4. Have specimen delivered to the laboratory immediately. If there is a delay, add 30 mL CytoLyt or methanol, or refrigerate. Please note on the container if CytoLyt or methanol has been added.

GYNECOLOGICAL CYTOLOGY SPECIMENS

CERVICAL/ENDOCERVICAL AND VAGINAL PAP TESTS

The adequacy of Pap test collection is determined by:

1. Accurate patient and specimen identification
2. The presence of an adequate squamous component
3. The presence of an adequate endocervical component (in premenopausal females with a cervix)
4. Adequate cellular preservation
5. Pertinent clinical history (see below)

The Pap is a screening test for cervical cancer. It is not a diagnostic test and is subject to false negative and false positive results. It is most reliable when a satisfactory sample, regularly obtained, is submitted with relevant clinical findings and history, and when the Pap result is evaluated along with historic and current clinical information.

Because of the importance of the patient's clinical history in interpreting the Pap test, be sure to note any relevant information such as:

Cigarette Smoker	Previous GYN Malignancy
Total hysterectomy	History of HPV or dysplasia
Supracervical hysterectomy	Immuno-compromised
Pregnant (weeks)	Abnormal GYN Exam (e.g., HPV, Cervical lesion)
Postpartum (weeks)	Abnormal Pap within last 3 yrs
Postmenopausal (year)	DES exposure
Family History Cervical Cancer	Estrogen Replacement therapy
Early onset of sexual activity	5 or more full-term pregnancies
IUD	Multiple sexual partners
Post-coital bleeding	Birth control pills
Postmenopausal bleeding	History of STI's
Routine examination	Pelvic radiation
Repeat Pap	Vaccinated for HPV

Pap test results are typically reported within 3 business days following receipt into the laboratory.

Procedure Notes for Pap test collection:

1. To ensure an adequate specimen:
 - Samples from both the ectocervix and endocervix including the transformation zone are essential.
 - The patient should be instructed not to use vaginal medications, spermicide, personal lubricant or douches 48 hours prior to collection of the Pap test.
 - Patient should refrain from intercourse for 24 hours prior to collection.
 - Vaginal discharge or secretion (when present in large amounts) should be removed before obtaining the cervical sample.
 - It is preferred that lubricant **NOT** be used when obtaining a Pap specimen. Instead, use lukewarm water to lubricate and warm the speculum. If lubricant is used, the following is a list of preferred lubricants that do not contain interfering substances:
 - *Pap Test Lubrication Jelly* from Aseptic Control Products
 - *Surgilube*® lubricant is a carbomer-free lubricant and approved for use with the ThinPrep Pap (Surgilube.com.)
 - For optimal cellular evaluation and decreased possibility of an Unsatisfactory Pap, collect the sample during mid-cycle, days 10-15, and avoiding menses.
2. If testing for sexually transmitted diseases is indicated, the cervical cytology sample should be taken *first*.
3. If a suspicious area is visualized, a separate sample from the area may be obtained and appropriately designated separate collection.
4. Complete the requisition form as previously instructed and include ALL of the following information:
 - a. specimen source (i.e., cervical/endocervical or vaginal)

<ul style="list-style-type: none"> b. relevant clinical history (as noted above) c. last menstrual period (LMP) d. collection date <p>5. No refrigeration is necessary.</p>	
Unacceptable Specimens	
<ul style="list-style-type: none"> • No or illegible patient identification on the specimen container or the test requisition • Mismatch between name of patient on specimen and name on test requisition • Slides broken beyond repair • Leakage of sample during transport • Expired liquid-based preservative/vial • SurePath Pap Test (blue vial) without a collection device 	
Imaged THINPREP™ PAP	
ThinPrep™ Pap test is a liquid-based cell preparation system, collected in PreservCyt® solution, and processed using the Hologic instrumentation. Monolayer preparations are screened by cytotechnologists using computer assisted imaging technology, with pathologist review of all abnormal cases.	
Supplies	Unlubricated speculum (warm water or saline may be used) PreservCyt® solution vial Endocervical brush/spatula or Broom-like device Requisition
Cervical/ Endocervical Brush/Spatula Procedure	Obtain cellular material as per Hologic's instructions from the cervix using a spatula or endocervical brush: <ol style="list-style-type: none"> 1. Insert vaginal speculum WITHOUT any lubricant. The use of lubricant has been known to interfere with the ThinPrep™ process, resulting in unsatisfactory for evaluation Paps due to low cellularity. 2. Obtain an adequate sampling from the ectocervix using a plastic spatula. 3. Rinse the spatula into the PreservCyt® Solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula. 4. Obtain an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate a quarter or half turn in one direction. Do NOT over-rotate. 5. IMMEDIATELY rinse the brush 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. 6. Tighten the cap so that the torque line on the cap passes the torque line on the vial. 7. Label the vial with the patient's first and last name, and 2nd identifier.
Broom-like Device Procedure	Obtain cellular material as per Hologic's instructions from the cervix using a broom device: <ol style="list-style-type: none"> 1. Insert vaginal speculum WITHOUT any lubricant. The use of lubricant has been known to interfere with the ThinPrep™ process, resulting in unsatisfactory for evaluation Paps due to low cellularity. 2. Obtain an adequate sample from the cervix using a broom-like device. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction 5 times. 3. IMMEDIATELY rinse the broom 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. 4. Tighten the cap so that the torque line on the cap passes the torque line on the vial.

	Label the vial with the patient's first and last name, and 2 nd identifier.
Additional Testing Available From ThinPrep™ Specimens	<p>Collect the following specimens alone, or with a Pap test as you would for a ThinPrep™ Pap.</p> <ol style="list-style-type: none"> 1. HPV E6/E7 mRNA 2. Chlamydia mRNA by TMA ** 3. Gonorrhea mRNA by TMA ** 4. Herpes Simplex Virus I/II (HSV) DNA 5. HPV Genotyping (16,18 & 16,18/45 mRNA by TMA) 6. Vaginitis Panel <ul style="list-style-type: none"> • Gardnerella DNA • Candida DNA • Trichomonas DNA • Trichomonas mRNA by TMA ** <p>**Chlamydia, Gonorrhea, and Trichomonas testing must have an aliquot removed (by performing lab) before performing cytology on ThinPrep™specimens, therefore, the tests cannot be added <u>after</u> cytology is performed.</p>
SurePath™ Pap without Imaging	
The SurePath™ Pap test is a liquid based thin layer cell preparation system, collected in SurePath™ Preservative Fluid, and processed using the PrepStain™ System. Slides are manually screened by cytotechnologists, with pathologist review of all abnormal cases.	
Supplies	<p>Unlubricated speculum (warm water or saline may be used) Brush (Rovers Cervex-Brush) SurePath™ Preservative Vial <i>Requisition</i></p>
Procedure	<p>Obtain cellular material as per instructions from the cervix using a Cervex device: SurePath (hyperlink)</p> <ol style="list-style-type: none"> 1. Label the SurePath™vial with the patient first and last name, and 2nd identifier. 2. After visualization of the cervix is completed, use the Rovers Cervex-Brush to collect an adequate sample. 3. Insert the central long tines into the cervical/endocervical canal applying gentle pressure. 4. As these are being inserted, the device should be twisted slowly. Maintaining gentle pressure, hold the stem between the thumb and forefinger, then rotate the brush five times in a clockwise direction. Do not alter the direction of the brush during sampling. 5. Transfer the entire sample by placing your thumb against the back of the brush pad, simply disconnect the entire brush from the stem into the SurePath™ preservative vial. <p><i>Recap the vial and tighten.</i></p>
Rejection Criteria	SurePath™ Pap specimens submitted without the collection devices in the vial are not compliant with the FDA approved Pap testing methodology and will be rejected for testing.

Additional Testing Available from SurePath™ Pap Specimens	<p>Collect the following specimens alone, or with a Pap test as you would for a SurePath™ Pap.</p> <ol style="list-style-type: none"> 1. HPV E6/E7 mRNA (cervical/endocervical sources only) 2. Chlamydia mRNA by TMA ** 3. Gonorrhea mRNA by TMA ** 4. Herpes Simplex Virus I/II (HSV) DNA 5. HPV Genotyping (16,18 & 16,18/45 mRNA by TMA) 6. Vaginitis Panel <ul style="list-style-type: none"> • Gardnerella DNA • Candida DNA • Trichomonas DNA • Trichomonas mRNA by TMA ** <p>**Chlamydia, Gonorrhea, and Trichomonas testing must have an aliquot removed (by performing lab) before performing cytology on SurePath™ specimens, therefore, the tests cannot be added <u>after</u> cytology is performed.</p>
Conventional Pap Smear	
Supplies	<p>Clean glass slide with frosted end Ayre spatula and cotton tipped swab Endocervical brush or cervical brush (Cervex brush) Spray fixative</p> <p>Requisition</p>
Procedure	<ol style="list-style-type: none"> 1. Label frosted end of slide with patient's first and last name, and 2nd identifier. 2. Ensure that fixative is readily available. 3. Insert vaginal speculum WITHOUT any lubricant. 4. Two areas of cervix are to be sampled - the portico and the endocervical canal. 5. Visually inspect the cervix. Using the Ayre spatula, insert long end into the external os and rotate in one direction at least one complete 360-degree turn. Gently smear contents adherent to the spatula onto the surface of the labeled slide. Spray with fixative immediately, covering smeared area with a thin film of the spray. 6. If the endocervical canal is to be sampled separately, use moistened cotton tipped applicator, or an endocervical brush. Insert into endocervical canal, rotate 360 degrees and withdraw. Smear specimen onto an unused portion of the slide with the spatula. Immediately spray with fixative. 7. The cervical brush (Cervex or "broom") samples the ectocervix and endocervix at the same time. Insert the longer central portion of the device into the endocervical canal, rotate at last 360 degrees and withdraw. Smear the material onto a slide in a sweeping movement and spray fix immediately. <p>Note: Immediate fixation is imperative. No delay should occur after the cytologic material is placed on the slide.</p>

HISTOLOGY (TISSUE) SPECIMENS

Tissue specimens submitted to Pathology must meet certain requirements before they will be accepted for examination. Please call 303.899.6900 with any questions.

Specimen Containers and Labeling

All specimens need to be placed in well-constructed containers with lids tightly secured to prevent leaking. Legibly label the container (not the lid) with the patient's first and last name, a 2nd identifier, and specimen source. Place multiple specimens in separate containers, each labeled with full name, a 2nd identifier, and source.

Most tissue specimens are submitted in formalin, which contains formaldehyde. Use caution when handling formaldehyde as it may be carcinogenic. It is toxic if inhaled or swallowed and can be irritating to the eyes, respiratory system and skin. Repeated or prolonged exposure increases health risks.

A formalin warning label must be attached to the container. Most containers are pre-labeled by the factory before use. If a pre-labeled container is not used, please identify the solution in the container by labeling the container appropriately (i.e., formalin, glutaraldehyde, saline, etc.).

Routine Specimen Requisitions

Routine specimens must be accompanied by a requisition form. Complete the requisition as instructed on Page 3-4, and include the following information:

- Any preoperative and postoperative diagnoses to the degree known
- Pertinent clinical information, including any pre- and post-operative findings
- Specimen source – listed numerically if multiple specimens

Routine Specimen Fixation and Transport

1. Place routine tissue specimens in a properly labeled container to which 10% formalin solution has been added. The size of the container should be proportionate to the size of the specimen so that the formalin to tissue ratio is approximately 20:1. At a minimum, the volume of formalin should be sufficient to completely immerse the specimen to assure optimal fixation of the tissue.
2. Seal the specimen into a biohazard bag, and place the requisition in the side pouch of the bag.
3. Notify the laboratory of the need for a pick-up if your clinic is not on a regular pick-up.

Unacceptable Specimens

- No or illegible patient identification on the specimen container or the test requisition
- Mismatch between name of patient on specimen and name on test requisition
- Leakage of sample during transport
- Expired preservative/vial

Result Reporting

Results are typically reported within 1 to 2 working days following receipt into the laboratory, depending on the special studies required. Procedures sent out to reference facilities may take longer.

SPECIMEN COLLECTION

Bone Marrow - Hematopathology

Supplies

1. AmeriPath Hematopathology Specimen Transport Kit containing:
 - 2 purple top (EDTA) tubes
 - 2 green top (Na Heparin) tubes
 - 2 fixative (10% zinc formalin) containers
 - 10 glass slides
 - Biohazard bag, transport box, absorbent material
2. AmeriPath Hematopathology Requisition

Additional Materials Required

- Always include most recent CBC results.

Procedure Notes

1. Label all containers and smears with the patient's full first name, last name, date of birth or second identifier, and specimen source.
2. Complete the hematopathology requisition including patient and billing information, tissue type, patient history, and studies requested.
3. Call the laboratory after collection to arrange for immediate pick-up. Specimens should be picked up 2 days prior to a holiday to assure that the testing is not compromised by holiday schedules.

Specimen Requirements

	Immunohisto-chemical stains (IHC)	Morphology Evaluation	Flow Cytometry	Cytogenetics	FISH	PCR/ Sequencing
Bone Marrow Core	Place in fixative	Place in Fixative	1.5 cm in length in TTM* or RPMI and 2-4 touch preps	1.5 cm in length in TTM* or RPMI	1.5 cm in length in TTM* or RPMI	1.5 cm in length in TTM* or RPMI
Bone Marrow Clot	Place in fixative	Place in fixative	Not acceptable	Not acceptable	Not acceptable	Not acceptable
Bone Marrow Aspirate	Not acceptable	6-8 bedside smears	4 mL in green top (Na heparin) and 1 bedside smear	2-3 mL in green top (Na heparin)	1-2 mL in green top (Na heparin)	1-3 mL in purple top (EDTA)
Peripheral Blood	Not acceptable	2-4 bedside smears	4 mL in green top (Na heparin) and 1 bedside smear	2-5 ml in green top (Na heparin), include WBC count and manual diff	3-5 mL in green top (Na heparin)	3-5 mL in purple top (EDTA)

*Tissue Transport Medium

Nail Clippings – Test for Fungi

Procedure

1. Clip the largest amount of nail possible.
2. Place specimen in formalin filled container.
3. Label container with patient's first and last name, a 2nd identifier, and specimen source.
4. Submit with completed requisition.

Urinary Stone (Calculus) Analysis

Procedure

1. Air dry stone after removal.
2. Place in a clean, dry container (such as a sterile urine container). Do not transport in liquid or tape, as analysis will be hindered and delayed, compromising results.
3. Label container with patient's first and last name, a 2nd identifier, and specimen source. Submit with completed requisition.

SPECIMENS REQUIRING SPECIAL HANDLING

The following specimens should be received fresh and require IMMEDIATE processing. Contact the laboratory at **303.899.6900** Monday-Friday, 8:00 am-5:00 pm, and state that you will have a specimen which requires immediate pick-up. 24 hour notice is requested. Call the laboratory if additional instructions are needed.

1. **Diagnostic Lymph Node Biopsies** (including flow cytometry and/or cytogenetics) – must be received fresh.
2. **Breast Biopsies** – must be received fresh for frozen section study. Otherwise place in formalin. The **time of collection** and the **time the specimen is placed in formalin MUST be documented** on the requisition. Formalin fixation and cold ischemia time (time from collection to time placed in formalin) are recorded per ASCO/CAP guidelines for prognostic markers.
3. **Products of Conception** – submit the sample fresh in sterile saline if cytogenetics testing is needed. Maintain at room temperature. Call for immediate pick-up. Place in formalin if cytogenetics is not required.
4. **Tissue biopsies for Immunofluorescence** – place a portion of the fresh tissue into a DIF fixative vial containing Michel's transport media. Specimens need to be received in the laboratory within 24 hours of collection, and no less than 2 days prior to a holiday, to preserve specimen viability.
5. **Tissue biopsies for Flow Cytometry (Immunophenotyping)** – must be received fresh in sterile saline or immediately placed in sterile tissue transport media.
6. **Tissue for Electron Microscopy** – must be received fresh in saline or immediately placed in 2.5% glutaraldehyde.

SPECIMENS FOR CLINICAL TESTING

ALL specimens should be labeled at the time of collection with at least 2 patient identifiers and source.

Chlamydia and Gonorrhea mRNA by TMA

Please note the specimen sources that are acceptable for this testing:
vaginal; cervical; endocervical; urethral; urine.

While vaginal samples are acceptable for Chlamydia testing, endocervical specimens are recommended for Gonorrhea. **Oral or anal specimens, or swabs from external lesions are not accepted.**

Chlamydia and Gonorrhea testing must have an aliquot removed (by performing lab) before performing cytology on PreservCyt® or SurePath® specimens, therefore, the tests cannot be added after cytology is performed.

A. **ThinPrep™ Pap**

1. Collect per ThinPrep™ protocol (see page 11)

Specimen stability

Room temperature: 14 days

Refrigerated: 30 days

B. **Aptima® Vaginal (orange tube), or Unisex (white tube) Swab Kits**

NOTE: Results from the Aptima® Combo 2 Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

1. Collect per instructions:

[Aptima Swab vaginal collection instructions](#) (hyperlink)

[Aptima Swab unisex collection instructions](#) (hyperlink)

C. **Preservative Fluid/Multi-swab**

1. Use Swab Collection and Transport Kit.
2. Rotate the swab 5-10 times while sampling to allow enough cells to adhere to the swab tip.
3. Place swab(s) in tube after collection.
4. No refrigeration is necessary.
5. Write "preservative fluid" on the requisition as specimen being submitted.

D. **Urine (must be received within 24 hours of collection)**

1. Patient must NOT have urinated for at least two hours prior to collection.
2. Collect 10 to 50 mL of FIRST catch urine into clean, polypropylene container without preservatives.
3. Refrigerate specimens (2-8 degrees) until pick-up by courier.
4. Write "urine" on the requisition as specimen being submitted.
5. Aptima urine kits may be used.

Specimen stability

Room temperature: 30 days if in Aptima transport medium

Refrigerated: 30 days if in Aptima transport medium

E. **SurePath™**

1. Collect as per SurePath protocol (see page 12): [SurePath](#) (hyperlink)

Specimen stability

Room temperature: 4 days from collection

Refrigerated: not acceptable

***Urine, Aptima Swab, urine kit**

Collect per Atima Urine Kit guidelines

Trichomonas testing must have an aliquot removed (by performing lab) before performing cytology on PreservCyt® or SurePath® specimens, therefore, the test cannot be added after cytology is performed.

A. ThinPrep™ Pap

1. Collect per ThinPrep™ protocol (see page 11):

Specimen stability

Room temperature: 14 days

Refrigerated: 30 days

B. Aptima® Vaginal (orange tube), or Unisex (white tube) Swab Kits

NOTE: Results from the Aptima® Combo 2 Assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.

1. Collect per instructions:

[Aptima Swab vaginal collection instructions](#) (hyperlink)

[Aptima Swab unisex collection instructions](#) (hyperlink)

C. Preservative Fluid/Multi-swab

1. Use Swab Collection and Transport Kit.
2. Rotate the swab 5-10 times while sampling to allow enough cells to adhere to the swab tip.
3. Place swab(s) in tube after collection.
4. No refrigeration is necessary.
5. Write “preservative fluid” on the requisition as specimen being submitted.

D. Urine (must be received within 24 hours of collection)

1. Patient must NOT have urinated for at least two hours prior to collection.
2. Collect 10 to 50 mL of FIRST catch urine into clean, polypropylene container without preservatives.
3. Refrigerate specimens (2-8 degrees) until pick-up by courier.
4. Write “urine” on the requisition as specimen being submitted.
5. Aptima urine kits may be used.

Specimen stability

Room temperature: 30 days if in Aptima transport medium

Refrigerated: 30 days if in Aptima transport medium

E. SurePath™

1. Collect as per SurePath protocol (see page 12): [SurePath](#) (hyperlink)

Specimen stability

Room temperature: 4 days from collection

Refrigerated: 4 days from collection

Group B Streptococcus DNA

Rapid GBS DNA ****Source Specific Vaginal/Rectal**

Supplies	Copan Swab
Specimen Stability	24 hours at room temperature 1-6 days if refrigerated
Preferred Sample	Combination vaginal/rectal samples placed into a single transport tube
Procedure Notes	**Drug susceptibility testing MAY be performed on this medium for penicillin-allergic patients** (REQUEST: "reflex for drug susceptibility testing" on requisition Excessive mucous, lubricant, and/or blood may cause inhibition of DNA amplification/detection resulting in a possible false negative.
Procedure	Rotate both swabs 5-10 times while sampling vaginal then rectal areas to ensure enough cells adhere to the swab tip. Place swabs in collection device.

Herpes Simplex Virus I/II by PCR

A. Preservative Fluid/Multi-swab (acceptable collection for male and female external genital lesions; cervical, or vaginal sampling)

1. Use Swab Collection and Transport Kit
2. Rotate the swab 5-10 times while sampling to allow enough cells to adhere to the swab tip.
3. Place swab(s) in tube after collection.
4. No refrigeration is necessary.
5. Note "Preservative Fluid" on requisition.
6. Label the specimen with patient name, 2nd identifier, and source.

B. ThinPrep™

1. **Collect per ThinPrep™ protocol (see page 11).**

C. M4-Viral Transport Media (Note: Only media acceptable for mouth, anal, and eye sources; acceptable for swab of vesicle fluid or scrapings)

1. Female –

- a. Clean area by removing any excess mucus, blood, or examination lubricants. **Discard this swab.**
- b. Insert second swab into the endocervical canal. Rotate clockwise for 3-5 seconds and withdraw.
- c. Insert swab into transport tube. Break shaft of swab and close securely. Do not force swab into the bottom of the tube, swab should be suspended in the media. **Leave swab in the media.**
- d. Note M4 on requisition.

2. Male-

- a. **Patient should not urinate 2 hours prior to sampling.**
- b. Insert the small sterile swab 2-4 cm into the urethra. Rotate 3-5 seconds and withdraw.
- c. Insert the swab into the transport media. Break shaft of swab and close securely. Do not force swab into the bottom of the tube, swab should be suspended in the media. **Leave swab in the media.**
- d. Note M4 on requisition.

D. SurePath™

1. **Collect per SurePath™ protocol (see page 12).**

Human Papilloma Virus (HPV)	
Aptima Human Papilloma Virus (HPV) E6/E7 mRNA by TMA	
<p>Note: Must include specimen source.</p> <p>A. ThinPrep™</p> <ol style="list-style-type: none"> 1. Collect per ThinPrep™ protocol (see page 11). 2. May be used for Anal/rectal collection. <p>B. SurePath™ (cervical/endocervical sources only)</p> <ol style="list-style-type: none"> 1. Collect per SurePath™ protocol (see page 12). 2. Specimen stability: 7 days from collection 	
Anal HPV Testing	
Preferred Sample	Dacron swab or anal-rectal brush collected in Digene Standard Transport Medium (STM)
Specimen Stability	Room temperature: 14 days Refrigerated: 21 days Frozen: 90 days
Procedure	<p>To collect an anal-rectal sample, a tap water-moistened Dacron swab is used. The Dacron swab is inserted about 5-6 cm into the anal canal past the anal verge, into the rectal vault. This is done without direct visualization of the anal canal. Firm lateral pressure is applied to the swab handle as it is rotated and slowly withdrawn from the anal canal, inscribing a cone-shaped arc.</p> <p>Avoid using cotton swabs on a wooden stick because the handle may break and splinter during collection.</p> <p>The sample may also be collected using the cervical sampler brush provided in the Digene Cervical Sampler Collection Kit. Brush or swab that is grossly contaminated with feces should be discarded and the collection repeated.</p> <p>Remove the cap from the Digene Standard Transport Medium (STM) supplied with the collection kit. Immediately insert swab or brush to the bottom of the Transport Tube. Snap off shaft at score line and cap tube securely.</p>
Anal HPV genotyping 16, 18/45	
Preferred Sample	Dacron swab in 3 mL Liquid Cytology (PreservCyt®) Preservative (ThinPrep®)
Minimum Volume	1.5 mL
Alternative Specimen(s)	Rectal Swab
Specimen Stability	Room temperature: 30 days Refrigerated: 28 days Frozen: Unacceptable
Procedure	<p>To collect an anal-rectal sample, a wet non-lubricated Dacron swab is used. The Dacron swab is inserted about 3 cm (or until resistance is met) into the anal canal past the anal verge, into the rectal vault. This is done without visualization of the anal canal.</p> <p>Firm lateral pressure is applied to the swab handle as it is rotated and slowly moved in and out. Slowly withdraw swab from the anal canal. Swish the swab vigorously in PreservCyt® fluid in the ThinPrep® vial. Discard the swab. Cap and tighten the ThinPrep® vial.</p> <p>Follow the same procedure if using a brush to collect an anal-rectal sample. Avoid</p>

using cotton swab on a wooden stick because the handle may break and splinter during collection. A swab that is grossly contaminated with feces should be discarded and the collection repeated.

ApTIMA HPV Genotyping 16/18/45 by TMA

Note: Must include specimen source.

A. ThinPrep™

1. Collect per ThinPrep™ protocol (see page 11).
2. May be used for Anal/rectal collection.

C. SurePath™ (Endocervical/Cervical sources only)**

1. Collect per SurePath™ protocol (see page 12).
[SurePath](#) (hyperlink)

Urine for UroVysion™ Testing

1. Use AmeriPath Urine Cytology Kit.
2. Collect 50-100 mL of urine in labeled collection container. Do NOT collect first morning urine.
3. Immediately pour an equal amount of fixative into the specimen collection container with the urine.
4. Place fixative bottle back into the kit box and return with the specimen.
5. Place cap on urine collection container and secure tightly.
6. Place urine collection container into plastic zip-lock specimen bag and seal.
7. Place sealed plastic bag containing the specimen collection container into the Urine Cytology Kit Box.
8. Complete test requisition.
9. Label specimen with patient name, 2nd identifier, and source

Vaginitis Panel (DNA)

(Includes Trichomonas CPT 87661, Gardnerella CPT 87511*, and Candida Albicans CPT 87481*, which can also be ordered individually)*

A. ThinPrep™

Collect per ThinPrep™ protocol (see page 11).

B. SurePath™

Collect per SurePath™ protocol (see page 12).

C. Preservative Fluid/Multi-Swab

1. Use Swab Collection and Transport Kit.
2. Rotate the swab 5-10 times while sampling to allow enough cells to adhere to the swab tip.
3. Place swab(s) in tube after collection.
4. No refrigeration is necessary.
5. Note "Preservative Fluid" and source on requisition.

* The CPT codes provided are based on AMA guidelines and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.

Vaginitis Panel by BD Affirm

(Includes Trichomonas CPT 87660*, Gardnerella CPT 87510*, and Candida, CPT 87480*)

(Note: Sample stability is 72 hours from time of collection)

1. Use BD Affirm VP8 Swab kit (Refer to kit instructions for transport instructions)
2. Collect vaginal sample using Pap collection method.
3. Using the sterile swab, obtain a sample from the posterior vaginal fornix. Twist or roll the swab against the vaginal wall 2 or 3 times, ensuring the entire circumference of the swab has touched the vaginal wall. Swab the lateral vaginal wall while removing the swab.
4. Immediately place the swab in the Sample Collection Tube.
5. 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. Discard the broken handle into an infectious waste container.
6. Place the cap on the tube and firmly press until properly sealed.
7. Label with tube with patient first and last name, and date & time collected.
8. Place into specimen transport bag with properly completed requisition form.

* The CPT codes provided are based on AMA guidelines and are provided for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.