PathGroup

Physician Centered. Patient Focused.

Directory of Services

2017

PathGroup.com

PathGroup provides comprehensive anatomic, clinical and molecular pathology services. We operate 24 hours a day, 7 days a week to deliver fast and accurate results, with a responsiveness that is unmatched in the industry. PathGroup is privately held and physician centered, designed to work seamlessly with medical practices.

Dear Valued Client,

In today's rapidly changing healthcare environment, it is increasingly important to provide healthcare services that improve the quality of patient care and reduce healthcare costs, all while enhancing physician and patient satisfaction. Strong partnerships are a critical success factor in this era of healthcare reform; PathGroup has the experience and history needed, successfully providing pathology services for nearly 50 years.

We take pride in providing superior diagnostics and clinical quality. With more than 80 pathologists representing every subspecialty, a comprehensive test menu and industry leading technology, PathGroup is truly One Lab providing Total Service.

PathGroup's ***Scope of Services*** provides expanded instructions for specimen collection and handling, as well as critical department contacts for assistance as needed. In addition to this guide, you may visit our online Directory of Services at pathgroup.com for the most current tests offered and specimen collection instructions. If you cannot find information about a test within this guide or online, please contact our Client Services department who will provide you with an answer or solution to your question. The Client Services department can be reached Monday through Friday, 8:00 a.m. until 5:00 p.m. CST at 888.474.5227 or via email at csissues@pathgroup.com.

We look forward to helping your medical practice deliver better patient outcomes through high-quality, high-service diagnostics. We trust that our services will exceed your expectation and truly enhance the care you provide.

Sincerely,

Pranil K. Chandra, DO, FCAP, FASCP
Vice President and Chief Medical Officer,
Genomic and Clinical Pathology

Derek C. Welch, MD, FCAP
Chief Medical Officer, Anatomic Pathology
and Vice President of Physician Services

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Scope of Services

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Scope of Services

Medical Directorship

PathGroup is privately held and physician centered, designed to work seamlessly with medical practices. Our team of more than 80 board-certified pathologists represents a broad range of pathology specialties and expertise within our organization. PathGroup's clinical and laboratory leaders are an academically focused group that offers superb range, depth of experience, and expertise in all subspecialty areas of pathology.

Pranil K. Chandra, DO, FCAP, FASCP
Vice President and Chief Medical Officer, Genomic and Clinical Pathology

Certification: Anatomic Pathology, Clinical Pathology, Hematopathology, Molecular Genetic Pathology, American Board of Pathology

Education: B.S., Cornell University, Ithaca, NY; D.O. New York College of Osteopathic Medicine (NYCOM), Old Westbury, NY

Post-Doctoral Training: Resident Physician, Department of Pathology, New York University Langone Medical Center, New York, NY; Osteopathic Rotation/Internship, Long Beach Medical Center, Long Beach, NY

Fellowship Training: Fellow in Molecular Genetic Pathology, Department of Hematopathology, University of Texas, MD Anderson Cancer Center, Houston, TX; Fellow in Oncological Surgical Pathology, Department of Pathology, University of Texas, MD Anderson Cancer Center, Houston, TX; Fellow in Hematopathology, Department of Pathology, New York University, Langone Medical Center, New York, NY

Professional Organizations: College of American Pathologists, American Society of Clinical Pathology, Association of Molecular Pathology

Derek C. Welch, MD, FCAP
Chief Medical Officer, Anatomic Pathology and Vice President of Physician Services

Certification: Anatomic and Clinical Pathology, American Board of Pathology

Education: B.S., University of Tennessee, Knoxville, TN; M.D. Vanderbilt University School of Medicine, Nashville, TN

Post-Doctoral Training: Resident Physician, Clinical and Anatomic Pathology, Department of Pathology, Vanderbilt University Medical Center, Nashville, TN; Resident Physician, Department of Pathology, Vanderbilt University Medical Center, Nashville, TN

Fellowship Training: Fellow in Anatomic and Surgical Pathology, Department of Pathology, Vanderbilt University Medical Center, Nashville, TN; Fellow in Gastrointestinal Pathology, Department of Pathology, Vanderbilt University Medical Center, Nashville, TN

Professional Organizations: College of American Pathologists

Billing

PathGroup is committed to providing a streamlined billing experience for hospitals, physician practices and patients alike. Our primary goal is to offer superior billing service and continually improve our quality. Our Business Office provides clients and patients with a direct customer service professional who will research and respond to all billing inquiries in a timely, accurate, and friendly manner. Our team is specially trained to help clients and patients with all billing questions—including complex billing issues that require research and follow-up.

The Business Office will bill all insurance companies on behalf of our clients and patients. It is, however, the responsibility of the client and/or patient to confirm coverage with their insurance provider prior to using our laboratories services. This will ensure that PathGroup is an in-network provider. If you have questions regarding our in-network provider status with an insurance company, please contact your **local PathGroup representative or Client Services at 888.474.5227.**

Patient Billing Customer Service *(regarding patient statements)*

Monday through Thursday – 8:00 a.m. to 4:30 p.m. CST

Friday – 7:30 a.m. to 4:00 p.m. CST

Toll Free: 877.456.6706

Client Billing Customer Service *(regarding client statements)*

Monday through Friday – 7:30 a.m. to 4:00 p.m. CST

Toll Free: 866.728.4435

In-House Managed Care Team
PathGroup provides clients with a dedicated team of knowledgeable staff to assist navigating the billing of claims through managed care. PathGroup will accept every insurance and bill patients in accordance with appropriate legal guidelines. Every effort is made to provide patients with a hassle-free experience, keeping their best interest in mind. If you have questions concerning our in-network provider status, contact your local PathGroup representative or Client Services for a full listing of contracted payers.

Client Services

For all inquiries, concerns, questions or requests, our Client Services Representatives are equipped to provide you with an answer or solution. If further investigation is needed, the client services team will forward your inquiry to the appropriate department for resolution. Such inquiries may include the following:

- Turnaround times
- Test information
- Specimen handling requirements
- Add-on testing
- Test results
- Test pricing
- Courier pickups
- Supplies

Regular hours of operation are Monday through Friday, 8:00 a.m. until 5:00 p.m. CST. All voice mails left in the client service mailbox after 5:00 p.m. CST on Friday will be answered the following Monday after 8:00 a.m. CST. If support is needed after hours, or on weekends and holidays, please call the number below and listen to the prompts to be transferred to the clinical laboratory for assistance.

Local Phone: 615.562.9300 **Toll Free Phone:** 888.474.5227

Local Fax: 615.562.9301 **Toll Free Fax:** 866.325.5890

Email: csissues@pathgroup.com

Client Consultation Services
Providing quality service is a critical component to the success of PathGroup. Offering an immediate point of contact for inquiries through direct physician to physician contact is an area that sets PathGroup apart from other pathology providers. For patients with complex cases where a consult is needed, we have the ability to route inquiries to an expert within PathGroup's internal network for colleague-to-colleague discussion.

Our laboratory managers and technical staff are also available to answer questions or offer in-office support. These professionals are available by calling **Client Services at 888.474.5227.**

Transportation and Courier Services

Courier services are available for transporting specimens to PathGroup from your medical practice under controlled conditions by trained professionals. This service is provided to you at no cost with pickup frequency determined by referral volume. Special courier services, including weekend pickups, will be established if appropriate arrangements can be made. To discuss your courier schedule criteria, please contact your local PathGroup representative.

Our Distribution Service Representatives provide regular pickups and delivery services Monday through Friday for laboratory specimens, client supplies and patient reports. If you have laboratory specimens for PathGroup and are not on a regular courier schedule, please call Client Services at 888.474.5227 to arrange a special pickup.

Weekend Pickups
Weekend courier services are provided to clients that have been approved and set-up in advance. Please confirm your local PathGroup representative is aware of any need for weekend transportation services. If you need verification, or your current needs have changed, please contact your **local PathGroup representative or Client Services at 888.474.5227.**

On weekends, clients who are set up for courier service may call 615.562.9353, which provides direct voice mail access to the Transportation Department.

Supply Requests

PathGroup provides all forms and supplies necessary for the collection and transport of laboratory testing at our facilities. Supplies can be requested online through PathSupply or PathConnect, by phone through our **Client Services Department at 888.474.5227**, or faxed directly to the **Supply Department at 615.562.9500**.

The goal of the Supply Department is to fulfill supply requests within 24 hours of an order with an expected arrival to the client office within 48 to 72 hours. Should a client become critically short of an item, they may contact Client Services and supplies can be overnighted directly.

Test Requests and Result Reporting

PathConnect
PathGroup's proprietary PathConnect™ system offers secure web-based test ordering from a single screen for all requisition types with enhanced data capture for Cytology, Histology, and Specialty testing information. With PathConnect, your practice will benefit by receiving results quicker giving you the capability to view and print results on-demand, and find it easier to comply with regulatory medical necessity requirements. Capabilities include:

- Single ordering screen for all requisitions with enhanced data capture for Cytology, Histology and Specialty testing information
- Ability to print results on demand (PDF files)
- Remote access to reports – office, home or away
- 24/7 on-line IT Help for PathConnect
- Add-on tests
- Cumulative Reports
- Directory of Services
- Electronic Supply Ordering
- Ability to edit patient demographics
- Request courier services online
- Updates on testing services and PathGroup news

The PathConnect Department employs a team of dedicated professionals who provide support for the PathConnect system and all associated features. Assistance is available for PathConnect 24 hours a day, seven days a week by emailing Help@pathgroup.com or calling our **IT hotline at 615.221.4511.**

PathConnect Results Review
PathConnect Results Review offers clients the ability to print results on demand (PDF Files) with full remote access to reports – office, home or on the go. Results Review is available to PathGroup clients from any computer with Internet access. For online access, visit pathgroup.com.

Fax Reporting
PathGroup will transmit test results directly from its LIS computer system via fax for clients that prefer to have reports delivered by fax. All clients, regardless of result delivery type, are required to provide PathGroup with a signed Fax Verification Form prior to receiving results. For more information about how you are receiving your results or to obtain a Fax Verification Form, please contact your local PathGroup representative.

EHR/EMR Interfaces
PathGroup is committed to meeting our client's needs, offering a full spectrum of technology solutions. We understand how significant laboratory interfaces, EHR/EMR adoption, and efficient ordering and report retrieval options are in the healthcare landscape in which you operate.

PathGroup utilizes the latest health care industry standards, such as Health Level Seven (HL7), Virtual Private Networks (VPN), and interface engine technology to develop and maintain interfaces for laboratory information systems and practice management systems. This direct exchange of patient data provides clients with full control of storage, access, and retrieval of patient data, and allows clients to use their own LIS to order and report referral testing.

With a full-service information technology team dedicated to Integration Services, you can trust that your practice will be serviced efficiently and without a waiting queue for support and implementation.

PathGroup Mobile™
PathGroup's iPhone/iPad application makes it possible for healthcare providers to review pathology, cytology, clinical and esoteric laboratory reports anywhere, any time. PathGroup Mobile provides access to patient results as soon as they are released, as well as providing historical trending capabilities.

Referral Testing

PathGroup is a full service laboratory offering a robust test menu. We perform most tests at our laboratory facilities with turnaround times often exceeding the industry standard; however, a few highly complex procedures are referred to reliable reference laboratories. Should an assay require send-out services, PathGroup will work with an alternate lab to perform and report test results with little to no interruption to your practice.

Specimen Collection and Preparation

Handling and Processing of Blood Specimens

There are multiple factors associated with the handling and processing of laboratory specimens that can introduce test result inaccuracy, both before the specimen has been obtained and after it has been collected.

These pre-analytical factors can produce pre-analytical changes that result in erroneous laboratory test results. Examples include:

- Failure to draw a patient at the correct time (fasting, post prandial, post- or pre-medication)
- Failure to centrifuge specimens in a timely manner
- Hemolysis secondary to venipuncture technique or specimen mishandling
- Analyte concentration changes due to evaporation
- Incorrect storage temperature
- Using improper Vacutainer® tube with inappropriate additive
- Incorrect transport

Recognition and control of these pre-analytical variables should reduce error and contribute to the medical usefulness of patient test results.

Labeling Specimens

Each specimen container must be labeled with at least **two** patient identifiers to include **patient name** in combination with one of the following:

- Date of Birth
- Medical Record Number
- Requisition Number

Specimen Packaging

Any specimen which must be stored for more than one hour prior to pick-up should be refrigerated unless otherwise indicated under specimen requirements. Do not refrigerate unspun potassiums.

Any specimen which requires freezing should be frozen as soon as possible after collection. Always freeze specimens in a plastic vial, never glass.

Confirm that the specimens are properly spun, properly labeled and accompanied by a requisition. Place the corresponding specimen(s) and requisition into a specimen transport bag.

OSHA requires that all shipments containing clinical specimens be marketed with a "Biohazard Label". Bags and labels for shipments sent to PathGroup will be provided.

Ambient Temperature (Room Temperature)
Our standard specimen bags are designed to transport serum and urine specimens that do not require special temperatures or handling.

If you have any concerns regarding the effect of extreme weather conditions on routine or refrigerated specimens, please call Client Services at 888.474.5227.

Exposure to Light
It is important to avoid exposing blood specimens for photosensitive analytes to artificial or sunlight for any length of time (examples include Vitamin B6 and porphyrins). These specimens are to be protected with an aluminum wrap or equivalent.

Refrigerated (On Coolant) Specimens
Place specimen in the refrigerator for storage before pick up by the courier. When packing for transport, place specimen tube or urine tube into zip-lock portion of bag and place the requisition into the outer sleeve. Place coolant in transport bag (box) along with any specimens in a way so that there is **no direct contact of the specimens with the coolant.**

Frozen Specimens
Label each tube with the patient's name, date and type of specimen (EDTA plasma, serum, etc.). Call Client Services at 888.474.5227 for special transport arrangements for all critical specimens.

Specimen Transport

Transportation should occur at correct temperature so that the specimen integrity is always maintained. Some tests require that the specimen be shielded from light. These specimens, such as those being assayed for Vitamin A, B6, and porphyrins, should be protected from light by wrapping the specimen with foil or using an amber transfer container. Strict adherence to specimen requirements is essential.

Laboratory biohazard zip-lock bags are available and must be used for the transport of all specimens. These bags are designed to transport specimens that do not require special temperatures or handling. Appropriate test requisition(s) must accompany labeled specimens and should be placed in the sleeve conveniently located on the front side of the transport bag.

Each bag should include the following:

- ONE patient ONLY per bag
- Requisition legibly filled out with all patient demographics, billing information, ICD codes and test information
- Labeled specimens

Rejection of Specimens

As part of our active quality assurance program and as part of the requirements of various certifying agencies, we have developed the following list of specimen rejection criteria. These criteria were developed with the intention of ensuring accurate, meaningful patient results.

Unsatisfactory Information

All specimens must be properly identified by full name. All specimens for blood group and type testing must be labeled with the patient's name, date of birth, Social Security Number, date and time, and initials of the phlebotomist.

All specimens must be accompanied by a requisition which includes name, birth date, sex, date and time of collection, and name of requesting physician.

- The source of the specimen should be noted when appropriate
- A specimen not labeled properly may be discarded

Inadequate Specimen Due to Collection and Transportation Problems

- Contamination of the specimen (e.g. bacterial contamination, hemolysis, incorrect order of draw, etc.)
- Insufficient specimen for test requested, such as quantities less than those stated in this Scope of Services guide.
- Collection in improper container (e.g. incorrect anticoagulant, unsterile container for cultures, improper preservative, or holding medium)
- Failure to follow special instructions (e.g. draw and place in ice, protect from light, separate plasma immediately)
- Prolonged delay in transportation

Inadequate Specimen Due to Patient Preparation

- Non-fasting patient for test that requires fasting state
- Incorrect preparation of patient for test
- Specimen drawn at incorrect time (e.g. drug levels which should be drawn at peak or trough concentrations)

If a compromised specimen is accepted, a note will be made on the final report as to the nature of the problem and caution should be used when interpreting the results. If a specimen is rejected, the client/physician will be contacted to decide disposition. Specimens rejected due to collection problems are held in proper storage for three to seven days depending on the specimen type.

All specimens are examined upon receipt by the laboratory to ensure suitability for analysis. If the specimen volume is insufficient or if the specimen has been improperly handled, the reliability of test results could be compromised and the specimen will not be processed. In this case, the client will be contacted.

Laboratory test results are dependent on the quality of the specimen submitted. It is important that all specimens and request slips be properly labeled with the full name of the patient, collection date, and the origin (source) of the sample, when applicable.

If there is any doubt or question regarding the type of specimen that should be collected, it is imperative that our Client Services department be called at 888.474.5227 to clarify the order and sample requirements.

Blood Collection – Performance of a Routine Venipuncture

Most laboratory tests are performed on anti-coagulated whole blood, plasma, or serum. Please see our individual Test Directory section for specific storage and transport requirements.

- **Plasma:** Draw a sufficient amount of blood with the indicated anticoagulant to yield the necessary plasma volume. Gently mix the blood collection tube by inverting eight to ten times immediately after collection. If required, separate plasma from cells by centrifugation within 30 minutes.

- **Serum:** Draw a sufficient amount of blood to yield the necessary serum volume. Gently mix the blood five times if SST or plain red tube is used. Allow blood to clot at ambient temperature, approximately 30 minutes for SST tube and 60 minutes for plain red tube. Separate serum from clot by centrifugation within two hours at RPMs required for a clean spin.

- **Whole Blood:** Draw a sufficient amount of blood with the indicated anticoagulant. Gently mix the blood collection tube by inverting eight to ten times immediately after collection.

Blood samples used for laboratory testing are typically obtained by venipuncture. The proper procedures for routine venipuncture are outlined below. All these procedures should be conducted observing OSHA's "Universal Precaution Procedures" regulations. When collection, processing, or handling specimens they should be considered biohazard sources with the potential of transmitting infectious diseases.

Venipuncture Procedure

Properly identify the patient by asking the patient to state his or her full name and confirming with a second identifier such as date of birth. Prepare the tubes and other needed equipment:

- Gloves
- Tourniquet
- 70% alcohol prep pads
- 2x2 Dry Gauze
- Appropriate evacuated tubes for test ordered
- Holder or syringe and needle (21-22 gauges, 1-1/5" long) with appropriate safety device
- Adhesive pressure strip (paper tape) or band aids
- Biohazard waste container

1. Review the request form(s) or physician order to determine that you have the appropriate evacuated tubes (see Table 1: PathGroup Specimen Tube Guide). Check for diet restrictions. If the test requires that the patient be fasting, make sure that these requirements have been followed.

2. Position the patient so that the arm is supported by a stationary object, such as a drawing chair, drawing table, or bed. Never draw blood from a standing patient. Do not draw blood from a compromised limb (i.e. due to mastectomy, stroke, surgery, etc.). Do not draw above an intravenous infusion.

3. Always wear gloves and work quickly so that the tourniquet does not remain on the patient's arm longer than one minute. Apply the tourniquet approximately two to four inches above the elbow, snug – not tight. Ask the patient to make and hold a fist; avoid vigorous hand pumping.

4. Palpate (feel) for a vein. The most commonly used veins are the median cubital, cephalic, and basilic veins. The preferred selection of veins is the median cubital first, then the cephalic, and last, the basilic vein. A vein should have an elastic feel and "gives" under pressure.

5. Clean the chosen puncture site using the alcohol pad, starting at the center of the site, moving in an ever-widening concentric circle. Allow the skin to dry. Place the index finger on the vein above the puncture site, the thumb on the vein below the puncture site, and pull the skin to prevent the vein from "rolling".

6. With the needle bevel facing upward, line up the needle with the vein at an upward angle of approximately 15-30 degrees. Puncture the vein in a rapid smooth motion, without penetrating through the vein. Push the evacuated tube forward until the back of the needle punctures the rubber stopper. Reassure the patient. Explain that there will be slight pain associated with the procedure. Never tell the patient it will not hurt.

Skin Puncture Procedure

Avoid a finger that is cold, cyanotic (blue), swollen, or inflamed.

1. A fresh pair of gloves must be worn

2. With your left thumb and index finger, grasp either the patient's long or ring finger about three inches from the tip. Moving your left hand toward the tip of the patient's finger, apply a massaging motion to the fleshy portion of the finger.

3. Repeat this massaging process five to six times.

4. Cleanse the ball or pad of the finger with an alcohol swab. Do not use iodine solutions to cleanse the skin.

5. Thoroughly dry the ball or pad of the finger with a piece of dry cotton or gauze to avoid hemolysis due to residual alcohol.

6. Pick up a sterile lancet device and remove the lancet from its container

7. With your right hand, firmly grasp the sterile lancet. With your left hand, firmly grasp the patient's finger

8. With a quick motion, depress the button on top of the lancet, making a deep cut on the side of the ball of the finger. The cut should be across the fingerprints.

9. If blood flows freely, wipe away the first drop with a clean piece of gauze.

10. If blood does not flow freely, increase the blood flow by holding the finger downward and gently massaging just above the puncture site. Avoid excessive massaging or rigorous pressure on the area since this may contaminate the blood sample with tissue fluid. If the blood does not flow easily after gentle massage, make another puncture at a different site.

11. Fill EDTA microtainer quickly, then stopper and mix thoroughly. Do not scrape the blood specimen from the finger as it may cause hemolysis. Blood specimen volume should be between 250-500ul (see lines on microtainer vial). Mix well by inverting eight to ten times.

12. Fill the appropriate microtainer tubes.

13. Label the tube with the patient's full name, date of birth, your initials, date and time drawn.

Microtainers

- **PLAIN with red cap:** No additive – used for blood bank or serum tests that cannot be collected in gel barrier tubes
- **AMBER/gel barrier with gold cap:** No additive – used for most chemistry tests
- **PLAIN/gel barrier with green cap:** Lithium heparin additive – used for chemistry tests requiring plasma
- **PLAIN with lavender cap:** EDTA additive – used for hematology tests (except Sed Rates)

Glucose Tolerance Test

Unless the physician tells the patient otherwise, for three days prior to testing, the patient should eat three balanced meals each day; include bread, starches or sweets (two slices of bread at each meal is adequate). Beginning after dinner on the night before the test, the patient should not eat or drink anything except water until coming to the laboratory. Patients who smoke should abstain from smoking from the time they go to bed the night before until completion of the entire procedure.

Specimen Preparation

Pre-Centrifugation Phase

Plasma specimens are obtained using a Vacutainer® tube, containing an anticoagulant. These specimens can be centrifuged within minutes after collection. Any vacuum tube containing an anticoagulant should be inverted gently eight to ten times immediately after blood collection to ensure the intended action of the additive.

Serum specimens are obtained from tubes when the blood has been allowed to clot. Prior to centrifugation, the specimen must be thoroughly clotted.

Clotting Instructions

Clotting instructions with minimum clotting time recommendations:

- Non-additive tubes (red stoppers): 60 minutes
- SST tubes: 30 minutes

Recommended times are based on an intact clotting process. Patients with abnormal clotting due to disease, or those receiving anticoagulant therapy require more time for complete clot formation. Separation of serum or plasma from cells should take place within two hours of collection to prevent erroneous test results.

When specimen requirements call for a chilled specimen (2-8°C), the specimen is to be immediately placed in a small plastic tube bag, tied and placed in crushed ice or a mixture of ice and water. Examples requiring a chilled specimen include ammonia, PT/APTT, and lactic acid.

Centrifugation

Blood specimens should **clot adequately prior to centrifugation.** Specimens should be centrifuged using the appropriate tube holders (Black - 125mm; Red - 100mm; Green - 75mm). The recommended centrifuge time is 10 minutes at 3125 rpms for Black, 3250 rpms for Red, and 3300 rpms for Green (all rpms (+/-) 100 rpms). All specimens collected in tubes with gel barriers should be properly centrifuged prior to transport.

After centrifugation of the gel tubes, the serum/plasma is separated from the cells by the gel barrier. It is recommended that serum/plasma be physically separated from contact with cells **as soon as possible,** with a maximum time limit of two hours from the time of collection. After proper centrifugation, serum can be left in contact with the gel barrier of SST tubes for up to seven days with proper storage.

The centrifuge must be properly balanced. This is to prevent excessive vibration and potential breakage of the specimen tube, and is also necessary to properly separate the serum/plasma from the cells.

Centrifuge Safety

With normal operation, the centrifuge does not present any safety hazards. It is important to follow the listed safety precautions while operating the centrifuge:

- **Lid:** Never open the lid while the rotor is moving. If the centrifuge comes with a safety interlock switch, do not tamper with this safety mechanism. If the switch is broken, do not operate the instrument until the switch is repaired.
- **Load Balance:** The centrifuge must be balanced before operating. When centrifuging single or multiple tubes, each tube has to be counterbalanced with a tube of blood or a tube filled with water to match the tube directly across from it in the centrifuge head. Never spin a single tube without installing a balance tube. Excessive noise or vibration is an indication that the centrifuge is not balanced.
- **Biohazard:** If a tube spills or breaks, there is a potential biological hazard and the instrument must be cleaned using an approved cleansing procedure.

Call PathGroup's Client Services Department at 888.474.5227 to answer any questions regarding specimen requirements.

For proper additive performance, invert SST tubes five times. Invert all other filled additive tubes eight to ten times. Do not shake. Vigorous mixing may cause hemolysis. Insufficient mixing or delayed mixing in tubes with anticoagulant may result in clotting, platelet clumping, and incorrect test results.

Urine Collection

Clean Catch Urine Collection

Male Collection Procedure:

- Remove lid of the container and carefully handle the outside of the container only.
- Wash hands with soap and water, rinse and dry with a disposable paper towel.
- Completely retract the foreskin and cleanse the glans penis with a towelette.
- Pass the first portion of the urine into the toilet bowl and without stopping, catch the remaining urine into the screw-capped, sterile container, but do not overflow the container. Pass the remainder of urine into the toilet.
- Place the lid securely onto the container.

Female Collection Procedure:

- Remove lid of the container and carefully handle the outside of the container only.
- Wash hands with soap and water, rinse and dry with a disposable paper towel.
- Using one hand, spread the labia apart and wipe the area from front to back with a towelette.
- Continue holding the labia apart
- Pass the first portion of the urine into the toilet bowl and without stopping, catch the remaining urine into the screw-capped, sterile container, but do not overflow the container. Pass the remainder of urine into the toilet.
- Place the lid securely onto the container.

24 Hour Urine Collection Procedure

For tests requiring a 12-hour or 24-hour urine collection, PathGroup will provide the appropriate containers. For such tests, patients must be instructed to:

- Time the collection accurately during the 24 hour period
- Collect all urine voided during the time period as described in the procedure below

Make sure that patients are warned of the presence of potentially hazardous preservatives if they were added to the container.

- To begin collection time, patient is to void and discard the first urine specimen.
- Write down (on the container) the time as this is the beginning of the 24 hour period.
- Collect all urine voided for 24 hours in this container. Care must be taken to save all of the urine during this 24 hour period.
- Collect urine in a separate container (a clean paper cup will suffice) and immediately transfer it the 24 hour container.
- At the end of the 24 hour period, save the last specimen and write the time on the urine container label (a full 24 hour collection is necessary for accurate test results).
- Refrigerate (if indicated) the collected urine between all voiding's. the 24 hour urine collection is stable for up to 6 days refrigerated.
- Keep the 24-hour urine specimen refrigerated (if indicated) and bring to the laboratory as soon as possible. Please include date and time started and date and time completed.

Microbiology Specimen Collection

General Collection Guidelines

1. Collect the specimen from the actual site of infection, avoiding contamination from adjacent tissues or secretions.

2. If appropriate, decontaminate the skin surface. Use 70-95% alcohol (ALC) and 1-2% tincture of iodine (TOI) to prepare the site. Allow a contact time of two minutes to maximize the antiseptic effect.

3. Collect the specimen at optimal times (e.g. early morning sputum for AFB cultures).

4. Collect a sufficient quantity of material and use appropriate collection devices - sterile, leak-proof specimen containers.

5. Use appropriate transport media - anaerobe transport vials; Amies or Stuart's for bacterial cultures; Cary-Blair for stool culture; M4 for viral, Chlamydia, and urea plasma cultures.

6. Whenever possible, collect specimens prior to administration of antimicrobials.

7. Properly label the specimen and complete the test request form. The source of specimen is required.

8. Minimize transport time. Maintain an appropriate environment between collection of specimens and delivery to the laboratory.

9. Package each specimen in a separate sealable transport bag.

General Transport Guidelines

1. Transport specimens to the laboratory as soon as possible. Prompt processing minimizes loss in viability of potential pathogens and ensures an accurate appraisal of the different flora present.

2. If a delay in transport is anticipated, a transport medium must be used.

3. Wound specimens for anaerobic workups must be submitted in an anaerobic transport medium.

4. Most specimens can be refrigerated at 2-8°C with the following exceptions:
   - Blood culture tubes (ambient temperature)
   - Lavender-top tubes (ambient temperature)
   - Genital specimens for Neisseria gonorrhoeae (ambient temperature)
   - CSF and other sterile body fluids, except urine (ambient temperature or 35-37° for CSF)
   - Stool in preservatives and/or transport medium (ambient temperature)
   - Eyes and inner ear specimens (ambient temperature)
   - Specimens already inoculated onto primary culture media at the bedside or at a doctor's office (ambient temperature)

5. Never transport syringes with needles to the laboratory; instead, transfer the contents to a sterile tube.

Procedures for Microbiologic Specimen Collection

Abscess

1. Decontaminate the surface with 70-95% ALC and 1-2% TOI

2. Collect purulent material aseptically from an undrained abscess using a sterile needle and syringe. Open miliary abscesses with a sterile scalpel and collect the expressed material with a sterile needle and syringe.

3. Expel air from the syringe, remove the needle, and cap the syringe. Alternatively, transfer 5-10 mL of the aspirated material to tightly sealed sterile container.

Blood (Bacterial Only)

1. Gather the collection blood bottles or tubes needed.
   - Note: Blood culture bottles will be sent to a reference laboratory.

2. Clean the tops of each blood culture bottle and/or the stopper of an isolator® tube with alcohol. Do not allow alcohol to pool, as it could enter the system and kill organisms. Allow to dry while preparing the patient.

3. Cleanse the skin with 70-95% ALC and 1-2% TOI.

4. Move in an ever-increasing circular pattern, starting at the point of projected needle insertion.

5. Apply a tourniquet proximal to the point of venous entry. The venipuncture site should not be palpated following disinfection unless sterile gloves are worn.

6. Use a sterile needle and syringe or closed system blood collection tubing. For fastidious microorganisms, use the Vacutainer system for isolator tubes.

7. Collect blood. Collecting the appropriate volume of blood is critical. Inoculate the bottles or tubes without changing needles.
   A. The adult isolator tubes will accommodate 9.5-10 mL blood. Allow the vacuum to draw in the proper amount of blood. Do not force the blood into the tube.

B. For adult bacterial culture, inoculate aerobic bottle with 10 mL of blood or the anaerobic bottle with 7 mL of blood. If less than 17 mL is collected for two bottles, inoculate the aerobic bottle with 10 mL and inoculate the anaerobic bottle with the remainder.
C. For pediatric specimens, inoculate 1-3 mL blood into a pediatric bottle or use the pediatric isolator tube. Allow the tube to draw 1.5 mL of blood.

8. For fungal and AFB cultures, inoculate 5 mL blood into a Bactec™ Myco/F Lytic bottle

9. Invert tubes several times after specimen collection.

10. Remove the iodine from the skin after collection of the specimen.

11. Label and transport specimens as soon as possible - do not refrigerate.

12. Hold at room temperature or at 35°C.

Body Fluids, Sterile (except Urine and CSF)

1. Prepare the skin as for blood cultures

2. Collect the fluid using a sterile needle and syringe

3. Submit 10 mL of the specimen for analysis

4. Transport the specimen in a capped syringe after expelling the air from the syringe and removing the needle. Transfer the aspirated material to a tightly sealed sterile container or collect with the appropriate transport vial as described below:
A. For aerobic and anaerobic organisms, use an anaerobic transport vial to insure the survival of anaerobic organisms.
B. 10 mL of peritoneal fluid may be added to a blood culture bottle. Peritoneal fluid is the only body fluid that may be cultured in blood culture media.
C. For viral isolation, send 3 mL of less fluid in viral transport medium or a sterile vial.
D. If tuberculosis or fungal infections are suspected, larger volumes are required. Collect in sterile container.

5. Immediately transport fungal specimens at 2-8°C, viral specimens at 2-8°C, and all other specimens at ambient temperature.

Bone Marrow

1. Physicians should wear gowns, masks, and gloves during specimen collection.

2. Prepare skin as for blood cultures

3. Drape the surrounding skin with sterile linen

4. Aspirate the marrow percutaneously using a sterile needle and syringe

5. Transfer 3-5 mL to a sterile tube containing SPS for bacterial AFB and fungal cultures. EDTA is required for viral cultures and molecular tests.

6. Transport specimens immediately at ambient temperature

Bordetella pertussis Culture and PCR

**Contact PathGroup's Supplies Department for Regan-Lowe tubes*

1. Allow two tubes of the transport medium (Amies Charcoal or Regan-Lowe) to equilibrate to ambient temperature.

2. Use two swabs on a flexible wire handle to collect the specimen. One swab is used to inoculate the transport medium.

3. Seat the patient comfortably and tilt their head back.

4. If available, insert a nasal speculum. Press the swab through the nares until resistance is met due to contact with the nasopharynx.

5. Rotate the swab gently and allow the swab to maintain contact with the nasopharynx for 20 to 30 seconds or until coughing is induced.

6. Place the swab into the transport medium. Label the tube with the patient's name and identification number. Leave the swab embedded in the tube during transport. Transport the specimens at ambient temperature.

- Note: Specimen will be sent to Tennessee Department of Health Laboratory Services for testing.

Bronchial Brush/Washing/Lavage

This technique should only be performed by an experienced individual. Descriptions of the methodology are readily available in literature. Transport in a tightly sealed sterile container at 2-8°C for cultures, or frozen for molecular tests.

Bullae, Vesicles

1. Cleanse the skin as for blood cultures

2. Aspirate the fluid/purulent material using a sterile needle and syringe

3. If an aspirate is obtained, place in appropriate viral or bacterial transport.

4. If no material is obtained, un-roof vesicle or bullous lesion and use a swab to collect cells from the base of the lesion. Place in appropriate viral or bacterial transport media.

Cellulitis

Swabs and leading-edge aspirates with or without injection of saline fail to yield etiologic agents in the majority of cases. If an unusual organism is suspected, a leading-edge (advancing margin) punch biopsy is the recommended specimen of choice.

Cerebrospinal Fluid

1. Physicians should wear gowns, masks, and gloves to collect the specimen. Because an open tube is held to collect the fluid, other personnel should stand away or wear masks in order to avoid respiratory contamination.

2. Decontaminate the skin with 1-2% TOI, followed by 70-90% ALC using an increasingly outward circular movement.

3. Drape sterile linen over the skin surrounding the puncture site.

4. Insert the needle and collect the fluid into three sterile leak-proof tubes. Collect an adequate volume of fluid as recommended below :

A. Bacterial culture > 1 mL
B. Fungal culture 8-10 mL
C. Molecular > 1 mL

D. Mycobacterial culture 8-10 mL
E. Viral culture > 2 mL

5. Cap the tubes tightly. Submit the third tube for culture to reduce the possibility of contamination due to skin flora. Transport immediately.

6. Transport other bacterial cultures at ambient temperature. If a delay in transport occurs, incubate at 37°C or leave the fluid at ambient temperature for transport.

7. Freeze specimens for molecular (PCR) analysis.

8. For viral culture, if volume is greater than 3 mL, refrigerate and transport at once. If volume is less than 3 mL, add fluid to M4 viral transport media and transport at 2-8°C.

Chlamydia/Gonorrhea

Chlamydia/Gonorrhea testing is available by several methods. A DNA amplification method that detects Chlamydia trachomatis/Neisseria gonorrhoeae nucleic acid in urogenital specimens is the preferred diagnostic method. The nonamplified direct DNA probe is also available; but in general, it is less sensitive than an amplified test. Culture for Chlamydia trachomatis or Neisseria gonorrhoeae is the method of choice in cases of treatment failure and sexual abuse and for nongenital sources. Test orders will be changed to match test-specific transport media submitted.

Specimens for all of the above can be collected following the procedures below. Test-specific collection and transport kits are required for DNA tests and are available through PathGroup's Supplies Department.

1. Females (endocervical):
   A. Place patient in the lithotomy position
   B. Insert speculum and visualize the cervical os
   C. Remove excess mucus from cervical os and surrounding mucosa using the large swab provided in the kit. Discard this swab.
   D. Insert second swab from kit, 1-1.5 cm into endocervical canal.
   E. Rotate swab for 30 seconds in endocervical canal to insure adequate sampling.
   F. Withdraw swab carefully, avoiding any contact with vaginal mucosa.

2. Males (urethral):
   A. Do not allow patient to urinate for at least one hour prior to collection.
   B. If purulent discharge is present, collect discharge directly on swab.
   C. If no discharge is present, insert smaller swab 2-4 cm into urethra. Rotate gently to insure contact with all urethral surfaces. Leave inserted for 2-3 seconds. Rotate gently while withdrawing swab.

Place swab into the test-specific transport tube:

   A. Break swab shaft to fit tube, if required.
   B. Cap tube tightly
   C. Transport at 2-8°C
   D. For culture, inoculate specimen as specified below.

For culture of N. gonorrhoeae, use calcium alginate or Dacron swabs for specimen collection. Cotton fibers contain fatty acids that are inhibitory to the gonococcus. Avoid swabs with wood sticks.

3. Rectal culture:
    A. Moisten a swab with sterile water and insert the swab into the anal canal just beyond the anal sphincter.
    B. Allow 10-30 seconds for absorption of the organisms onto the swab.
    C. Withdraw swab gently and inoculate plate as described above.
    D. Stool is not an acceptable specimen for gonorrheal culture.

If disseminated gonococcal infection is suspected, culture blood and suspicious sites (e.g. petechiae or joint fluid).

Cutaneous (Fungus Only)

1. Hair
    A. Scrape the scalp with a blunt scalpel
    B. Place specimen in a dry sterile container
    C. Transport at ambient temperature
    D. The following specimens are also acceptable:
        - Hair stubs, contents of plugged follicles, skin scales, hair plucked from the scalp with forceps
    E. Cut hair is NOT an acceptable specimen

2. Nails
    A. Cleanse the nail with 70-95% ALC
    B. Remove the outermost layer by scraping with a scalpel
    C. Place specimen in a dry, sterile container
    D. Transport at ambient temperature
    E. The following specimens are also acceptable:
        - Clippings from any discolored or brittle parts of nail
        - Deeper scrapings and debris under the edges of the nail

3. Skin
    A. Cleanse the skin with 70-95% ALC
    B. Collect epidermal scales with a scalpel, at the active border of the lesion
    C. Place specimen in a dry, sterile container
    D. Transport at ambient temperature

Ear

1. External ear cultures are processed as superficial wounds

2. Middle ear fluid will be processed as a sterile body fluid. If the diagnosis is otitis media, the specimen of choice is middle ear fluid collected by tympanocentesis.

Eye

1. Cleanse the skin around the eye with a mild antiseptic

2. Purulent conjunctivitis:
    A. Collect purulent material with a regular cotton swab
    B. Place the swab into transport media and transport at ambient temperature or 2-8°C for viral cultures

3. Corneal infections:
    A. Swab the conjunctiva as described above
    B. Collect multiple corneal scrapings and inoculate directly onto bacterial agar media (chocolate agar, potato dextrose agar, and sheep blood agar) or viral transport media
    C. Transport at ambient temperature or 2-8°C for viral cultures

4. Intraocular fluid:
    A. Collect fluid by surgical needle aspiration.

B. Transport bacterial cultures at ambient temperature, viral cultures at 2-8°C, or frozen for molecular tests.

Nasopharyngeal Aspirates/Washings (Virus Only)

1. For aspirate, attach mucus trap to suction pump and catheter, leaving wrapper on suction catheter. Turn on suction and adjust to suggested pressure.

2. Without applying suction, insert catheter into the nose, directed posteriorly and toward the opening of the external ear.
   - Note: Depth of insertion necessary to reach posterior pharynx is equivalent to distance between anterior nares and external opening of the ear.

3. Apply suction and using a rotating movement, slowly withdraw the catheter.

4. Transport at 2-8°C for viral cultures or frozen for molecular tests

5. For washings, suction 3-5 mL of sterile saline into a new sterile bulb

6. Insert bulb into one nostril until nostril is occluded

7. Instill saline into one nostril with one squeeze of the bulb and immediately release bulb to collect recoverable nasal specimen

8. Empty bulb into suitable dry, sterile specimen container or add 3 mL or less to viral transport media (M4)

9. Transport at 2-8°C

Nasopharyngeal Swab

1. Seat the patient comfortably and tilt the head back

2. Insert a nasal speculum

3. Insert a nasopharyngeal swab (on a malleable wire) through the speculum into the nasopharyngeal area

4. Rotate the swab gently and allow it to remain inside the nasopharyngeal area for 20-30 seconds

5. Remove the swab and place in a non-growth promoting transport medium (such as the culturette container from which the original swab has been removed). Place swab in M4 media for viral cultures.

6. Transport at ambient temperature or 2-8°C for viral culture

Note:
- Transport media must be used because the swab tip is small and vulnerable to drying. The organisms likely to be present are fastidious.
- For infants, special bulb suction procedures are available.
- If unusual organisms such as Bordetella pertussis are suspected, special culture media is necessary for collection and transport (refer to Bordetella pertussis culture).

Nose

**This is an inappropriate specimen for anything other than assessment of staphylococcal colonization.*

1. Collect anterior nares culture with a regular cotton swab. In small children, use a nasopharyngeal swab to facilitate collection.

2. Transport at ambient temperature

Prostate
1. Cleanse the glans with soap and water

2. Obtain prostate fluid by digital massage through the rectum

3. Collect fluid using a sterile swab

4. Transport at room temperature

5. Alternatively, a urine specimen obtained immediately before and after massage may be submitted for culture

Skin
Refer to Abscess, Bullae, Cellulitis, Vesicles, and Wounds.

Sputum
Instruct the patient as follows:

1. Assure patient cooperation is vital to get an adequate specimen

2. Rinse mouth with tap water to remove food particles and debris

3. Have patient breathe deeply and cough several times to receive deep specimen

4. Patient should expectorate into dry, sterile container

5. If patient is unable to produce sputum, induce using saline nebulization.

6. Transport immediately at ambient temperature. Refrigerate if a delay of more than one hour is anticipated; freeze for molecular tests.

Stool, Feces
1. Collect specimen in a clean bed pan or use plastic wrap placed between the toilet seat and the bowl. Do not submit feces contaminated with urine or toilet water.

2. Immediately transfer specimen into a clean, dry container or the appropriate preservative

3. Transport unpreserved stool refrigerated

Note:

- Only loose or diarrheal stools are recommended for routine bacterial and C. difficile cultures.
- Place the specimen in an appropriate stool preservative or transport media, immedi ately after collection. For ova and parasite, use SAF vial or 10% formalin and modified PVA; for routine stool culture, use Cary-Blair transport media.
- If a stool specimen is not available, the following are suitable alternatives for culture:
    - A swab of rectal mucus, or
    - A rectal swab inserted one inch into the anal canal (not acceptable for Rotavirus/Adenovirus EIA)

Throat

1. Use a cotton or Dacron swab

2. Use a tongue blade and an adequate light source to insure proper visualization

3. Reach behind the uvula and swab:
    A. Both tonsillar fauces, and
    B. The posterior pharynx, and
    C. Any ulceration, exudate, lesion or area of inflammation

4. Place the swab into the transport media and transport at ambient temperature or 2-8°C for viral cultures.

Tissues

1. Tissue collection is an invasive procedure and requires surgery by a trained physician.

2. Collect tissue aseptically. Include material from both the center and the edge of the lesion. Submit actual tissue specimen; not swab of tissue surface.

3. Place the specimen in a sterile container on sterile gauze moistened with sterile non-bacteriostatic saline.

4. Transport immediately at ambient temperature, in a manner to insure recovery of anaerobic organisms. For virology cultures, do not allow the tissue to dry. Transport tissue suspended in viral transport media (M4) at 2-8°C, or frozen for molecular tests.

5. Do not submit tissue in formalin or containers that once contained formalin.

Urethra

Refer to Chlamydia/Gonorrhea.

Urine

1. Instructions for female patients to collect midstream urine for bacterial culture:
    A. Remove undergarments
    B. Wash hands thoroughly with soap and water, rinse them, and dry them on a disposable paper towel or shake off excess water.
    C. Spread labia with one hand, and keep them continuously apart.
    D. Take the open sterile cup in the other hand, without touching the rim or inner surface of the cup or lid.
    E. Void 20-25 mL into the toilet and catch a portion of the rest of the urine in the container without stopping the stream. Do not touch the legs, vulva, or clothing with the cup.
    F. Place the lid on the cup.

2. Instructions for male patients to collect midstream urine for bacterial culture:
    A. Wash hands
    B. Retract the foreskin completely
    C. Void 20-25 mL into the toilet and catch a portion of the remaining urine in the cup without stopping the stream. Do not touch the cup with the penis.
    D. Place the lid on the cup.
    E. First-void urine for nucleic acid amplification tests (Chlamydia/Gonorrhea)
    F. Patient must not have urinated during the previous two hours
    G. Collect the first 10-50 mL of the urine stream in a clean, empty plastic cup.
    H. Place the lid on the cup.
    I. Transport urine refrigerated in test-specific transport media.

3. Suprapubic aspiration:
This is not a routine technique and is best performed by an experienced individual. Descriptions of the

method are readily available in literature. These specimens are acceptable for anaerobic culture and should be submitted in an anaerobic environment if an anaerobic culture is requested.

4. Indwelling catheter urine:
   A. Do not collect urine from the drainage bag because growth of bacteria outside the catheter may have occurred at this site.
   B. Clean the catheter with an alcohol pad.
   C. Use a sterile needle and syringe to puncture the tubing. Aspirate the urine directly from the tubing.
   D. Transfer the urine to a sterile specimen container.

5. Urine catheter tip cultures are not acceptable.

6. Specimen handling:
   A. Label the container immediately and refrigerate at 2-8°C within ten minutes of collection or transfer > 2 mL urine into a boric acid transport tube.

Wounds

1. For closed wounds, refer to Abscess and Bullae, Cellulitis, Vesicles.

2. For open wounds:
   A. Clean the sinus tract opening of the wound surface mechanically, without using a germicidal agent, to remove as much of the superficial flora as possible.
   B. Attempt to culture the base or edges of the wound to avoid collection "normal flora" organisms.
   C. The following are preferred specimens for sinus tracts:
      – Aspiration material obtained by needle or catheterization
      – Curettings from the lining of the sinus tract

   D. Specimen swabbings of sinus tracts are acceptable only if the above cannot be obtained. Swabs of sinus tracts may not accurately reflect underlying disease process.

   E. Do not submit cultures of superficial lesions for anaerobic culture. Do not submit specimens from areas with normal anaerobic flora (feces, genital, throat) unless the collection is an aspirate. Biopsy of advancing margin of wound is the preferred specimen for anaerobes, mycobacteria, and fungi.

Viral Transport Media (M4)

Some specimens can be submitted without utilizing a transport media, with a reasonable expectation of virus viability. Specimens in this category include: sterile fluids such as cerebrospinal fluid, pleural fluid, blood or bone marrow submitted in EDTA, urine, as well as some non-sterile specimens such as nasopharyngeal washings, sputum, bronchoalveolar lavage, and feces. Whenever there is a question of stability, the specimen should be placed in a suitable virus transport media. Refer to a specific test in PathGroup's Directory of Services for more information.

1. Tissue and biopsy material can be placed directly into the viral transport media. Each specimen need not be more than 1-2 cm in diameter.

2. Abscess material, bullae, pustules, vesicles, lesions, and skin scrapings can be collected o the swab and placed directly into viral transport media. If the material has been aspirated, place no more than 3 mL (equal to the amount of transport media) in the vial of M4.

3. CSF should be submitted in a sterile container.

4. Urine should be submitted in a sterile container.

5. Bronchoalveolar washings, nasopharyngeal washings, sputums, and other sterile body fluids can be submitted in sterile containers or no more than 3 mL placed in the M4 tube.

6. Stool should be submitted in a sterile container, or a small aliquot the size of a walnut can be placed in the M4 tube.

7. Blood and bone marrow should be submitted in an EDTA tube. Do not extract the buffy coat.

8. Viral transport media (M4) criteria is the same for other liquid viral transport media such as those available from Bartels, Syva, etc. labeled for viral/Chlamydia transport. Swabs that are made of calcium alginate and wood are known to interfere with the recovery of some viruses. These can also act as PCR inhibitors and are not appropriate for this type of testing.

9. Not all types of viral transport media have been validated for all testing; some may require a disclaimer, dependent on the assay.

Cytopathology/Gynecologic Collection

Our Cytopathology Laboratory is a full service department providing routine screening and diagnostic cytopathology services, including gynecologic and non-gynecologic specimens. Special studies, including flow cytometry, Cervical FISH, and Urovysion FISH are also available. Consultations are available on all cytologic materials. Please refer to PathGroup's Directory of Services for information regarding the collection and handling requirements for individual tests, or call our Client Services department at 888.474.5227 for additional instructions.

Cytopathology Specimen Submission

1. Complete a cytopathology test requisition. Be sure to include the following:
   - Date specimen collected
   - Patient's first and last name
   - Sex of patient
   - Patient's date of birth
   - Patient's Social Security Number or other patient identifier
   - Patient's complete mailing address
   - Patient's insurance information
   - Patient's pertinent clinical history and appropriate ICD-9 code(s)
   - Check proper box for specimen(s) submitted and test(s) requested
   - Source of Specimen/specimen type

2. Label all specimen containers and slides submitted with patient's first and last name and second identifier.

3. Fix all slides and fluids immediately following specimen collection

4. Close all specimen containers securely and place each specimen into a specimen bag with accompanying requisition.

Gynecologic Collection and Submission

Patient Preparation

- Ideal sampling date is 14 days after the first day of the last menstrual period.
- Patient should not use douches, vaginal medication, lubricants, or vaginal contraception for 48 hours prior to sampling.
- The speculum should be introduced with no lubricant.

ThinPrep® Pap Test
Endocervical Brush/Spatula Protocol:
1. Record patient's name and ID number on a ThinPrep® vial and complete cytology requisition with all requested information.

2. Obtain sampling from the ectocervix using a plastic spatula.

3. Rinse spatula into the PreservCyt vial by swirling it vigorously in the vial ten times. Discard spatula.

4. Obtain sampling from the endocervix using an endocervical brush. Insert brush into cervix until only bottommost fibers are exposed. Slowly rotate quarter (1/4) to a half (1/2) turn in one direction. DO NOT OVER-ROTATE.

5. Rinse brush in PreservCyt vial by rotating in solution ten times while pushing against the vial wall. Swirl brush vigorously to further release material. Discard brush.
6. Tighten vial cap.

7. Place vial and completed requisition into specimen bag for transport to lab.

Conventional Pap Smear
Cervical/Endocervical:
1. Using a lead pencil, label frosted end of the slide with patient's first and last name.

2. Complete requisition with all requested information.

3. Tear open fixative pouch or place spray fixative bottle beside slide.

4. Rotate cervical scraper around ectocervix and spread material evenly in the middle section of the glass slide.

5. Insert endocervical brush into endocervical canal until only the bottommost fibers are exposed. Rotate brush 90 to180 degrees. Gently remove brush and spread material from brush evenly onto slide on the end farthest from the frosted end (endocervical brush should not be used on pregnant patients).

6. Fix smear immediately by flooding entire slide with pouch fixative or spraying evenly and completely with fixative.

7. When slide is dry, secure in Pap Pak and place Pap Pak in specimen bag with accompanying requisition.

Vaginal:
1. Using a lead pencil, label frosted end of the glass slide with patient's first and last name.

2. Complete requisition with all requested information.

3. Tear open fixative pouch, or place spray fixative bottle beside slide.

4. Take vaginal smear with spatula end of cervical scraper and spread evenly in center of the slide.

5. Fix smear immediately by flooding entire slide with pouch fixative or spraying evenly and completely with spray fixative.

6. When slide is dry, secure in Pap Pak and place Pap Pak in specimen bag with accompanying requisition.

Human Papillomavirus (HPV)
HPV testing utilizing the Roche cobas system for HPV DNA detection is offered on the ThinPrep® Pap vial. The test may be ordered by requesting it on the Cytology requisition. Refer to the Directory of Services for more information regarding the collection and handling requirements for individual tests, or call Client Services at 888.474.5227 for additional instructions.

Non-Gynecologic Collection and Submission

Lesion Scrapings
Label slide(s) with the patient's first and last name and source of sample. Remove crust or dome from lesion. Scrape ulceration with a moistened tongue blade or cotton swab. Spread material on slide(s). Spray-fix immediately or immerse slide(s) onto a cytology fixative. Do not allow drying of smear(s) before fixing. Do not use aerosol fixative.

Urine
Label specimen container with the patient's name and source of specimen. Fix material by adding an equal amount of cytology fixative. Mark requisition: "Voided" or "Catheterized" as appropriate.

Voided Urine
Instruct patient to drink three 8 ounce glasses of water before bedtime. Provide patient with an appropriate volume of cytology fixative (e.g. 50 ml). Have patient collect the second A.M. urine specimen and mix an equal volume with the fixative. Do not submit a 24-hour urine for cytological evaluation.

Breast Cyst Aspiration
If aspirate is scanty, fluid may be smeared one drop at a time on clean, dry slides and immediately fixed. If aspirate is abundant, mix material with an equal volume of cytology fixative. Label slide and/or specimen container with the patient's name and source of specimen.

Breast Secretion (Nipple discharge)
Label slide with the patient's name and source of the specimen. Smear drops of fluid from the nipple directly onto a clean glass slide(s) and fix immediately with spray or pouch fixative or immerse in cytology fixative.

Sputum
Label specimen container with the patient's name and source of specimen. Submit early morning deep-cough specimen prior to any food ingestion. Have patient rinse mouth with plain water. Collect separate specimens on three consecutive mornings. Do not combine specimens. Fix with at least 10 ml of cytology fixative. If specimen is greater than 10 ml, mix with an equal volume of fixative.

Bronchial Brushing
Label slide with the patient's name and source of the specimen. Roll brush over a clean, dry slide. Fix immediately with spray or pouch fixative or immerse in a container of cytology fixative. The brush used to prepare the slides may be swished in a container of cytology fixative to dislodge additional specimen. Submit slides and liquid specimen together using one requisition.

Bronchial Washing
Label specimen container with the patient's name and source of specimen. Fix material with an equal volume of cytology fixative.

Cerebrospinal Fluid
Label specimen container with the patient's name and source of specimen. Refrigerate immediately and submit to lab within 24 hours. If specimen will be submitted beyond 24 hours, fix material with an equal volume of cytology fixative.

Effusion
Label specimen container with the patient's name and source of specimen. Fix material with an equal volume of cytology fixative.

Esophageal Brushings
Label slide(s) with patient's name and source of specimen. Roll brush over a clean, dry slide(s). Fix immediately with spray or pouch fixative or immerse in cytology fixative container. The brush used to prepare the slide(s) may be swished in a container of cytology fixative to dislodge additional cells. Label container with patient's name. Submit slide(s) and liquid specimen together with one requisition.

Esophageal Washing
Label specimen container with the patient's name and source of specimen. Fix material with an equal volume of cytology fixative.

Gastric Brushing
Label slide(s) with patient's name and source of specimen. Roll brushes over clean, dry slide(s). Fix immediately with spray or pouch fixative or immerse in a container of cytology fixative. The brush used to prepare slide(s) may be swished in a container of cytology fixative to dislodge additional cells. Submit slide(s) and liquid specimen together with one requisition.

Gastric Washing
Label specimen container with the patient's name and source of specimen. Fix material by adding an equal amount of cytology fixative.

Fine Needle Aspiration
1. Label all slide(s) and specimen container(s) with patient's first and last name and source of sample.

2. Complete cytology requisition including patient clinical history, FNA site, and whether the lesion is solid or cystic and gross appearance of aspirate if applicable.

3. Attach a 25 gauge needle to a 20 ml syringe. Pull 2cc air into syringe.

4. Insert syringe into a fine needle aspiration holder.

5. Insert needle into lesion. While applying pressure, move needle in short, stabbing motions, changing angle of direction with the lesion.

6. Release negative pressure. The specimen should not be drawn into the barrel of the syringe. Pressure should be released as fluid/blood appears in the needle hub. The cells and tissue fragments obtained from a solid lesion should remain in the barrel of the needle. (If excessive blood is aspirated, repeat aspiration without suction might be considered.)

7. Carefully eject one drop of specimen onto a slide. Use another slide to smear material. Fix both slides immediately using spray fixative or immersing into slide holder containing cytology fixative, supplied by the lab.

8. Repeat procedure three to four times with an attempt to sample different areas of the mass each time.

9. If blood, fluid, or cellular material in excess of one drop is obtained with a needle pass, the excess should be expressed into a container of cytology fixative. The needle and syringe should be rinsed with this same alcohol. Submit the liquid specimen with the fixed slides together using one cytology requisition.

Surgical Pathology

A full spectrum of surgical pathology and consultative services are available through PathGroup. Our team of board-certified pathologists offer a wide range of anatomic, clinical and molecular services to hospitals, multi-specialty groups, surgery centers, physician offices and other clinical reference laboratories, and have done so since 1965.

All requests for histopathologic examination and diagnosis are viewed as a request for consultation by another physician and, as such, you are welcome to contact our pathologists concerning their findings.

Submission Requirements – Routine:

- A completed request form supplied by PathGroup must accompany the specimen(s). Please complete this form as indicated on the requisition.
- Submit each specimen separately in a plastic screw-capped container filled with 10% Neutral Buffered Formalin supplied by PathGroup.
- The container must be labeled with the patient's name, second patient specific identifier (DOB, MRN, etc.) and specimen. For large specimens, use large containers with enough 10% neutral buffered formalin to achieve a ratio of five parts fixative to one part tissue.
- Small specimens are to be placed in the sealable plastic bag supplied by PathGroup. The folded request form is placed in the sleeve on the back of the plastic bag, separated from the specimen container to avoid possible contamination from leakages of the specimen container.
- A PathGroup courier will transport the specimen together with the completed request form to the laboratory where the specimen routinely will be processed overnight for slide preparation and diagnosis the next day.
- For procedures and requirements of non-routine specimens (e.g. skin biopsies for immunofluorescence studies), consult the specific section of PathGroup's Directory of Services.
- Specific CAP guidelines for ER/PR and Her2 specimens fixation is as follows:
    - Specimens should be immersed in fixative within one hour of the biopsy or resection procedure.
    - If delivery of a resection specimen to the pathology department is delayed (e.g. specimens from remote sites), the tumor should be bisected prior to immersion in fixative. In such cases, it is important that the surgeon confirms the identity of the resection margins is retained in the bisected specimen; alternatively, the margins may be separately submitted.
    - The time of tissue removal and time of tissue immersion in fixative should be recorded and submitted to the laboratory.

Oncology/Hematopathology Specialty Testing

PathGroup is committed to providing diagnostic expertise, precision technologies and innovative services and relationships — all to give our clinician partners personalized information for targeted therapies that lead to the best possible patient outcomes. Morphologic review and interpretation of biopsy material continues to be the backbone of oncology diagnostics, and is the basis on which PathGroup deploys complementary technologies to give the clearest, most accurate picture of a patient's malignancy from original diagnosis to the presence of minimal residual disease.

Every case is managed by a board-certified hematopathologist that works in concert with the ordering physician to understand the patient's clinical history. That information is then integrated with the results of any testing to provide diagnostic, prognostic and therapeutic guidance for the best patient management and outcome. PathGroup works with leading individual and contract research partners in developing platforms for improved molecular intelligence. Our molecular diagnostics facility includes a dedicated CLIA validation laboratory to accelerate delivery of new tests and modalities to the physicians we serve and the patients they treat.

As part of this approach PathGroup offers the iPath® Comprehensive Assessment for blood and bone marrow disorders. With one simple order, iPath includes a clinical pathology evaluation, bone marrow and/or blood morphology, flow cytometry, cytogenetics, FISH, microarray, and PCR- based genomic profiling as medically necessary to establish a diagnosis or follow disease progression. All findings are then presented in a concise summary report correlating the technologies for easy review. Through our collaboration with GenoSpace™ we can provide unparalleled information on genes, gene variants and their therapeutic implications, and place diverse real-time data into clinically actionable context for oncologists and researchers. Because the knowledgebase is continuously updated, new biological relevance for existing genes or new gene discoveries are captured and seamlessly integrated.

Submission Requirements

Bone Marrow

Bone Marrow kits are supplied by PathGroup and will contain a Hematopathology requisition and appropriate containers for collection. For detailed specimen requirements, see the back of the requisition. Complete the requisition as indicated and submit with the appropriate specimens.

- Each specimen container should be labeled with:
  - Patient's Name and second identifier such as date of birth, medical record number or requisition number.

A PathGroup courier will transport the specimen together with the completed requisition to the laboratory where the specimen will be processed.

Molecular Profiling

Specific requisitions for Molecular Profiling Studies can be requested from PathGroup's Oncology Customer Support at 888.854.6473. For detailed specimen requirements, see the back of the requisition. This requisition should accompany slides or blocks submitted to PathGroup.

For additional information about test requests, consult the specific section of PathGroup's Directory of Services.

Hematopathology Consultations

Hematopathology offers a variety of comprehensive laboratory and pathology tests for benign and malignant disorders of the peripheral blood and bone marrow. Our goal is to provide the referring physicians with an accurate hematologic evaluation in the most efficient and cost-effective manner. All requests will be processed as a consultation first. Special studies will be performed only if diagnostically indicated.

iPath Comprehensive Assessment
Diagnostic hematopathology has become an increasingly complex subspecialty, particularly with neoplastic disorders of blood and bone marrow. The clinical, therapeutic, and prognostic features of these disorders are often distinctive; while the pathologic features are quite subtle, requiring the application of ancillary studies (e.g. cytochemistry, immunohistochemistry, flow cytometric immunophenotyping, cytogenetics, microarray and molecular genetics) to establish a diagnosis. Furthermore, these ancillary studies are expensive, labor- intensive, and are most efficiently utilized and interpreted in the context of the morphologic features.

- Tests can include, but are not limited to: morphologic examination, flow cytometry, cytogenetics, FISH, molecular studies including PCR and SmartGenomics™ next-generation sequencing (NGS) and cytogenomic array (aCGH), as deemed medically necessary.

Flow Cytometry
Flow cytometry is a rapid way to measure the characteristics of individual cells. Hematopoietic cells (from peripheral blood, bone marrow aspirate, bone marrow core biopsies, and lymph nodes) are labeled with selective fluorescent antibodies and quantified according to their surface antigens. These fluorescent antibodies bind to specific abnormal cells in a pattern of antigen expression that is used to identify particular malignant cell types. Panels of antibodies are often used to help define which malignant cell types are present. Panels include acute and chronic leukemias, lymphomas, and myelodysplastic syndromes and plasma cell neoplasms.

Cancer Cytogenetics
Cytogenetics is the study of the structure of chromosome material. Acute leukemias, lymphomas, chronic myeloid and lymphoid disorders are examined cytogenetically in order to establish the exact nature of the acquired genetic change. Rearrangements, also known as translocations, inversions, deletions, etc., can usually be detected under a light microscope. In most leukemias and lymphomas, changes in chromosome number (ploidy) or chromosome structure (rearrangements) are often observed.

FISH
FISH (Fluorescent in situ hybridization) is a technique that is used to detect chromosomal abnormalities that are difficult to detect by conventional cytogenetics. FISH uses fluorescent probes that specifically target certain genes. FISH testing is performed on interphase cells, rather than metaphase cells, and thus can be used on a wider variety of tissues than cytogenetics, including FFPE samples. Because specific abnormalities occur in certain neoplastic disorders, defined FISH panels are used to target the common abnormalities associated with each type of disorder.

- A complete list of FISH probes and FISH panels is available in PathGroup's Directory of Services.

Cancer Microarray
Cytogenomic array analysis detects chromosome losses and gains, as well as losses of heterozygosity, which are important in the diagnosis and prognosis of cancer. Cytogenomic information also assists in selection of therapies which might be most effective based upon chromosomal changes present. Gains and losses that are large, typically seen in cytogenetics, as well as submicroscopic, such as microdeletions and microduplications, are detectable. Loss of heterozygosity can assist in determining homozygosity of mutations detected via gene sequencing. In addition to higher resolution than a traditional cytogenetic karyotype, a cytogenomic array analysis provides information across the genome including gains and losses that couldn't be detected in hard-to-culture solid tumors.

Molecular Diagnostics
Molecular diagnostic testing seeks to detect genetic errors that cause disease at the molecular level. The progression of a neoplastic clone from benign to a malignant state is the result of several successive genetic mutations. These mutations are detected by highly sensitive and specific assays that are inclusive of restriction digestion, PCR, RT-PCR, sequencing, and point mutation analyses using state-of-the-art technologies to provide the pathologist and oncologist with genetic information about the disease state. A variety of tests are currently available to characterize leukemias, lymphomas, and carcinomas.

A complete list of Molecular tests is available in PathGroup's Directory of Services.

Constitutional Genetics Collection

Constitutional Cytogenetics
Cytogenetic analysis, to determine if constitutional abnormalities are present, is performed for a variety of indications including multiple congenital abnormalities, mental retardation of unknown etiology, abnormalities of growth, features of a recognized genetic syndrome, recurrent pregnancy loss, prenatal diagnosis via amniocentesis, mosaicism, stillbirth, fetal loss, or molar pregnancy. Adjunct studies such as fluorescence in situ hybridization (FISH) or other molecular and biochemical testing can be performed in addition to chromosomal analysis.

Constitutional Microarray
Constitutional cytogenomic array analysis is considered first-tier testing for determining the underlying etiology when children are born with multiple congenital abnormalities, developmental delay, and/or mental retardation. Because it possesses higher resolution than conventional cytogenetics, the detection rate in this scenario is approximately 15% compared to 6% in conventional cytogenetics.

Also, products of conception can be assessed for cause of miscarriage (aneuploidy) or to rule out molar pregnancies. Cytogenomic arrays are routinely used to diagnosis fetal abnormalities using tissues such as amniocytes when genetic disease is suspected due to abnormal ultrasound, maternal serum screen and advanced maternal age.