



**Piedmont Pathology Associates
Office Procedure & Specimen Collection Manual
Updated January 2019**

Office Procedure & Specimen Collection Manual

**Piedmont Pathology Associates Inc.
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Office Procedure & Specimen Collection Manual
Updated January 2019

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Overview of Services

Piedmont Pathology Associates, Inc. provides anatomic pathology services in the forms of gynecologic and non- gynecologic cytology, molecular, surgical and histology testing. Our inpatient service area spans the entire western Piedmont, while our outpatient service area has expanded outside the confines of North Carolina to include Florida, South Carolina, Georgia, West Virginia, New York, and New Jersey (check for accuracy). Piedmont Pathology Associates, Inc. was established in 1970. We have professional affiliations with Catawba Valley Medical Center, Frye Regional Medical Center, Caldwell Memorial Hospital, Alleghany Memorial Hospital, Ashe Memorial Hospital, Davis Regional Medical Center, Iredell Memorial Hospital, Wilkes Regional Medical Center, and Lake Norman Regional Medical Center

Mission Statement

Piedmont Pathology Associates, Inc. will lead the region in point of service anatomic pathology testing by providing quality patient care through technical accuracy prompt turn-around times and service excellence.

Testing Services Offered

The anatomic pathology services provided include the preparation and examination of all surgical and cytological specimens to include but not limited to GI specimens, GU, gynecological specimens, dermatologic specimens, breast needle aspiration and discharge specimens, body cavity fluids, cerebral spinal fluid, respiratory specimens, urine specimens, tissue biopsies from all anatomic sites, bone marrow specimens, fresh specimens, fixed specimens, frozen section examinations, gynecological cytology and, molecular tests.

Ancillary Services

Piedmont Pathology Associates, Inc. will provide the access to ancillary testing of all anatomic specimens. Our laboratory, upon receipt of the specimen and completed test request form from your office, will submit the specimen to qualified testing sites for any specialized studies which are necessary and not directly performed at Piedmont Pathology. The ancillary tests may include, but are not limited to: Flow Cytometry / Cytogenetics, Breast Cancer Profiles, Direct Immunofluorescence and Molecular Diagnostics. We have chosen high quality laboratories to provide these ancillary testing services. Please call if you have questions regarding the referral laboratories. We will be happy to provide any information you deem necessary.

Customer Service

Our dedication to customer service is demonstrated by our ability to immediately provide you with the status of testing in progress when you have a question regarding your specimens. We will be happy to discuss specialized handling and collection requirements of specimens in question. "Stat / Rush" service is available for any type of specimen upon your request. This service is provided at no additional charge. We can fax test



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results for stat situations and we will be happy to discuss any billing concerns regarding fees and policies.

Reporting of Test Results

Final diagnostic reports for routine surgical specimens (biopsy / tissue) and Non-gynecologic cytology specimens are most often available within 24 to 48 hours from the time the specimen is received in the laboratory (excluding weekends and holidays).

Complicated cases requiring special stains and/or outside consultation will have preliminary reports issued within 24 hours.

Normal and abnormal cytology Pap test reports will require 3 to 5 days. The 4 or 5 day time frame will be due to specimen evaluation by both technical and medical staff members.

Professional Staff

Our professional staff includes board certified or board eligible pathologists, pathology assistants, certified cytotechnologists, certified histotechnologists and staff specialists. These personnel are always available for consultation regarding test results and technical concerns.

Courier Services

Our courier department provides prompt specimen pick-up and quick, dependable delivery of laboratory test results and necessary supplies. The courier network presently encompasses a vast area covering North Carolina and it continues to broaden to meet our client's needs. Outside this area UPS and FEDEX serve to transport samples directly to our facility. The delivery schedule is designed in partnership with our clients to most effectively meet their patient's needs. These services specifically track samples sent so the whereabouts of any specimen is immediately available 24 hours a day 7 days a week.

Our Courier Service personnel/Customer Service Representatives are trained to answer many of your questions. If they do not know the answers to your questions, they will have the Client Services Representative contact your office to help meet your needs. Please feel free to communicate any questions or concerns to your Courier/Customer Service Representative. For courier service information and supply requests please contact our Courier Service Manager at (828) 322-3821 or FAX your supply order to 828-322-1122.

Clients that do not have our direct courier services, please contact the Practice Manager or Client Services at 828-322-3821 for assistance with any questions or issues.

Client Services

Our Marketing / Client Services Representative contacts clients on a regular basis. She/he will keep you informed of new technical, procedural and legislative information.



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This person is available to answer questions and address any issues that arise. The goal of our Marketing / Client Service Representative is to make sure that our services meet your needs. Do not hesitate to call (828) 322-3821 if you need assistance or have questions regarding Piedmont Pathology Associates services.

Quality Assurance, Quality Control & Continuous Quality Management

Quality assurance (QA), quality control (QC) and continuous quality management (QM) are an integral part of Piedmont Pathology Associates, Inc. daily undertaking. We utilize both internal and external systems to monitor the accuracy of patient testing. The internal quality assurance plans are executed daily by trained medical staff members. The external quality assurance plan includes the participation in several externally administered blind quality assessment programs. Consistent acceptable performance in these assessment programs is a requirement for continued licensure and accreditation. Our Laboratory is accredited by the College of American Pathologists (CAP) inspection program, whose standards for accreditation greatly exceed the minimal standards set by CLIA.

The internal Cytology, Molecular and Histology quality assurance plan addresses all areas necessary for licensure and accreditation. We also incorporate many non-required quality control methods to insure technical excellence. A quality assurance plan to address excellence in service is monitored daily to detect problems in the areas of courier service, transcription, and reporting. The internal quality assurance plan at Piedmont Pathology Associates, Inc. is continually monitored and expanded to meet the changing needs of the medical community.

The external quality assurance plans consist of participation in College of American Pathologist (CAP) PIP Slide Review program and participation in the Continuing Education in Cytology (CEIC) program, as well as PT (Interlaboratory Proficiency Testing Correlations) in immunohistochemistry, cytology and molecular.

Monthly and cumulative statistics are calculated from the QC data, graphically summarized and presented for retrospective analysis. The management personnel at Piedmont Pathology Associates, Inc. meet monthly to review the quality control methods, the quality control findings and evaluate performance on external blind assessments. These monthly evaluations provide the management with the opportunity to evaluate the accuracy of patient testing, procedure validity and service performance.

Laboratory Licensure

CLIA Identification No.: 34D0246881

CAP Participant No.: 1413001



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Visiting Piedmont Pathology Associates Inc Laboratory

We are proud of our testing. Contact our Practice Manager or Client Services Manager to make an appointment to tour our laboratory.



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Non-Gynecologic Cytology

Cytologic studies are performed on non-gynecologic specimens to detect malignant, premalignant, and other pathologic findings.

Federal regulations require all specimens to be accurately identified. The patient's name and anatomic site sampled must be written on the side of the specimen container and the name and site sampled on the container must match the same information on the test request form. This is a CLIA mandated standard and unidentified specimens will be returned to the submitting office unprocessed. Please include the patient's date of birth and social security number on the Requisition Form. This information will aid in the compiling of a database for retrieval of previous cytology diagnoses. Please include all pertinent clinical information. This will aid in more accurate diagnostic interpretations.

A copy of the patient's insurance card should be attached to the test request for third party billing. Lack of accurate billing information could lead to billing your office directly for services.

Preferred Method of Submission - non-gynecologic specimens are to be submitted to the laboratory in *Cytolyt* fixative, except large volume body cavity fluids and cerebrospinal fluids which are to be submitted to the laboratory in their fresh state.

Preferred Laboratory Methodology - non-gynecologic specimens collected and submitted in *Cytolyt* fixative will be processed using the ThinPrep 2000 Processor. The specimen is agitated, centrifuged and, decanted. The cells are transferred to a glass slide in a monolayer via the ThinPrep 2000 Processor. Microscopic examination is performed.

Breast Aspiration

1. Label the side of a vial containing *Cytolyt* fixative with the patient's name, social security number and anatomic site sampled.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source, reason for performing the aspiration and include all pertinent clinical data such as previous malignancy, drug therapy, and radiation therapy, etc. If a cyst is aspirated, indicate this on the request form (specimen will most likely be hypocellular, but will not be a false negative). Please include clinical impression, such as size and location of mass, fixed or movable mass, skin changes, appearance of nipple discharge, and presence of localized adenopathy. This information is critical to an accurate diagnosis on breast aspiration specimens.
3. A minimum of two separate passes is recommended, preferably more.
Inadequate specimens may result in a false-negative diagnosis.
4. Use a small gauge (22 or 25) needle to minimize dilution with blood.



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5. Immobilize the palpable mass with the non-dominant hand. Using a syringe holder will allow the mass to be continually immobilized.
6. Insert the needle into the mass and make short “in and out” movements until you visualize material in the hub of the needle. Stop when you see material in the hub.
7. Release negative pressure on the syringe and remove the needle from the mass. Do not aspirate material into the syringe.
8. Remove the needle from the syringe and pull back the plunger before reattachment of the needle to gain positive pressure.
9. Express the specimen into the *Cytolyt* vial.
10. Rinse the needle by drawing up a small amount of solution from the *Cytolyt* vial and aspirating it back into the container.
11. Place the cap on the labeled vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
12. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Breast Discharge / Secretion

1. Label several glass slides with the patient’s name on the frosted end.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source and include all clinical data such as previous malignancy, drug therapy, and radiation therapy, etc. Please include clinical impression such as skin changes, appearance of nipple discharge, and presence of localized adenopathy. This information is critical to an accurate diagnosis on breast secretion specimens.
3. Gently apply pressure to the sub areolar area and nipple with thumb and forefinger. When secretion occurs, allow a small amount to accumulate at the nipple.
4. Touch a clean glass slide to the nipple and swipe.
5. Withdraw the slide from the nipple quickly and immediately spray the slide with fixative.
6. Repeat procedure until all secretions are collected on one or more slides.
7. Spray fix the smeared slide(s) within 1-2 seconds of applying specimen (avoid spraying the frosted area of the slide). **The slide must be spray fixed immediately to prevent air-drying of the cellular specimen.** Allow the fixed slide to dry completely before packaging for transport.
8. Place the slide(s) in a cardboard mailer and secure with a rubber band. Place the specimen mailer and the completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Body Cavity Fluid (effusion, paracentesis, thoracentesis)

1. Label the side of a vacuum bottle or clean container with the patient’s name, social security number and anatomic site.



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2. Identify the specimen type (abdominal, pleural, cul-de-sac, pericardial) on the Non-Gynecologic Cytology Test request form.
3. Place the specimen in the container.
4. Complete the Non-Gynecologic Cytology Test request form. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, alcohol abuse and all other pertinent data. This information is critical to an accurate diagnosis on body cavity fluid specimens.
5. Place the labeled specimen container and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.
6. Specimen should be transported to the laboratory within a short period of time to minimize cellular breakdown.
7. If there will be more than a 24 hour delay between collection and transport of the specimen to the laboratory, add 1 ml (1000 units) of heparin for each 300 ml of specimen and place the specimen in a refrigerator.

Cerebral Spinal Fluid

1. Label the side of a sterile container with the patient's name, social security number and "CSF."
2. Identify the specimen type on the Non-Gynecologic Cytology Test request form.
3. Place the specimen in the container. Do **not** add fixative.
4. Complete the Non-Gynecologic Cytology Test request form. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, and all other pertinent data. This information is critical to an accurate diagnosis on cerebrospinal fluid specimens.
5. Place the labeled specimen container and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.
6. Specimen should be transported to the laboratory within a short period of time to minimize cellular breakdown.
7. If there will be more than a 24 hour delay between collection and transport of the specimen to the laboratory, add 1 ml (1000 units) of heparin for each 300 ml of specimen and place the specimen in a refrigerator.

FNA Palpable Masses

1. Label the side of a vial containing *Cytolyt* fixative with the patient's name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source and clinical impression. If a cyst is aspirated, indicate this on the request form (specimen will most likely be hypocellular, but will not be a false negative). Please include clinical data such as previous malignancy, drug therapy, radiation therapy, all other pertinent data, and reason for performing the aspiration. This information is critical to an accurate diagnosis on aspiration specimens.
3. A minimum of two separate passes is recommended preferably more. *Inadequate specimens may result in a false-negative diagnosis.*



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4. Use a small gauge (22 or 25) needle to minimize dilution with blood.
5. Immobilize the palpable mass with the nondominant hand. Using a syringe holder will allow the mass to be continually immobilized.
6. Insert the needle into the mass and make short “in and out” movements until you visualize material in the hub of the needle. Stop when you see material in the hub.
7. Release negative pressure on the syringe and remove the needle from the mass. Do not aspirate material into the syringe.
8. Remove the needle from the syringe and pull back the plunger before reattachment of the needle to gain positive pressure.
9. Express the specimen into the *Cytolyt* vial.
10. Rinse the needle by drawing up a small amount of solution from the *Cytolyt* vial and aspirating it back into the container.
11. Place the cap on the labeled vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
12. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

FNA Deep Masses – usually under radiologic & ultrasonographic guidance

1. Label the side of a vial containing *Cytolyt* fixative with the patient’s name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source and clinical impression. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, all other pertinent data, and reason for performing the aspiration. This information is critical to an accurate diagnosis on aspiration specimens.
3. A minimum of two separate passes is recommended preferably more. *Inadequate specimens may result in a false-negative diagnosis.*
4. Assemble pre-packaged sterile Fine Needle Aspiration tray containing stainless steel needles, obturating stylet, 20-ml disposable plastic syringe, and scalpel.
5. Select entry site, clean and anesthetize the skin.
6. Make an approximate 2-3 mm skin incision.
7. Under radiologic guidance, insert the needle with stylet into the mass at a previously determined angle and depth. The insertion of the needle is performed during suspended respiration.
8. Perform short “in and out” movements with the needle in the mass.
9. Remove the stylet, attach the syringe and apply small amount of suction.
10. Release negative pressure on the syringe and remove the needle from the mass. Do not aspirate material into the syringe.
11. Remove the needle from the syringe and pull back the plunger before reattachment of the needle to gain positive pressure.
12. The procedure is performed several times, through the same skin incision, using a different needle and with a slightly different angle of approach to be determined



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- by the performing physician.
13. Express the specimen into the *Cytolyt* vial.
 14. Rinse the needle by drawing up a small amount of solution from the *Cytolyt* vial and aspirating it back into the container.
 15. Place the cap on the labeled vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
 16. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

GI Specimens (oropharyngeal, esophageal, gastric and intestinal brushings)

1. Label the side of a vial containing *Cytolyt* fixative with the patient's name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source, site brushed, and clinical impression. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, alcohol abuse, and all other pertinent data. This information is important when evaluating GI specimens.
3. Following the brushing procedure, protrude the brush from the outer sheath over the *Cytolyt* fixative vial. Clip the brush, leaving approximately a one-inch extension, and let the brush fall into the *Cytolyt* fixative vial.
4. Place the cap on the labeled vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
5. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Direct smears may be made by rolling the brush onto a labeled glass slide. The slide must be spray fixed immediately. Placing the brush in Cytolyt fixative is the preferred method of specimen preparation.

Respiratory Specimens:

Sputum

1. Label the side of a vial containing *Cytolyt* fixative with the patient's name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, exposure to carcinogens, and all other pertinent data. This information is important when evaluating respiratory tract specimens.
3. Instruct patient to thoroughly cleanse mouth prior to expectoration into the container.
4. Collect first morning sputum directly into *Cytolyt* fixative vial. Out of office collection by the patient may be obtained by collecting 3 consecutive morning sputa into the *Cytolyt* fixative.
5. Place the cap on the vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial. Shake the specimen vigorously.



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6. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Bronchial Brush

1. Label the side of a vial containing *Cytolyt* fixative with the patient's name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source, site brushed, and clinical impression. Please include clinical data such as previous
3. Malignancy, drug therapy, radiation therapy, chemotherapy, radiographic findings, bronchoscopic findings, and all other pertinent data. This information is important when evaluating respiratory tract specimens.
4. Following the brushing procedure, protrude the brush from the outer sheath over the *Cytolyt* fixative vial. Clip the brush, leaving approximately a two-inch extension, and let the brush fall into the *Cytolyt* fixative vial.
5. Place the cap on the labeled vial. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
6. Place the labeled vial and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Direct smears may be made by rolling the brush onto a labeled glass slide. The slide must be spray fixed immediately. **Placing the brush in Cytolyt fixative is the preferred method of specimen preparation.**

Bronchial Wash

1. Label the side of one or more vials containing *Cytolyt* fixative with the patient's name, social security number and anatomic site.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen source, site brushed, and clinical impression. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, chemotherapy, radiographic findings, bronchoscopic findings, and all other pertinent data. This information is important when evaluating respiratory tract specimens.
3. The washings or aspirate collected during the endoscopic procedure should be mixed with an equal amount of *Cytolyt* fixative.
4. Place the cap on the labeled vials. Tighten the cap so that the torque line on the cap passes the torque line on the vial.
5. Place the labeled vials and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Note: A post bronchoscopy sputum should be collected if possible. Many times the post bronchoscopy sputum yields more diagnostic cells than those collected during the bronchoscopy procedure.



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Urine Specimens

1. Label the side of a clean container with the patient's name, social security number and type of urine specimen collected (ie: voided or catheterized or scope).
2. Complete the Non-Gynecologic Cytology Test request form. Identify the collection method (voided/catheterized/bladder washing). Please include clinical data such as previous malignancy, drug therapy, radiation therapy, alcohol abuse and all other pertinent data. This information is critical to an accurate diagnosis.
3. Second morning specimens are preferred. A first morning voided specimen is **not suitable** for cytologic evaluation.
4. Place specimen in the labeled container.
5. Place the labeled container and completed Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.
6. Specimen should be transported to the laboratory within a short period of time to minimize cellular breakdown.

Miscellaneous Specimens Collected on a Glass Slide (includes Tzank preps, scrapes, etc)

1. Label several glass slides with the patient's name on the frosted end.
2. Complete the Non-Gynecologic Cytology Test request form. Identify the specimen type. Please include clinical data such as previous malignancy, drug therapy, radiation therapy, and all other pertinent data. This information is critical to an accurate diagnosis.
3. Smear the specimen on a clean glass slide. Try to create a monolayer specimen.
4. Spray fix the smeared slide(s) within 1-2 seconds of applying specimen (avoid spraying the frosted area of the slide). **The slide must be spray fixed immediately to prevent air-drying of the cellular specimen.** Allow the fixed slide to dry completely before packaging for transport.
5. Place the slide(s) in a cardboard mailer and secure with a rubber band. Place the specimen mailer and the Non-Gynecologic Cytology Test request form in a specimen bag for transport to the laboratory.

Note: Placing the specimen on brush in Cytolyt fixative is the preferred method of specimen preparation.



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Autopsy Requests

Piedmont Pathology Associates Inc will perform autopsies when indicated. The laboratory can perform autopsies on private cases, Hospital and Medical Examiner (ME) cases.

A private autopsy case is a death caused by a known medical condition and is usually requested and paid for by the decedent's family/legal next of kin. Private autopsies are performed on decedents who were not hospital inpatients and who are not ME cases. Autopsies on patients who expire while they are a hospital inpatient should be performed by the Pathology Department at the hospital they were an inpatient. Other cases will be reviewed on a case by case basis by our medical staff.

A hospital autopsy case is an autopsy on an inpatient of a hospital. Legal consent from the family/next of kin is obtained by the hospital staff.

A Medical Examiner's case is a death resulting from homicide; suicide; accident; trauma; disaster; violence; unknown / unnatural or suspicious circumstances; death occurring in police custody, jail or prison; death caused by poisoning or suspicion of poisoning; death caused by public health hazard (such as acute contagious disease or epidemic); deaths during surgical or anesthetic procedures; sudden unexpected deaths that are not reasonably related to known disease (includes infants and children); deaths without medical attendance; and deaths of migrant agricultural workers and their dependents.

Autopsies are not performed at Piedmont Pathology Associates. Autopsies are performed at area hospitals.

Autopsy Request Procedure

1. Contact Piedmont Pathology Associates Inc. and schedule the autopsy with the Pathologist Assistant. If calling after normal business hours, telephone the number provided by the answering service for the on-call Pathologist Assistant.
2. Please provide the following information: name, address, date of birth and social security number of decedent if known, time and date of death if known, suspected cause of death, medical history (including prescription medication) and, name of family doctor.
3. The autopsy procedure will be performed by national and state guidelines in a timely fashion.
4. A final autopsy report will be issued within 30 days if private or hospital case and 60 days if ME case. Consults, special testing, toxicology results, etc can delay reports.
5. A copy of the report can be obtained via FAX or mail.



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Histopathology Specimens

Routine Surgical Specimens

Routine surgical specimens are tissue / biopsy specimens submitted for pathologic evaluation. *A routine surgical specimen is a specimen that does not require a special procedure such as decalcification, Flow Cytometry, Cytogenetics, Immunofluorescence, etc.*

Federal regulations require all specimens to be accurately identified. It is imperative that the patient's name and anatomic site sampled is written on the side of the specimen container and the name and anatomic site sampled on the container must match the name and anatomic site sampled on the test request form. Proper identification and fixation of surgical specimens is imperative for reliable testing. The test request form must indicate the preoperative diagnosis and source of specimen. Unidentified specimens or specimens with a mismatch between the labeling on the side of the container and the test requisition will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Complete the Surgical Specimen test request form including: specimen procurement date, anatomic site of the sample, patient's name, social security number, complete address, patient phone number, age, date of birth, sex, specimen submitted, surgical site, clinical data (pertinent previous history), and surgeon's differential diagnosis.

A copy of the patient's insurance card should be attached to the test request for third party billing. The lack of accurate insurance and billing information could lead to direct billing of services to the submitting physician.

Patient Preparation

The patient is prepared and the specimen is collected in the physician's office or hospital operating room suite. For more information on patient preparation see the physician's office and/or hospital procedure manuals. Patient preparation is outside the purview of this manual.

Specimen Preparation & Handling Biopsy / Tissue (routine surgical specimens)

1. Place all routine biopsy specimens immediately in ten times its volume of 10% buffered neutral formalin. Small pieces of tissue can be ruined in a short time period (seconds) by placing in saline or allowing to dry.
2. At the time the tissue is removed by the physician, label the side of the tissue container (**not the lid**) with **at least two patient identifiers**, (Name, Social Security Number, Date of Birth, etc.) and type of tissue. If multiple specimens are submitted for a single patient, identify each specimen container as A...B...C... or D. In addition to labeling with the patient's name and anatomic site of the biopsy (the description of A..B..C..D on the Test request form must match each container



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- submitted and labeled as A...B...C...D).
3. Place the lid on the specimen container and close tightly to prevent leakage.
 4. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. This information is critical to an accurate diagnosis on surgical specimens.
 5. Place the labeled specimen container and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory. Include only one patient specimen(s) per bag.



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Bone Marrow Specimens

Bone marrow specimens consist of aspirated material from the hematopoietic (medullary) bone in the form of aspirate smears and clot samples as well as a core biopsy of the bone and marrow cavity. *A peripheral smear and hematology report should accompany every bone marrow case submitted for evaluation.*

Federal regulations require all specimens to be accurately identified. It is imperative that the patient's name and anatomic site sampled is written on the side of the specimen container and the name and anatomic site sampled on the container must match the name and anatomic site sampled on the test request form. Proper identification and fixation of surgical specimens is imperative for reliable testing. The test request form must indicate the preoperative diagnosis and source of specimen. Unidentified specimens or specimens with a mismatch between the labeling on the side of the container and the test requisition will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Complete the Surgical Specimen test request form including: specimen procurement date, anatomic site of the sample, patient's name, social security number, complete address, patient phone number, age, date of birth, sex, specimen submitted, surgical site, clinical data (previous history), and surgeon's differential diagnosis.

A copy of the patient's insurance card should be attached to the test request for third party billing. The lack of accurate insurance and billing information could lead to direct billing of services to the submitting physician.

Patient Preparation

The patient is prepared and the specimen is collected in the physician's office or hospital operating room suite. For more information on patient preparation see the physician's office and/or hospital procedure manuals. Patient preparation is outside the purview of this manual.

Bone Marrow Technique

1. Place the bone marrow core biopsy in ten times its volume of 10% buffered neutral formalin. Touch preps may be prepared before the core is placed in formalin (This is left up to the discretion of the physician). Label the side of the tissue container (**not the lid**) with the patient's name and type of tissue.
2. Collect one or more bone marrow aspirates and make approximately 6 smears from each aspirate at the time of collection. Piedmont Pathology Associates prefers frosted end slides; therefore, the patient name can be identified on the frosted end of the slides. There is less risk of misidentification of the sample than with coverslips especially if more than one biopsy is obtained on the same patient or multiple biopsies are obtained on different patients in the same office.
3. Place the smears in a slide folder, tape the folder closed and label the outside of the folder with the patient name.
4. Complete the Surgical Specimen test request form. Identify the specimen source,



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- operative diagnosis and all pertinent clinical data. This information is critical to an accurate diagnosis on bone marrow specimens.
5. Place the peripheral smears, core biopsy, and aspirate smears in a specimen bag for transport to the laboratory. Include only one patient's specimen per bag. Do not place unstained aspirate smears or peripheral blood in the same bag as the formalin fixed tissue.
 6. Place the completed Surgical Specimen test request form, Hematology Report and peripheral Smear Report in the outside pocket of the transport bag.

Specimen Collection & Preparation – Ancillary Tests

Introduction

Piedmont Pathology Associates, Inc. will provide the access to ancillary testing of specimens. Our laboratory, upon receipt of the specimen and completed test request form, will submit the specimen to qualified testing sites for specialized studies. These specialized tests include but are not limited to FLOW CYTOMETRY / CYTOGENETICS, BREAST CANCER PROGNOSTIC ANALYSIS and, DIRECT IMMUNOFLUORESCENCE.

Flow Cytometry / Cytogenetics / Fluorescence in situ Hybridization (FISH)

Flow cytometry / cytogenetics can be performed on bone marrow, bone marrow core biopsy specimens, blood, placental tissue and fresh surgical tissue specimens. Flow Cytometry / cytogenetics, including polymerase Chain Reaction (PCR), can be utilized to ascertain the definitive diagnosis of various pathologic processes. The test is utilized to detect cell surface antigenic markers and DNA aneuploidy in solid tumors of the breast, colon, bladder, prostate, kidney, ovary, thyroid, adrenal gland, and bone. All collection tubes, containers and solutions are supplied by the laboratory.

Federal regulations require that all specimens be accurately identified. It is imperative that the patient's name is written on the specimen container and the name on the container must match the name on the test request form. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Please include the patient's name, date of birth and social security number on the Surgical Test request form. *Write on the request form “**Flow Cytometry and/or Cytogenetics or PCR**” testing.* A copy of the patient's insurance card should be attached to the test request for third party billing.

If the doctor is unsure what test to order or set of tests may be useful please call Piedmont Pathology and a Pathologist will assist the ordering physician with the test selection.



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Patient Preparation

The patient is prepared and the specimen is collected in the physician's office or hospital operating room suite. For more information on patient preparation see the physician's office and/or hospital procedure manuals. Patient preparation is outside the purview of this manual.

Bone Marrow

1. Collect a minimum of 2-3 ml of sterile bone marrow in a green top tube containing sodium heparin.
2. If flow cytometry **and** cytogenetic techniques are to be both performed, two specimens of 2-3 ml of sterile bone marrow in two green top tubes are required.
3. PCR gene rearrangement by Southern Blot requires approximately 7 ml of bone marrow collected in a purple top tube containing EDTA.
4. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
5. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Flow Cytometry and/or Cytogenetic or PCR" testing.
6. Place the labeled specimen tube(s) and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.

Blood

1. Cytogenetic testing requires a minimum of 5-10 ml of blood in a green topped tube containing sodium heparin.
2. Flow cytometry requires 10-20 ml of blood in a yellow-topped tube containing ACD. (This specimen tube must accompany all bone marrow specimens.)
3. PCR gene rearrangement by Southern Blot requires a minimum of 15 ml of blood in a purple top tube containing EDTA.
4. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
5. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Flow Cytometry and/or Cytogenetic or PCR" testing.
6. Place the labeled specimen tube(s) and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.

Fresh Biopsy / Tissue

Submit fresh tissue as for a frozen section. The Pathologist will select appropriate areas of the sample for analysis.



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Bone Marrow Core Biopsy

1. Flow cytometry / cytogenetics / PCR gene rearrangement - require an approximately 1 cm in length bone marrow core biopsy placed in RPMI media.
2. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
3. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Flow Cytometry and/or Cytogenetic or PCR" testing.
4. Place the labeled specimen tube(s) and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.

Body Fluids

1. Flow cytometry requires 10-20 ml of fluid mixed with an approximate equal volume of RPMI media.
2. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
3. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Flow Cytometry testing.
4. Place the labeled specimen tube(s) and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.

Cerebral Spinal Fluid

1. Flow cytometry requires approximate equal volumes of CSF and RPMI media. As much CSF fluid as possible should be collected and submitted.
2. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
3. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Flow Cytometry testing.
4. Place the labeled specimen tube(s) and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.

Breast Cancer Prognostic Analysis

The Breast Cancer Prognostic Analysis is a test utilized to help determine treatment options for those patients diagnosed with breast cancer. The malignant breast tissue is analyzed with a battery of antibodies. A range of therapeutic markers and DNA analysis can be reported. This service is performed in addition to the pathologist's microscopic evaluation of the malignant breast tissue. Most of these tests are performed on the



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paraffin embedded tissue at the discretion of the pathologist in appropriate cases. Other tests may be ordered and will be performed on appropriate malignant tumor blocks designated by the pathologist. Sometimes there is too little tumor left for meaningful analysis. In this event the pathologist will inform the ordering physician who can determine if additional samples should be obtained from the patient for analysis.

All malignant breast biopsies are reflexed for Hormone Receptor and Her-2 analysis by immunohistochemistry (IHC). The results of the analysis will be available for use in determining treatment options within approximately 2 to 3 days after the final report on the biopsy.

All negative and equivocal Her-2 IHC's are reflexed to Her-2 by FISH analysis with the exception of DCIS. This process could extend the turn-around time additional 2-3 days.

Direct Immunofluorescence

Immunofluorescent staining of histopathology specimens can yield information relevant to the diagnosis of disease. This information can be of relevance in planning primary treatment modalities for the patient. This takes extra planning and Piedmont Pathology should be contacted at least 1 day prior to obtaining a biopsy for Immunofluorescence in order to allow time to get the required transport media to the office.

Federal regulations require that all specimens be accurately identified. It is imperative that the patient's name is written on the specimen container and the name on the container must match the name on the test request form. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Please include the patient's name, date of birth and social security number on the Surgical Test request form. *Write on the request form "Direct Immunofluorescence" testing.*

A copy of the patient's insurance card should be attached to the test request for third party billing. The lack of accurate insurance and billing information could lead to direct billing of services to the submitting physician.

Patient Preparation

The patient is prepared and the specimen is collected in the physician's office or hospital operating room suite. For more information on patient preparation see the physician's office and/or hospital procedure manuals. Patient preparation is outside the purview of this manual.

Procedure

Note: Direct Immuno Transport Tissue fixative is used for this procedure. Please obtain this media from the laboratory one day in advance of the procedure.



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1. Label the side of a clean and empty specimen container with the label the side of the tissue container (not the lid) with at least two patient identifiers, (Name, Social Security Number, Date of Birth, etc.) and identification of tissue type and source of specimen.
2. Complete the Surgical Specimen test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the request "Direct Immunofluorescence" testing.
3. Obtain desired tissue biopsy.
4. Open tissue fixative vial and submerge the biopsy specimen into the fixative immediately.
5. Replace screw cap on vial and secure tightly.
6. Place the labeled specimen tube and completed Surgical Specimen test request form in a specimen bag for transport to the laboratory.



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Specimen Collection & Preparation – Stat / Rush Specimen Requests

Introduction

Stat / Rush specimen requests are honored at Piedmont Pathology Associates, Inc. Please follow the outlined procedure for this special request. This procedure must be followed to insure the laboratory staff is immediately aware that the submitted specimen requires special handling. Stat / Rush cases receive top priority designation in the laboratory. Surgical specimens and Cytology specimens will be signed out as soon as possible by the pathologist and the results will be immediately communicated to the physician or designee.

Federal regulations require all specimens to be accurately identified. It is imperative that the patient's name is written on the specimen container and the name on the container must match the name on the test request form. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Please include the patient's name, date of birth and social security number on the test request form. Also include all relevant clinical data for increased accuracy of the final diagnosis.

Procedure

1. Complete the appropriate test request form with all required information.
2. Write the word "**STAT**" or "**RUSH**" in the **upper left corner** of the test request form. Please do not obscure the clinical or demographic information. Include a telephone number or other contact information so the pathologist can call the physician as soon as a diagnosis is available.
3. Place the labeled specimen container and completed test request form in a specimen bag for transport to the laboratory.

Specimen Rejection Criteria

Each specimen received in the laboratory must be properly and accurately identified. The name on the specimen container or slides must match the name on the test request form. Any additional paperwork received in the laboratory from the submitting office must also contain the same name as the specimen container, slide and test request form. This procedure insures the quality of the specimen meets Federal CLIA '88 guidelines. **In the event a specimen is received in the laboratory and is not identified or does not meet the appropriate guidelines outlined in the "Specimen Collection & Preparation" chapter of this manual, the laboratory will return the specimen to the submitting office unprocessed.**

Specimens will be rejected and returned to the submitting office for the following reasons:



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- A specimen (slide, formalin bottle, *Cytolyt* vial, specimen container) received in the laboratory without patient identification on the side of the container/bottle. Labeling on specimen container lids is unacceptable and not allowed by CLIA standards. Slides must be labeled on the frosted end and on the outside of the slide holder.
- Specimens with an incomplete requisition
- Any specimen that has not been properly submitted in fixative
- Urine that has been collected for more than two (2) hours and allowed to sit at room temperature, i.e. non-refrigerated
- Any specimen grossly unsatisfactory in volume, i.e. specimen container appears empty
- Any specimen and/or container that may pose an excessive health risk to the courier or processing staff, i.e. specimen has leaked outside of the collection container, broken containers or glass slides
- Any syringe with an attached needle
- Any specimen that is submitted by an unauthorized source

Attestation Policy for Patient-Specimen Identification

When a specimen is received by Piedmont Pathology Associates, Inc. and a discrepancy is noted:

- ➔ the name on the requisition, slides, specimen container and test request forms do not match
- ➔ incomplete test request forms (the forms must contain patient name, date of birth, social security number and insurance billing information)

The submitting office will be contacted to provide clarification of the noted error. A completed attestation statement must be submitted to the laboratory for each discrepant specimen.

Telephone Verification

1. Lab personnel will call your office and inform you of the discrepancy.
2. The office contact person's name, telephone number, date and time of the discussion are recorded on the test request form.
3. The entry is initialed and dated by the Piedmont Pathology Associates, Inc. employee who placed the call.
4. This same employee will fax an **Attestation Statement for Patient-Specimen Identification** to the submitting office.
5. The submitting office will complete and fax the completed attestation statement to the laboratory. Following the completion of this procedure the specimen in question will be submitted for processing
6. The attestation statement is attached to the requisition and remains a part of the patient's record.
7. This information is recorded in the laboratory information system under the non-printed comment section.



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Returning Specimens to Submitting Office for Verification

1. Specimen(s), accompanying paperwork and an **Attestation Statement for Patient-Specimen Identification** are returned to the submitting office via the courier.
2. The submitting office will review the problem and return the corrected specimen, paperwork, and completed attestation statement to the lab via the courier.
3. The attestation statement is attached to the requisition and remains a part of the patient's record.
4. This information is recorded in the laboratory information system under the non-printed comment section.



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Rejection Forms:

Histology Rejection Forms:



Specimen Rejected Form

Client: _____ Date: _____

Enclosed is the Surgical/Non Gyn cytology specimen and requisition sent to us by your office.

Patient's name on requisition: _____

Patients' name on specimen(s): _____

They are being returned to you for the following reason(s):

- ☐ Patient's name on container and requisition do not match.
- ☐ Second Patient Identifier missing from one or more specimen container(s).
- ☐ Patient's name is missing from container or requisition.

-Federal and State regulations do not permit us to process any specimens that are not labeled with the patient's name. Therefore, please clearly write the patient's name on the container or requisition.

- ☐ Patient's name is missing from slide.

-Federal and State regulations do not permit us to process any slides that are not labeled with the patient's name. Please clearly write the patient's name in pencil on the frosted end of the slide.

- ☐ Other: _____

PPA Laboratory Personnel: _____
Signature

**** Please specify correction made:**

Please return this copy with your signature that correction has been made along with any changes to the attention of Piedmont Pathology Surgical Pathology.

Correction made by (Print Name) : _____ Date: _____

Signature: _____

For PPA Personnel only: Date sent back: _____ Date received back from client: _____



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Specimen Rejected Form (Fed-Ex)

Client: _____ Date: _____
Fax Number: _____
Telephone Verification: _____
(if necessary) Name of who spoke with: Date/Time spoke with: _____

This pertains to a discrepancy found on a Surgical/Non Gyn cytology specimen and requisition sent to us by your office.

Patient's name on requisition: _____

Patients's name on specimen(s): _____

They are being rejected due to the following reason(s):

- ☐ Patient's name on container and requisition do not match.
- ☐ Second Patient Identifier missing from one or more specimen container(s).
- ☐ Patient's name is missing from container or requisition.

-Federal and State regulations do not permit us to process any specimens that are not labeled with the patient's name. Therefore, please clearly write the patient's name on the container or requisition.

- ☐ Patient's name is missing from slide.

-Federal and State regulations do not permit us to process any slides that are not labeled with the patient's name. Please clearly write the patient's name in pencil on the frosted end of the slide.

- ☐ Other: _____

For PPA Use: Please specify correction made based on above documented phone call.

PPA Laboratory Personnel: _____
Signature

Please fax back this copy with your signature verifying that correction made above is correct. PPA FAX NUMBER: 828-322-1122

Client Signature (Sign) : _____ (Print Name): _____ Date: _____

For PPA Personnel Only: Date Faxed: _____ Date Fax Returned: _____

Guide to Completing Test Request Forms

Please refer to the attached Appendices for sample copies of Piedmont Pathology requisitions.



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Billing Information

The appropriate billing check box must be marked on all test request forms. In the event this area has not been marked, laboratory personnel will contact your office to clarify who the responsible party is for payment of laboratory services. Piedmont Pathology Associates, Inc. is required to bill all Medicare and Medicaid claims.

Please include a copy of the patient's insurance or Medicare card (front and back) or complete the appropriate billing information boxes on the test request form. The following information is required:

- Patient's complete name
- Patient's date of birth
- Patient's sex
- Patient's address
- Patient's telephone number
- Physician's name
- Specimen procurement date
- Responsible party's name if different than patient's
- Responsible party's mailing address
- patient's relationship to policy holder
- Subscribers ID number on the insurance card
- Group number on the insurance card
- Employer name
- All applicable ICD-9 or ICD-10 diagnosis codes
- Complete name of the insurance company, address and phone number
- Provide secondary insurance information if applicable
- Previous history

Piedmont Pathology Associates, Inc. prefers a copy of the third party payer card.

This procedure eliminates the mistakes caused by illegible hand writing and missing necessary information.



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Non-Gynecological Cytology Test Request Forms

Please include the following information on *all* Non-Gyn Cytology Test Request Forms to facilitate accurate record keeping and patient tracking:









- Patient's social security number
- Patient's full name
- Patient's date of birth
- Submitting physician name

The following information must be included on the Non-Gyn Cytology Test Request Form to aid in a more accurate diagnosis:

- Specimen procurement date
- Source of specimen
- Collection technique
- Relevant clinical findings and patient history
- Previous abnormal cytology or biopsy information (date of procedure and diagnosis rendered)



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 Piedmont Pathology		NON-GYNECOLOGICAL REQUISITION FORM		 NGP001398	
CLIENT INFORMATION PHYSICIAN: _____ 			BILLING INFORMATION <input type="checkbox"/> CLIENT <input type="checkbox"/> INSURANCE* <input type="checkbox"/> MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> PATIENT BILL <small>*Please specify if insurance code, not primary or secondary</small> <small>(Medi-Cal, Health Care Savings Account, Medicaid require Employer's Name)</small> MEDICARE NUMBER: _____ PRIMARY INSURANCE INSURANCE COMPANY NAME: _____ STREET ADDRESS: _____ CITY/STATE/ZIP CODE: _____ POLICY # _____ GROUP # _____ GROUP EMPLOYEE: _____ NAME OF POLICY HOLDER: _____ SECONDARY INSURANCE INSURANCE COMPANY NAME: _____ STREET ADDRESS: _____ CITY/STATE/ZIP CODE: _____ POLICY # _____ GROUP # _____ GROUP EMPLOYEE: _____ NAME OF POLICY HOLDER: _____		
PATIENT INFORMATION SOCIAL SECURITY NUMBER: _____ RACE: _____ SEX: <input type="checkbox"/> M <input type="checkbox"/> F DATE OF BIRTH (MM/DD/YYYY): _____ LAST NAME: _____ FIRST NAME: _____ MI: _____ STREET ADDRESS: _____ CITY/STATE/ZIP CODE: _____ HOME TELEPHONE NUMBER: _____ HOME TELEPHONE NUMBER: _____ DATE OF SERVICE: _____ MRN: _____					
NON-GYN CYTOLOGY					
Specimen Submitted (Specify site below and match with container) URINE <input type="checkbox"/> VOIDED <input type="checkbox"/> CATHETERIZED <input type="checkbox"/> MIDSTREAM <input type="checkbox"/> RT <input type="checkbox"/> LT <input type="checkbox"/> BLADDER WASHING BREAST <input type="checkbox"/> RT <input type="checkbox"/> LT <input type="checkbox"/> QUADRANT _____ <input type="checkbox"/> DRAINAGE <input type="checkbox"/> CYST ASPIRATE <input type="checkbox"/> SOLID MASS RESPIRATORY <input type="checkbox"/> SPUTUM <input type="checkbox"/> BRONCHIAL WASHING <input type="checkbox"/> RT <input type="checkbox"/> LT <input type="checkbox"/> BRONCHIAL BRUSHING <input type="checkbox"/> RT <input type="checkbox"/> LT <input type="checkbox"/> NEEDLE ASPIRATE FLUIDS <input type="checkbox"/> CSF <input type="checkbox"/> PERITONEAL <input type="checkbox"/> PLEURAL <input type="checkbox"/> PERICARDIAL THYROID FNA <input type="checkbox"/> RT <input type="checkbox"/> LT <input type="checkbox"/> CYST <input type="checkbox"/> NODULE Description: _____ ASPIRATE SMEARS SPECIFY: _____ NEEDLE ASPIRATE SITE: _____ OTHER SITES: SPECIFY: _____			Relevant Clinical Finding/Clinical History <input type="checkbox"/> SCREENING <input type="checkbox"/> SMOKER <input type="checkbox"/> ALCOHOL SIGNS & SYMPTOMS: _____ HISTORY: _____ RULE OUT: _____ OTHER: _____ ICD/ICD-10: _____		
Gross Description of Specimen: _____ (Quality/Color) _____ <input type="checkbox"/> Received Fresh <input type="checkbox"/> Received Fixed <input type="checkbox"/> Client Prepared Slide Number Received: _____ <input type="checkbox"/> Lab Prepared Slide			Prepared By: _____ Cell Block <input type="checkbox"/> Yes <input type="checkbox"/> No		
<div style="text-align: center;"> *** IMPORTANT *** </div>					
<div style="text-align: center;"> IMPORTANT: PLACE APPROPRIATE LABEL ON SPECIMEN VIAL. WRITE SPECIMEN SITE ON LABEL. </div>					
<div style="text-align: center;"> WARNING: LABELS ARE NUMBERED AND SPECIFIC FOR EACH FORM. DO NOT INTERCHANGE. </div>					
 NGP001398		 NGP001398		 NGP001398	
 NGP001398		 NGP001398		 NGP001398	
Piedmont Pathology Associates • 1699 Tate Blvd. SE, Suite 1105, Hickory NC 28602 • 1.888.339.8147 • (P) 828.322.3821 • (F) 828.322.1122					



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Surgical Specimen Test Request Form (black print with highlighted sections)

Please include the following information on *all* Surgical Specimen Test Request Forms to facilitate accurate record keeping and patient tracking:

- Patient's social security number
- Patient's full name
- Patient's date of birth
- Submitting Physician's name
- Submitting Physician's signature

The following information must be included on the Surgical Specimen Test Request Form to aid in a more accurate diagnosis:

- Specimen procurement date
- Description/source and location of specimen removed (i.e. mole / left upper arm)
- Multiple specimens must be placed in different containers labeled as A...B...C...D (the description at A...B...C...D on the Test request form must match the description on each container submitted. For example, a specimen labeled "A: RT Breast" on the side of the container should say on the requisition at line "A" – Right Breast. The label on the side of the container that the specimen is in should always match the requisition.
- Operative diagnosis
- Previous abnormal biopsy information (date of procedure and diagnosis rendered)
- Current conditions / comorbidities / complications (Patient is tobacco dependent, Patient has COPD, Alcohol use, polyp with fistula, cholecystitis with obstruction)
- Relevant Personal History (History of bladder cancer, History of smoking)
- Relevant Family History (Family history of colon cancer in father at age 60)
- Current signs and symptoms (diarrhea, lower GI bleeding, Shortness of breath, headaches, gross hematuria) *** GI bleeding is very important with GI cases.
- Laterality (left, right bilateral)
- Site specific (leg, sigmoid colon, anterior bladder wall)
- Type of fracture
If this is an initial or subsequent encounter, or if the patient is being seen for a sequel (late effect) *** especially in musculoskeletal conditions/fractures
- Screenings (colon screening for malignant neoplasms)
- Current conditions / comorbidities / complications (Patient is tobacco dependent, Patient has COPD, alcohol use, polyp with fistula, cholecystitis with obstruction)
- Gestational date on all placentas or miscarriages (week 5, week 35.4)



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- Stage of pressure ulcer / Stage of CKD

The Surgical Specimen Test Request Form is used for all types of histology specimens (routine surgical specimens, bone marrow specimens and, frozen section specimens) submitted for pathologic evaluation. It is imperative that the source and type of specimen be indicated on every request form.

|



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SURGICAL SPECIMEN																															
PIEDMONT PATHOLOGY ASSOCIATES, INC. 1899 TATE BOULEVARD S.E., SUITE 1105 HICKORY, NC 28602 828-322-3821 1-888-339-8147 (Toll Free) FAX: 828-322-1122		 HA1086081																													
<input type="checkbox"/> ACCOMPANYING PAP Physician (PRINT) _____ Physician (SIGNATURE) _____		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: center; padding: 2px;">LAB USE ONLY</th> </tr> <tr> <td style="width: 50%; padding: 2px;">SURGICAL# S</td> <td style="width: 50%; padding: 2px;">DATE REC'D</td> </tr> </table>		LAB USE ONLY		SURGICAL# S	DATE REC'D																								
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GUARANTOR																															
TELEPHONE		MEDICAL RECORD																													
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Specify site below and match with container	ICD-10	Clinical History/Diagnosis																													
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Billing Info: <input type="checkbox"/> Client <input type="checkbox"/> Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Hospital <input type="checkbox"/> Patient/No Insurance *Please send copy of insurance cards and mark primary and/or a secondary*																															
Primary Insurance		Secondary Insurance																													
Insurance:	Insurance:																														
Address:	Address:																														
Policy #:	Policy #:																														
Group #:	Group #:																														
Policyholder:	Policyholder:																														
Relation to Pt:	Relation to Pt:																														
Employer:	Employer:																														
Per the 2009 FTC "Red Flags" Rule the referral source has verified the medical information above belongs to this patient.																															
<table style="width: 100%; text-align: center;"> <tr> <td style="width: 33%;"> A HA1086081 Patient Name: _____ </td> <td style="width: 33%;"> B HA1086081 Patient Name: _____ </td> <td style="width: 33%;"> C HA1086081 Patient Name: _____ </td> </tr> <tr> <td> D HA1086081 Patient Name: _____ </td> <td> E HA1086081 Patient Name: _____ </td> <td> F HA1086081 Patient Name: _____ </td> </tr> </table>				 A HA1086081 Patient Name: _____	 B HA1086081 Patient Name: _____	 C HA1086081 Patient Name: _____	 D HA1086081 Patient Name: _____	 E HA1086081 Patient Name: _____	 F HA1086081 Patient Name: _____																						
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**Piedmont Pathology Associates
Office Procedure & Specimen Collection Manual
Updated January 2019**

Urology Test Request Forms

Please include the following information on *all Urology* Test Request Forms to facilitate accurate record keeping and patient tracking:

- * Patient's social security number
- * Patient's full name
- * Patient's date of birth
- * Submitting physician name

The following information must be included on the Urology Test Request Form to aid in a more accurate diagnosis:

- * Specimen procurement date
- * Specific description/source and location of each specimen removed
- * Operative diagnosis
- * ICD-10 code
- * Relevant clinical findings and patient history



Piedmont Pathology Associates **Office Procedure & Specimen Collection Manual** **Updated January 2019**

Piedmont Pathology Associates, Inc. 1899 Tate Boulevard, S.E., Suite 1105 Hickory, NC 28602 828-322-3821 FAX: 828-322-1122 1-888-339-8147 (Toll Free)		LAB NO/DATE REC'D		 UA002465																																							
Submitting Physician: _____ Collected Date: _____		<table border="1" style="width:100%; border-collapse: collapse;"> <tr> <td colspan="2">PATIENT NAME: LAST</td> <td colspan="2">FIRST</td> <td colspan="2">MI</td> </tr> <tr> <td colspan="2">SOCIAL SECURITY NUMBER</td> <td colspan="2" rowspan="2"> <div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">➔</div> </td> <td colspan="2" rowspan="2">MED RECORD #</td> </tr> <tr> <td><input type="checkbox"/> FEMALE</td> <td>AGE</td> </tr> <tr> <td><input type="checkbox"/> MALE</td> <td colspan="2">DOB</td> <td colspan="2">/</td> <td>/</td> </tr> <tr> <td colspan="6">ADDRESS</td> </tr> <tr> <td colspan="2">CITY</td> <td colspan="2">STATE</td> <td colspan="2">ZIP CODE</td> </tr> <tr> <td colspan="4">GUARANTOR</td> <td colspan="2">PATIENT TELEPHONE (Work & Home)</td> </tr> </table>				PATIENT NAME: LAST		FIRST		MI		SOCIAL SECURITY NUMBER		<div style="border: 1px solid black; width: 20px; height: 20px; display: flex; align-items: center; justify-content: center;">➔</div>		MED RECORD #		<input type="checkbox"/> FEMALE	AGE	<input type="checkbox"/> MALE	DOB		/		/	ADDRESS						CITY		STATE		ZIP CODE		GUARANTOR				PATIENT TELEPHONE (Work & Home)	
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CITY		STATE		ZIP CODE																																							
GUARANTOR				PATIENT TELEPHONE (Work & Home)																																							
Test Submitted:																																											
HISTOLOGY <input type="checkbox"/> Prostate Biopsy Right: # _____ Left: # _____ <input type="checkbox"/> Bladder Biopsy <input type="checkbox"/> Other	CYTOLOGY <input type="checkbox"/> Urine Cytology <input type="checkbox"/> FISH Specimen Source: <input type="checkbox"/> Voided Urine <input type="checkbox"/> Cath Urine <input type="checkbox"/> PostCyto Void <input type="checkbox"/> Bladder Wash <input type="checkbox"/> Clean Catch <input type="checkbox"/> Other	CHEMISTRY <input type="checkbox"/> PSA <input type="checkbox"/> Free & Total PSA <input type="checkbox"/> Testosterone <input type="checkbox"/> Testosterone, Free <input type="checkbox"/> Comp. Metabolic Panel <input type="checkbox"/> Creatinine/BUN <input type="checkbox"/> Calcium <input type="checkbox"/> Uric Acid <input type="checkbox"/> CBC w/Diff/PLT <input type="checkbox"/> ProTime w/INR <input type="checkbox"/> Other	MICROBIOLOGY <input type="checkbox"/> Culture Sensitivity <input type="checkbox"/> Culture <input type="checkbox"/> Organism ID <input type="checkbox"/> Gram Stain <input type="checkbox"/> Urinalysis w/Micro <input type="checkbox"/> Chlamydia <input type="checkbox"/> GC Specimen Source: <input type="checkbox"/> Voided Urine <input type="checkbox"/> Cath Urine <input type="checkbox"/> Clean Catch <input type="checkbox"/> Other	STONE ANALYSIS <input type="checkbox"/> Stone Analysis Specimen Source: <input type="checkbox"/> Ureter <input type="checkbox"/> Bladder <input type="checkbox"/> Kidney Specimen Obtained: <input type="checkbox"/> Spontaneously Passed <input type="checkbox"/> Surgically Removed																																							
PLEASE INDICATE INDIVIDUAL SPECIMEN(S)* <div style="text-align: center;"> </div> Other Site(s): _____ Biopsy Date: _____		<table border="1" style="width:100%; border-collapse: collapse;"> <tr><td colspan="2">A.</td><td colspan="2">E.</td></tr> <tr><td colspan="2">B.</td><td colspan="2">F.</td></tr> <tr><td colspan="2">C.</td><td colspan="2">G.</td></tr> <tr><td colspan="2">D.</td><td colspan="2">H.</td></tr> <tr> <td colspan="2" style="height: 40px; vertical-align: top;">Clinical History/ Diagnosis</td> <td colspan="2"></td> </tr> </table>				A.		E.		B.		F.		C.		G.		D.		H.		Clinical History/ Diagnosis																					
A.		E.																																									
B.		F.																																									
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Clinical History/ Diagnosis																																											
PROGNOSTIC INFO (Optional for Partin/Kattan Predictions)																																											
Clinical Stage <input type="checkbox"/> T1c <input type="checkbox"/> T2b <input type="checkbox"/> T2c <input type="checkbox"/> T3 Last Total PSA _____ ng/ml on _____ / _____ / _____ Last Free PSA _____ Digital Rectal Exam <input type="checkbox"/> Suspicious <input type="checkbox"/> Non-suspicious Hypochoic Lesion <input type="checkbox"/> Previous Biopsy <input type="checkbox"/> None <input type="checkbox"/> Negative <input type="checkbox"/> Suspicious <input type="checkbox"/> Positive Treatment: <input type="checkbox"/> Prostatectomy <input type="checkbox"/> Radiation <input type="checkbox"/> Cryotherapy <input type="checkbox"/> Medication for BPH <input type="checkbox"/> TURP																																											
LAB USE ONLY																																											
Gross Description of Specimen: (Quantity/Color) _____ Prepared by _____ <input type="checkbox"/> Received Fresh <input type="checkbox"/> Received Fixed <input type="checkbox"/> Client Prepared Slides _____ Number Received _____ <input type="checkbox"/> LAB Prepared Slides _____ Billing Info: <input type="checkbox"/> Client <input type="checkbox"/> Insurance <input type="checkbox"/> Medicare <input type="checkbox"/> Medicaid <input type="checkbox"/> Hospital <input type="checkbox"/> Patient Bill **Please send copy of insurance cards and mark primary and/or secondary** MAMS!, HealthCare Savings, Alliance and MedCost require Employer's Name																																											
PRIMARY INSURANCE			SECONDARY INSURANCE																																								
Insurance:			Insurance:																																								
Address:			Address:																																								
Policy #:			Policy #:																																								
Group #:			Group #:																																								
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A Left Lateral Base B Left Lateral Mid C Left Lateral Apex D Right Lateral Base	E Right Lateral Mid F Right Lateral Apex G Left Transition Zone (TZ) H Right Transition Zone (TZ)	Urine Serum/PSA Stone Prostate Bx Right #	Prostate Bx Left # Other Other Other																																								

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Ancillary Test Requests

Flow Cytometry / Cytogenetics/ Fluorescence in situ Hybridization

- The Surgical Test Request Form is utilized for submitting specimens for Cytometry / Cytogenetics testing / FISH testing. *Write on the request form “Flow Cytometry and/or Cytogenetics or FISH Testing”.*
- Please include the following information on *all* Surgical Specimen Test Request Forms to facilitate accurate record keeping and patient tracking:
 - Patient’s social security number
 - Patient’s full name
 - Patient’s date of birth
 - Submitting physician name
- The following information must be included on the Surgical Specimen Test Request Form to aid in a more accurate diagnosis:
 - Specimen procurement date
 - Description/source and location of specimen removed (i.e. mole / left upper arm)
 - Multiple specimens must be placed in different containers labeled as A...B...C...D (the description at A...B...C...D on the Test request form must match the description on each container submitted. For example, a specimen labeled “A: RT Breast” on the side of the container should say on the requisition at line “A” – Right Breast. The label on the side of the container that the specimen is in should always match the requisition.
 - Operative diagnosis
 - Relevant clinical findings and patient history
 - Previous abnormal biopsy information (date of procedure and diagnosis rendered)

Breast Cancer Prognostic Analysis

All breast specimens considered to be malignant by final tissue diagnosis will be automatically submitted by the pathologist for Breast Cancer Prognostic Analysis. The clinician need not request this procedure.

Direct Immunofluorescence

The Surgical Test Request Form is utilized for submitting specimens for Direct Immunofluorescence testing. *Write on the request form “Direct Immunofluorescence Testing”.*

Please include the following information on *all* Surgical Specimen Test Request Forms to facilitate accurate record keeping and patient tracking:

- Patient’s social security number
- Patient’s full name
- Patient’s date of birth



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- Submitting physician name

The following information must be included on the Surgical Specimen Test Request Form to aid in a more accurate diagnosis:

- Specimen procurement date
- Description/source and location of specimen removed (i.e. mole / left upper arm)
- Multiple specimens must be placed in different containers labeled as A...B...C...D (the description at A...B...C...D on the Test request form must match the description on each container submitted. For example, a specimen labeled “A: RT Breast” on the side of the container should say on the requisition at line “A” – Right Breast. The label on the side of the container that the specimen is in should always match the requisition.
- Operative diagnosis
- Relevant clinical findings and patient history
- Previous abnormal biopsy information (date of procedure and diagnosis rendered)



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Reports

Non-Gynecologic Cytology

The Non-Gynecologic Cytology report will include:

- Patient's name, social security number, medical record number, address, date of birth, age, sex,
- Submitting physician name
- Laboratory accession number
- Date specimen collected and received
- Date specimen reported
- Clinical information
- Tissue submitted and gross description
- Microscopic description
- Diagnosis
- Pathologist's signature
- Location of submitting physician



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Sample Non-Gynecologic Cytology Report



NON-GYN CYTOLOGY REPORT

Patient Name

Phone:

SSN:

MRN:

Adm No:

Address:

Physician:

DOB/Gender/Race:

Location:

Accession No:

Collected:

Received:

Reported:

DIAGNOSIS

Pertinent Clinical Information

TISSUE SUBMITTED AND GROSS DESCRIPTION

MICROSCOPIC DESCRIPTION

Electronically Signed Out
Pathologist Name



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Histology - Surgical Specimens / Biopsy / Tissue Report

The Surgical pathology report will include:

- Patient's name, social security number, medical record number, address, date of birth, age, sex
- Pertinent clinical information
- Tissue submitted and gross description
- Microscopic description
- Diagnosis
- Submitting physician name
- Laboratory accession number
- Date specimen collected and received
- Signature of pathologist
- Date specimen reported
- Submitting physician's location
- Clinical Summary



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Sample Surgical Report



SURGICAL PATHOLOGY REPORT

Patient Name		Accession No:
Phone:	Physician:	Collected:
SSN:	DOB:	Received:
MRN:	Gender:	Reported:
Adm No:	Race:	
Address:	Add'l Phy:	

DIAGNOSIS

Electronically Signed Out
Pathologist Name

PERTINENT CLINICAL INFORMATION

TISSUE SUBMITTED AND GROSS DESCRIPTION

MICROSCOPIC DESCRIPTION



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AUTOPSY PATHOLOGY

The AUTOPSY PATHOLOGY REPORT could include any of the following:

- Deceased's name, social security number, address, date of birth, age, sex
- Gross Result
- Microscopic Result
- Laboratory accession number
- Final Anatomic Diagnosis and Diagnosis comment
- Toxicology Results
- Expiration Date
- Signature of pathologist
- Autopsy Date and Reported Date
- Authorized by person
- Relationship to patient
- Reason for autopsy
- Autopsy Restrictions



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Sample Autopsy Report



1899 Tate Blvd., SE - Suite 1105
Hickory, NC 28602
(828) 322-3821
(828) 322-1122
Toll Free: (888) 339-8147

AUTOPSY REPORT

Patient Name

Accession No:

DOB:

Medical Examiner:

Expiration Date:

Race/Gender:

Prosecutor:

Autopsy Date:

Soc. Sec. No:

Physician:

Reported Date:

Address:

Authorized by:

Relationship to Patient:

Reason for Autopsy:

Autopsy Restrictions:

FINAL ANATOMIC DIAGNOSIS:

DIAGNOSIS COMMENT

Electronically Signed Out
Pathologist Name

CLINICAL SUMMARY

Autopsy location:
Persons present:
Clothing:

Body condition:
Body development:
Body nourishment:
Body build:
Body temperature:



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Ancillary Tests –

Flow Cytometry / Cytogenetics/ Fluorescence in situ Hybridization

The report will include:

- patient's name, social security number,
- medical record number, address, date of birth, age, sex
- submitting physician name
- laboratory accession number
- date specimen collected and received
- date diagnosis reported, tissue submitted and clinical data
- diagnostic results
- signature of pathologist evaluating specimen
-

Ancillary Tests - Breast Cancer Prognostic Analysis

The report will include:

- patient's name, social security number, record number, address, date of birth, age, sex
- submitting physician name
- laboratory accession number
- date specimen collected and received
- date diagnosis reported, tissue submitted and clinical data
- results including antibody tests, % tumor staining / intensity and prognostic groupings
- comments
- signature of evaluating pathologist

Ancillary Test – Her-2 FISH

The report will include:

- patient's name, social security number, record number, address, date of birth, age, sex
- submitting physician name
- laboratory accession number
- date specimen collected and received
- date diagnosis reported, tissue submitted and clinical data
- results including antibody test, marker for, and results
- interpretation
- signature of pathologist evaluating specimen



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Ancillary Tests – Direct Immunofluorescence

The report will include:

- patient's name, social security number, record number, address, date of birth, age, sex
- submitting physician name
- laboratory accession number
- date specimen collected and received
- date diagnosis reported, tissue submitted and clinical data
- results including antibody test, marker for, and results
- interpretation
- signature of pathologist evaluating specimen



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Billing Procedures

Billing procedures for each office will be established when the physician's account is set up. Changes in billing arrangements may be made by contacting the Practice Manager or the Client Services Representative. **Please check the appropriate billing box on the test request form.**

Client / Physician Office Billing

Clients will be billed monthly. The physician's office will receive an itemized invoice containing the date, patient's name, specimen identification number, test performed, and fee for service for each specimen processed and interpreted. The invoice is payable upon receipt. If you have any questions regarding your account, please call the Billing Specialist / Client Billing office at Piedmont Pathology Associates (828) 322-3821 or 1-888-339-8147. Any adjustments will appear on the next month's bill.

Insurance / Third-Party Billing

Piedmont Pathology Associates, Inc. is enrolled with a large number of private insurance companies and managed care organizations. You may request a copy of the most current Participating Plans list. Our participation with these companies will be ever changing as contracting opportunities for pathology services become available. If you or the patient have questions regarding third party billing (private insurance, managed care, Medicare or Medicaid), please call our Insurance / Third Party Billing office at 828-322-3572 or toll free 1-866-520-9915.

As a service to your patients, Piedmont Pathology Associates, Inc. will bill your patient's primary insurance company and managed care organization directly when provided with **complete and accurate** billing information. **Please provide a photocopy of the insurance card including the front and back.** As a general rule, third-party payers request the following information in order to process a claim: (Please include this information on every test request form. Please note that failure to provide **accurate** billing information may result in direct billing to the physician office that ordered the test.)

- specimen procurement date
- patient's complete name
- patient's sex
- patient's date of birth and age
- patient's telephone number
- responsible party if other than insured and relationship to responsible party
- patient's complete mailing address or responsible party
- referring physician's name
- ICD-10 diagnosis code
- complete name of insurance company and address
- patient member identification number
- group identification number
- Previous History



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Medicare

Piedmont Pathology Associates, Inc. is a participating supplier with the Medicare program and we are required by HCFA to file all claims for laboratory services rendered. Piedmont Pathology Associates, Inc. agrees to accept the Medicare-allowed amount as full payment for covered services. This assignment does not preclude billing of the patient for services denied by Medicare.

Medicare only pays for those services that it deems to be medically necessary for the diagnosis and treatment of disease and/or other health related problems. HCFA and Medicare carriers have developed a system using ICD-10 diagnosis codes to prevent payment of claims that they determine not to be medically necessary. It is critical that the code used for ordering the anatomic pathology service / test is consistent with the documentation in the patient's medical records. The ICD-10 code or clinical description used must be specific to the patient's medical condition and the anatomic pathology service / test requested by the physician for that date of service.

If you or the patient have questions regarding third party billing (private insurance, managed care, Medicare or Medicaid), please call our Insurance / Third Party Billing office at 828-322-3572 or toll free 1-866-520-9915.

The following information must be provided to Piedmont Pathology Associates, Inc. for Medicare billing: **Please provides a photocopy of the Medicare card including the front and back.** Please note that failure to provide accurate billing information may result in direct billing to the physician office that ordered the test.

- Patient's full name (as it appears on the card)
- Patient's complete address
- Patient's sex and date of birth
- Medicare number
- Referring physician name
- ICD-10 diagnosis code or clinical description
- Signed ABN form

Medicaid

Piedmont Pathology Associates, Inc. is a participating supplier with Medicaid agencies and we are required by the state to file all claims for laboratory services rendered. The following information must be provided to Piedmont Pathology Associates, Inc. for Medicaid billing: **Please provide a photocopy of the Medicaid card.** Please note that failure to provide accurate billing information may result in direct billing to the physician office that ordered the test.

- Patient's full name (as it appears on the card)
- Patient's complete address
- Patient's sex and date of birth



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- Patient's Medicaid number
- Referring physician name
- ICD-10 diagnosis code or clinical description

Other

Piedmont Pathology Associates, Inc. will file claims and accept payment from Champus, Workman's Compensation and Vocational Rehabilitation, etc. Please include all appropriate information on test request form. Please call our Billing Department at 828-322-3572 or toll free 1-866-520-9915 if you have questions.

Questions Regarding Billing

If you or your patients have questions regarding bills the patient has received from the laboratory, please refer them to our Insurance / Third Party Billing office at 828-322-3572 or toll free 1-866-520-9915.

Financial Hardship Patients

Piedmont Pathology Associates, Inc. recognizes the inability of some patient's to pay for necessary anatomic pathology testing and screening. This also includes patients who do not have insurance coverage for specified anatomic pathology testing and screening. The laboratory will work with the referring physicians office to determine how best to assist these patients on a case to case basis. Please call our Billing Department at 828-322-3572 or toll free 1-866-520-9915.



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Contact Information

Laboratory Main Line	828-322-3821
Toll Free	888-339-8147
Fax	828-322-1122
Pathologists	828-322-3821
Practice Manager	828-322-3821 Ext. 542
Billing Manager	828-322-3821 Ext. 522
Billing Specialist / Client Billing	828-322-3572 866-520-9915
Client Services Manager	828-322-3821 Ext. 575
Network Administrator	828-322-3821 Ext. 560
Copy of all Final Reports	828-322-3821
Request for Courier Pick-up	828-322-3821
Request for Supplies or Fax supply request to	828-322-3821 828-322-1122
Answering Service available to take after hour messages and to contact on-call personnel	
Hours of Operation	8:00 am to 5:00 pm M – F
Please visit our website at www.piedpath.com	
Address for main laboratory:	

PIEDMONT PATHOLOGY ASSOCIATES INC.
1899 TATE BOULEVARD SE. SUITE 1105
HICKORY, NORTH CAROLINA 28602