

APP-ECP Specimen Collection Manual

Table of Contents

Overview of Services	2
Overview of Services	3
Overview of Services and Licensures.....	4
Specimen Collection and Preparation Identification	5
Specimen Collection for Cervical/Vaginal Cytology	6
Specimen Collection for Non-Gynecologic Cytology	8
Specimen Collection for Histopathology/Biopsy	14
Specimen Collection for Bone Marrow	15
Specimen Collection for Frozen Section	16
Specimen Collection for Autopsy Request	18
Specimen Collection for HPV DNA Assay	19
Specimen Collection for Flow/Cytogenetics/Molecular/Special Studies	20
Specimen Collection for Stat/Rush Specimens	24
Specimen Rejection Criteria	25
Guide to Completing Test Request Forms	27
Information Returned on Reports	30
Billing Procedures	32
Important Phone Numbers and Addresses	36

APP-ECP Specimen Collection Manual

Overview of Services

Eastern Carolina Pathology provides anatomic pathology services in forms of cytology and histology testing. Our service area covers Wilson, Edgecombe, Johnston, Halifax and Nash counties. Eastern Carolina Pathology was established in 1990. We have professional affiliations with Wilson Medical Center, Heritage Hospital, and Halifax Regional Medical Center

Mission Statement

Eastern Carolina Pathology will lead the region in point of service anatomic pathology and cytopathology testing by providing quality patient care through technical accuracy and service excellence.

Testing Services Offered

The anatomic pathology services provided include cytology preparation and interpretation of liquid-based pap tests, breast aspiration and discharge specimens, body cavity fluids, cerebrospinal fluid, FNA of palpable masses, FNA of deep masses, GI specimens, respiratory specimens, urine specimens, and miscellaneous cytology specimens.

Our pathology testing services also include the preparation and interpretation of histology specimens including routine surgical (biopsy/tissue), bone marrow, and frozen sections.

Ancillary Services

Eastern Carolina Pathology will provide the access to ancillary testing of specimens. Our laboratory, upon receipt of the specimen and completed test request from your office, will submit the specimen to qualified testing sites for specialized studies. The ancillary tests offered include HPV DNA Assay, Flow Cytometry/Cytogenetics, Breast Cancer Profile, Direct Immunofluorescence, and molecular studies or other specialized studies. 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 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 or call with test results for stat situations and we will be happy to discuss any billing concerns regarding fees and policies.

APP-ECP Specimen Collection Manual

Overview of Services

Reporting of Test Results

Final diagnostic reports for routine surgical specimens (biopsy/tissue) and Non-gynecologic cytology specimens are most often available within 24 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 verbal preliminary reports. Cytology Pap test results will usually be complete within 12 days including HPV results to the client's office as appropriate.

Professional Staff

Our professional staff include board certified pathologists and certified cytotechnologists. 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 eastern North Carolina and it continues to broaden to meet our clients needs.

Client Services

The Client Service Representative is trained to answer many of your questions. If he/she does not know the answers to your questions, they will find out the necessary information and get back to you in a timely manner. Please feel free to communicate any questions or concerns to your Client Service Representative. For courier service information and supply requests, please contact your Client Service Representative or pathologist at (252) 234-2841 or fax your supply order to (252) 234-9270.

Our Client Service Representative contacts clients on a regular basis. She/he will keep you informed of new technical, procedural, and pertinent information regarding pathology/patient requirements. This person is available to answer questions and address any issues that arise. The goal of our Client Service Representative is to make sure that our services meet you needs. Do not hesitate to call if you need assistance or have questions regarding Eastern Carolina Pathology services.

APP-ECP Specimen Collection Manual

Overview of Services

Quality Assurance and Quality Control

Quality assurance (QA) and quality control (QC) are an integral part of Eastern Carolina Pathology's 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 staff members and pathologists. The external quality assurance plan includes the participation in several externally-administered quality assessment programs. Consistent acceptable performance in these assessment programs is a requirement for continued licensure and accreditation.

The internal Cytology and Histology quality assurance plan addresses 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 continuously to detect problems in the areas of courier service, transcription, and reporting. We also use our technology such as our automated screening devices to ensure patient care. The internal quality assurance plan at Eastern Carolina Pathology is continually monitored and expanded to meet the changing needs in the medical community.

The external quality assurance plans includes participation in College of American Pathologist (CAP) PIP, PAP, HER 2, ER/PR, HPV and Non-GYN slide review programs and proficiency testing and technical staining and immunohistochemistry education surveys.

Laboratory Licensure

CLIA Identification No: 34D0947174

CAP Participant No: 6932701

North Carolina Medical Board No: 39232

Visiting Eastern Carolina Pathology Laboratory

We are proud of our testing facility and services. Contact the Client Service Representative or laboratory manager at (252) 234-2841 to make an appointment to tour our laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Introduction

Anatomic pathology laboratory tests contribute significant information about your patient's health. Appropriate patient management relies in part on the accuracy of the test results. Acceptable specimen collection and specimen handling are essential prerequisites for accurate testing. Diagnostic accuracy of the test results is dependent upon the integrity of the specimens submitted for evaluation.

Preparation of the Specimen

Prior to each collection, review the APP-Eastern Carolina Pathology **Procedure and Specimen Collection Manual** for specimen requirement. Note the specimen to be collected, the amount (if applicable), the procedure, the collection materials, and handling procedures.

Confirm identification of the specimen with the test requisition. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number, date of collection, and specimen site and source, and the name on the container **must** match the name on the test form. Careful attention to detail can eliminate most errors in specimen collection and preparation. Some common errors include:

- Failure to label a specimen with correct identification
- Failure to provide pertinent information related to the patient and/or specimen
- Insufficient quantity of specimen submitted for evaluation
- Failure to tighten specimen container lids, resulting in leakage and contamination of specimen
- Failure to submit the test request form with the specimen

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Cervical / Vaginal Cytology

Regulatory agencies require that all specimens be accurately identified. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number and this name 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, patient's date of birth, patient's unique ID number on the test request form. This information will aid in the compiling of a database for retrieval of previous cytology diagnoses. Also include all pertinent clinical information (previous abnormal results, drug or radiation therapy, LMP, surgery, exogenous hormones, abnormal vaginal bleeding, IUD, hysterectomy, etc.) on the request form. This will aid in a more accurate Pap diagnosis.

A copy of the patient's insurance card should be attached to the test request for third party billing.

Patient Preparation

The optimal time for collection of the Pap test specimen is two weeks after the first day of the last menstrual period. The patient should be instructed not to use vaginal medications, spermicide, or douches 48 hours prior to the collection of the specimen. The patient should also refrain from intercourse 24 hours prior to the collection of the Pap test specimen.

Warm water should be used to lubricate the speculum. Lubricant jelly should be avoided as it often obscures cellular material making cytologic interpretation difficult or impossible. The speculum must be positioned so that the outer surface of the cervix appears at the end of the instrument, since a sample from this area is necessary for adequate specimen collection. Remove excess blood, mucus, or inflammatory material gently with a dry gauze, without forcibly removing and cellular material so this material will not compromise the evaluation of the Pap test specimen.

Liquid-Based Pap Test

1. Assemble all required supplies (speculum, collection device, vial, pen, request form).

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

2. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number, date of collection, and specimen site and source.

3. Gloves should be worn during the procedure. Care should be taken to avoid contaminating of the Pap test specimen with powder from the gloved hands.

4. Insert the speculum without lubricant-it may be moistened slightly with warm water or saline, if necessary.

5. Take the Pap test specimen prior to performing other tests on the cervix.

6. Sample the cervix with the collection device by placing gentle pressure until the bristles form against the cervix. Rotate the brush five times in a clockwise direction.

7. Remove the tip of the brush and place inside the vial.

8. If an endocervical brush is used, place the brush $\frac{2}{3}$ into the canal leaving $\frac{1}{2}$ of the brush exposed. Rotate the brush $\frac{3}{4}$ turn to scrape the mucosa in the cervix. Withdraw the instrument carefully to avoid vaginal contamination.

9. Break tip of brush and place inside the vial.

10. Dispose of the handles of the collection devices in a biohazard container.

11. Place cap on liquid-based Pap vial.

12. Place the labeled vial and test request form in a specimen bag for transport to the laboratory.

*Please note collection diagram located in the back of the **Office Procedure and Specimen Collection Manual**

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Non-Gynecologic Cytology

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

Regulation agencies require all specimens to be accurately identified. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number 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. Please include the patient's date of birth and social security number on the test request for. 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.

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

Breast Aspiration

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number, date of collection, and specimen site and source.
2. Complete the test request form. Identify the specimen source, reason for performing the aspiration and include all clinical data such as previous malignancy, drug therapy, and radiation therapy, etc. If a cyst is aspirated, indicate this on test 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 false-negative diagnosis.
4. Use a small gauge (22 or 25) needle to avoid collection and dilution with blood.
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 in to 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.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

8. Remove the needle from the syringe and pull back on the plunger before reattachment of the needle to gain positive pressure.
9. Express the specimen onto a labeled slide and make a smear.\
10. Place the slides into the alcohol fixative container.
11. Place the cap on the labeled container. Tighten the cap so as to prevent any leakage.
12. Place the labeled container and test request into a specimen bag for transport to the laboratory.

Breast Discharge / Secretion

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 subareolar and nipple with thumb and forefinger. When secretion occurs, allow a small amount to accumulate at nipple.
4. Touch a clean glass slide to the nipple and swipe.
5. Withdraw the slide from the nipple quickly and place in to alcohol fixative container.
6. Repeat procedure until all secretions are collected on one or more slides.
7. Place the labeled container and test request into a specimen bag for transport to the laboratory.

Body Cavity Fluid (effusion, paracentesis, thoracentesis)

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Identify the specimen type (adominal, pleural, cul-de-sac, pericardial) on the test request form.
3. Place the specimen in the container.
4. Complete the 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 specimens.
5. Place the labeled specimen container and completed test request 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.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Cerebral Spinal Fluid

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Identify the specimen type on the test request form.
3. Place the specimen in a Thin Prep Non-Gyn cytology vial or add Cytolyte solution to the container (one part solution to one part CSF fluid – 1:1).
4. Complete the 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 spinal fluid specimens.
5. Place the labeled specimen container and completed 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.

DO NOT SEND CSF FLUID SUSPECTED OF HAVING CREUTZFELDT-JACOB DISEASE

FNA Palpable Masses

1. Please include 2 of the following on specimen container(s) and slides: the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 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 a 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 a 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.
 - a. Place a small sample of the specimen in the middle of the labeled slide.
 - b. Invert another labeled slide against the first and gently press the slides together so the specimen spreads evenly.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

- c. Grasp the labeled ends that overhang opposite one another and slide the slides apart lengthwise .
 - d. After separation , fix the smears immediately place the slide in 95% alcohol
12. The procedure is performed several times, through the same skin incision, using a different needle and with a slightly different angle of approach.
 13. Express the specimen into the alcohol fixative vial.
 14. Rinse the needle by drawing up a small amount of alcohol from the container and aspirating it back into the container.
 15. Place the cap on the labeled container and tighten to avoid leakage.
 16. Place the labeled container and completed test request form in a specimen bag for transport to the laboratory.

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

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 alcohol fixative container. Clip the brush, leaving approximately a two inch extension, and let the brush fall into the container.
4. Place the cap on the labeled container and tighten to avoid leakage.
5. Place the labeled container and complete 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 and placing in the alcohol fixative container.

Respiratory Specimens:

Sputum

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 container.
5. Place cap on the labeled container and tighten to avoid leakage.
6. Place the labeled container and completed test request form in a specimen bag for transport to the laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Bronchial Brush

1. Label an alcohol fixative container with the patient's name and an identifying number.
2. Complete a 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. Following the brushing procedure, protrude the brush from the outer sheath over the alcohol fixative container. Clip the brush, leaving approximately a two inch extension, and let the brush fall into the alcohol fixative container.
4. Place the cap on the labeled container and tighten to avoid leakage.
5. Place the labeled container and completed 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 and placing in the alcohol fixative container.

Bronchial Wash

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 into the alcohol fixative container.
4. Place cap on the labeled container and tighten to avoid leakage.
5. Place the labeled container and completed test request form in a specimen bag for transport to the laboratory.

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

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Urine Specimens

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete a test request form. Identify the collection method (voided or catheterized). 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. A morning specimen following emptying of the bladder from the previous evening is optimal. A first morning voided specimen is **not optimal** for cytologic evaluation.
4. Place specimen in the labeled container.
5. Place the labeled container and completed 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.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Miscellaneous Specimens Collected on a Glass Slide

1. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Complete the 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 an even thin smear across the entire slide or part of slide.
4. Place slide directly into a labeled alcohol fixative container.
5. Place the labeled container and completed test request form in a specimen bag for transport to the laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Histopathology Specimens

Routine Surgical Specimens

Routine surgical specimens are tissue / biopsies specimens submitted for pathologic evaluation. A routine surgical specimen is a specimen that does not require a special procedure such as decalcification.

Regulatory agencies require all specimens to be accurately identified. It is imperative that the patient's name be written on the specimen container and the name on the container must match the name on the test request form. Proper identification and fixation of surgical specimen is imperative for reliable testing. The test request form must indicate the operative diagnosis and source of the specimen. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Complete test request forms include: specimen procurement date, patient's name, unique ID number, complete address, patient phone number, age date of birth, sex, specimen submitted, surgical site, submitting provider's name, clinical data (previous history), and surgeon's diagnosis..

A copy of the patient's insurance information should be attached to the test request for third party billing if not filled out on test request.

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, contact the physician.

Biopsy / Tissue (routine surgical specimen)

1. Place all routine biopsy specimens immediately in ten times it's volume of
2. 10% buffered neutral formalin. Small pieces of tissue can be ruined in a short time by placing in saline or allowing to dry.
2. At the time the tissue is removed by the physician, label the tissue container (not the lid) with the patient's name and type of tissue. If multiple specimens are submitted for a single patient, identify each specimen container as A...B...C...or D (the description at A...B...C...D on the test request form must match each container submitted and labeled as A...B...C...D).
3. Place the lid on the specimen container and close lid tightly to prevent leakage.
4. Complete the 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.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

5. Place the labeled specimen container and completed test request form in a specimen bag for transport to the laboratory. Include only one patient specimen(s) per bag.

Bone Marrow Specimens

Bone marrow specimens consist of aspirated and biopsy material from the hematopoietic (medullary) bone. A peripheral smear and CBC report must 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 be written on the specimen container and the name on the container must match the name on the test request form. Proper identification and fixation of surgical specimen is imperative for reliable testing. The test request form must indicate the operative diagnosis and source of the specimen. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Complete test request forms include: specimen procurement date, patient's name, social security number, complete address, patient phone number, age date of birth, sex, specimen submitted, surgical site, clinical data (previous history), surgeon's diagnosis, and referring physician.

A copy of the patient's insurance card should be attached to the test request for third party billing if not filled out on test request.

Patient Preparation

The patient is prepared and the specimen is collected in the physician's office or hospital. For more information on patient preparation, contact the physician.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Bone Marrow Technique

1. Place the bone marrow core biopsy in ten times its volume of 10% buffered neutral formalin. Touch preps may be made before the core is placed in formalin (this is left up to the discretion of the physician). Label 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 several from each aspirate at the time of the collection. These smears may be placed on frosted end slides or on coverslips. Eastern Carolina Pathology requires frosted end slides, therefore the patient's name can be identified on the frosted end.
3. Place the smears in a slide folder, tape the folder closed and label the outside of the folder with the patient's name.
4. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent data. This information is critical to an accurate diagnosis on bone marrow specimens.
5. Place the peripheral smears, core biopsy, and aspirate biopsy in a specimen bag for transport to the laboratory. Include only one patient's specimen per bag.
6. Place the completed test request form, hematology report, peripheral smear report in the outside pocket of the transport bag.

Frozen Section Specimens

Frozen section specimens consist of specimens removed, frozen, and examined microscopically at the time of surgery. Surgical test request for frozen sections should include operative diagnosis and must include source of specimen.

Regulatory agencies require all specimens to be accurately identified. It is imperative that the patient's name be written on the specimen container and the name on the container must match the name on the test request form. Proper identification and fixation of surgical specimen is imperative for reliable testing. The test request form must indicate the operative diagnosis and source of the specimen. Unidentified specimens will be returned to the submitting office unprocessed. It will be the physician's office responsibility to correct errors in specimen identification.

Complete test request forms include: specimen procurement date, patient's name, social security number, complete address, patient phone number, age date of birth, sex, specimen submitted, surgical site, clinical data (previous history), surgeon's diagnosis, and referring physician.

A copy of the patient's insurance card should be attached to the test request for third party billing if not filled out on test request.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

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, contact the physician.

Frozen Section Procedure

1. Contact the pathology department and coordinate the frozen section procedure with the staff pathologist.
2. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. This information is critical to an accurate diagnosis on frozen section specimens.
3. Label a sterile/clean and empty specimen container as appropriate with the patient's name and identification of tissue type and source of specimen.
4. Place the piece of fresh tissue in the clean specimen container. Do not put the specimen in fixative/formalin solution.
5. Place labeled specimen container and frozen section test request form in a specimen bag for transport to the laboratory.
6. The pathologist will phone the attending physician with the preliminary diagnosis.
7. A final report will be issued after permanent sections of the tissue submitted is evaluated.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Autopsy Requests

Eastern Carolina Pathology will perform autopsy analysis when requested.

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 contagious disease or epidemic); deaths without medical attendance; and deaths of migrant agricultural workers and their dependents.

Autopsy Request Procedure

1. Contact Eastern Carolina Pathology and schedule the procedure with the pathologist on-call. If calling after normal business hours, telephone the Wilson Medical Center switchboard at (252) 399-8040 and have the pathologist on-call paged.
2. Please provide the following information: name, address, date of birth if known, time and date of death if known, suspected cause of death if known, medical history (including prescription medications), 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 90 days from the date of the procedure for the majority of cases.
5. A copy of the report can be obtained via fax or mail, or in medical examiners cases from the Office of Chief Medical Examiner at (919)966-2253.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Introduction

Eastern Carolina Pathology 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 HPV DNA ASSAY, FLOW CYTOMETRY / CYTOGENETICS, DIRECT IMMUNOFLUORESCENCE, and molecular studies.

REFLEX HPV DNA ASSAY (Liquid Based Pap Test Specimen Procedure)

The assay will aid in the diagnosis of sexually transmitted HPV infections with types 6, 11, 16, 18, 31, 33, 35, 42, 44, 45, 51, 52, and 56. The assay will distinguish between HPV types 16, 18, 31, 33, 35, 45, 51, and 56 which are typically associated with all grades of squamous intraepithelial lesions, especially high grade squamous intraepithelial lesions (HGSIL) and invasive cancer of the cervix. The assay can be utilized to identify those individuals at increased risk for squamous intraepithelial lesions (SIL) and to aid in the triage of patients with equivocal or ASCUS (atypical squamous cells of undetermined significance) Pap results in order to better determine the need for colposcopy.

Regulatory agencies require that all specimens be accurately identified. It is imperative that the patient's name be 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 off responsibility to correct errors in specimen identification.

Eastern Carolina Pathology does offer reflex DNA testing. Please include the patient's name, date of birth, and social security number on the test request form. Write on the request for "Please send for HPV testing" if your office has not signed an **HPV REFLEX AGREEMENT** with Eastern Carolina Pathology. These agreements can be obtained through the client service representative and can be made with many different diagnosis. The liquid-based pap will be performed first, followed by the HPV DNA ASSAY. The HPV DNA ASSAY may be requested after the pap test results have been received by the clinician's office. The patient's specimen is kept in storage for 4 weeks. The order can be taken by phone or by filling out the "Request for HPV" form provided by your client service representative.

A copy of the patient's insurance information should be attached to the test request and fax request for third party billing.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Test Methodology for HPV DNA Assay – Liquid-Based Pap Test

1. Assemble all required supplies (speculum, collection device, vial, pen, request form).
2. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
3. Gloves should be worn during the procedure. Care should be taken to avoid contaminating of the Pap test specimen with powder from the gloved hands.
4. Insert the speculum without lubricant-it may be moistened slightly with warm water or saline, if necessary.
5. Take the Pap test specimen prior to performing other tests on the cervix.
6. Sample the cervix with the collection device by placing gentle pressure until the bristles form against the cervix. Rotate the brush five times in a clockwise direction.
7. Remove the tip of the brush and place inside the vial.
8. If an endocervical brush is used, place the brush $\frac{2}{3}$ into the canal leaving $\frac{1}{2}$ of the brush exposed. Rotate the brush $\frac{3}{4}$ turn to scrape the mucosa in the cervix. Withdraw the instrument carefully to avoid vaginal contamination.
9. Break tip of brush and place inside the vial.
10. Dispose of the handles of the collection devices in a biohazard container.
11. Place cap on liquid-based Pap vial.
12. Place the labeled vial and test request form in a specimen bag for transport to the laboratory.

*Please note collection diagram located in the back of the **Office Procedure and Specimen Collection Manual**

FLOW CYTOMETRY AND/OR CYTOGENETICS/MOLECULAR – SPECIAL STUDIES

Flow Cytometry/Cytogenetics/Molecular or other studies can be performed on bone marrow, bone marrow core biopsy specimen, blood, placental tissue, molecular studies on body fluid and fresh surgical tissue specimens. Flow Cytometry / Cytogenetics, or molecular studies, can be utilized to ascertain the definitive diagnosis of various pathologic processes or as a guide to treatment All collection tubes, containers, and solutions can be supplied by the laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Regulatory agencies require that all specimens be accurately identified. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number 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 off 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. Write on the test request form "FLOW CYTOMETRY and/or CYTOGENETICS /MOLECULAR TESTING. A copy of the patient's insurance card should be attached to the test request for third party billing.

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, contact the attending physician.

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. Rearrangement by Southern Blot requires 7 ml of bone marrow collected in a purple top tube containing EDTA.
4. Label the specimen containers with the patient's name and tissue type.
5. Complete the test request form. Identify the specimen source, operative diagnosis and all pertinent clinical data. Indicate on the test request "Flow Cytometry and/or Cytogenetic or other testing.
6. Place the labeled specimen tube(s) and completed 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 top tube containing sodium heparin.
2. Flow Cytometry requires 10-20 ml of blood in a heparin/EDTA tube containing ACD. (This specimen tube must accompany all bone marrow specimens.)
3. Gene rearrangement by Southern Blot requires a minimum of 15 ml of blood in a purple top tube containing EDTA.
4. Label the specimen containers with the patient's name and tissue type.
5. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. Indicate on the test request "Flow aCytometry and/or Cytogenetic or PCR" testing.

Specimen Collection and Preparation

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

6. Place the labeled specimen tube(s) and completed test request form in a specimen bag for transport to the laboratory.

Fresh Biopsy / Tissue

1. Flow cytometry requires a minimum of one 0.5 x 0.5 x 2.5 cm piece of fresh tissue placed in RPMI media. (Four or more pieces are preferred.)

2. Cytogenetics requires one piece of fresh tissue, 2.0 x 2.0 x 0.2 cm placed in RPMI media.

3. FISH or molecular studies can be performed on fresh tissue or paraffin embedded formalin fixed tissue dependent upon test. Please contact lab for specific directions.

4. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. Indicate on the test request "Flow Cytometry and/or Cytogenetic" testing.

5. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number and site.

6. Place the labeled specimen tube(s) and completed 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 equal volume of appropriate fixative.

2. Label the specimen container with the patient's name and tissue type.

3. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. Indicate on the test request "Flow Cytometry" testing.

4. Place the labeled specimen tube(s) and completed test request form in a specimen bag for transport to the laboratory.

Cerebrospinal Fluid

1. Flow Cytometry requires equal volume of CSF and appropriate fixative. As much CSF as possible should be collected and submitted.

2. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number and tissue type.

3. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. Indicate on the test request "Flow Cytometry" testing.

4. Place the labeled specimen tube(s) and completed test request form in a specimen bag for transport to the laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

DIRECT FLUORESCENCE

Immunocytochemistry 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.

Regulatory agencies require that all specimens be accurately identified. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number 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 off responsibility to correct errors in specimen identification.

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

A copy of the patient's insurance information should be attached to the test request for third party billing.

Please contact Eastern Carolina Pathology at (252) 234-2841 for instructions for special media.

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, contact the attending physician.

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.

1. Label specimen container with patient's name and tissue type.
2. Complete the test request form. Identify the specimen source, operative diagnosis, and all pertinent clinical data. Indicate on the test 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 test request in a specimen bag for transport to the laboratory.

APP-ECP Specimen Collection Manual

Specimen Collection and Preparation

Stat / Rush Specimen Requests

Stat / Rush specimen requests are honored at Eastern Carolina Pathology. 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 communicated to the physician ir designee.

Regulations require that all specimens be accurately identified. Please include 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number 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 off 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 test request form with all required information.
2. Please write the word "STAT" or "RUSH" on the test request form. Please do not obscure the clinical or demographic information.
3. Place the labeled specimen container and completed test request form in a specimen bag for transport to the laboratory.

APP-ECP Specimen Collection Manual

Specimen Rejection Criteria

Each specimen received in the laboratory must be properly and accurately identified. The name on the 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 and Preparation” chapter of this manual, the laboratory will return the specimen to the submitting office unprocessed. Before returning, APP-ECP will call the submitting client to discuss the case regarding handling.**

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

1. A specimen (slide, formalin bottle, liquid-based pap vial, alcohol fixative container) received in the laboratory without 2 of the following on specimen container(s): the patient's name, patient's date of birth, patient's unique ID number.
2. Specimens with incomplete test request form.
3. Any specimen that has not been properly submitted in fixative.
4. Urine that has been collected for more than two (2) hours and allowed to sit at room temperature, i.e. non-refrigerated.
5. Any specimen grossly unsatisfactory in volume, i.e. specimen container is empty.
6. 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 container or glass slides.
7. Any syringe with an attached needle.
8. Any specimen that is submitted by an unauthorized source.

Attestation Policy for Patient-Specimen Identification

When a specimen is received by Eastern Carolina Pathology and a discrepancy is noted:

- The name on the requisition, slides, specimen container and test request form does not match.
- Incomplete test request forms (the forms must contain patient name, date of birth, identification 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.

1. Telephone Verification
 - Lab Personnel will call your office and inform you of the discrepancy.
 - The office contact person's name, telephone number and date and time of the discussion is recorded on the test request form.

APP-ECP Specimen Collection Manual

Specimen Rejection Criteria

- The entry is initialed and dated by the Eastern Carolina Pathology/Wilmed employee who placed the call.
 - The same employee will fax an Attestation Statement For Patient-Specimen Identification to the submitting office.
 - 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.
 - The attestation statement is attached to the requisition and remains a part of the patient's record.
2. Returning Specimens to Submitting Office for Verification
- Specimen(s), accompanying paperwork, and a Attestation Statement Form-Specimen Identification are returned to the submitting office by courier.
 - The submitting office will review the problem and return the corrected specimen, paperwork, and completed attestation statement to the lab by the courier.
 - The attestation statement is attached to the requisition and remains part of the patient's record.

APP-ECP Specimen Collection Manual

Guide to Completing Test Request Forms

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. Eastern Carolina Pathology 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 from patient
- 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 diagnosis codes
- complete name of the insurance company, address, and phone number
- provide secondary insurance information if applicable

Eastern Carolina Pathology prefers a copy of the third party payor card. This procedure eliminates the mistakes caused by illegible hand writing and missing necessary information.

APP-ECP Specimen Collection Manual

Guide to Completing Test Request Forms

Please include the following information on all test request forms to facilitate accurate record keeping and patient tracking.

All Test Request Forms Should Have:

- patient's unique identifying number
- patient's full name
- patient's date of birth
- submitting physician's name
- billing information

Requests For Paps Should Have:

- source of specimen
- specimen procurement date
- collection technique
- date of last menstrual period (LMP)
- previous treatment procedures (date of procedure and results)
- patient clinical data (preg., lactating, oc's, post menopause, HRT, PP, IUD, PMP bleeding, etc...)
- previous cytology information (WNL, atypical, dysplasia , CA-in-situ, previous number and date)

Requests For Non-Gyns Should Have:

- 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)

Requests For Surgical Specimens Should Have:

- 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 each container submitted and labeled as A..B..C..D)
- operative diagnosis
- relevant clinical findings and patient history
- previous abnormal biopsy (date of procedure and diagnosis rendered)

APP-ECP Specimen Collection Manual

Guide to Completing Test Request Forms

Please include the following information on all test request forms to facilitate accurate record keeping and patient tracking.

Ancillary Test Requests Forms Should Have:

- patient's identifying number
- patient's full name
- patient's date of birth
- submitting physician's name
- billing information

Requests For HPV DNA Assays Should Have:

- source of specimen
- specimen procurement date
- collection technique
- date of last menstrual period (LMP)
- previous treatment procedures (date of procedure and results)
- patient clinical data (preg., lactating, oc's, post menopause, HRT, PP, IUD, PMP bleeding, etc...)
- previous cytology information (WNL, atypical, dysplasia , CA-in-situ, previous number and date)

Requests For Flow Cytometry and/or Cytogenetics or PCR Testing Should Have:

- 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 each container submitted and labeled as A..B..C..D)
- operative diagnosis
- relevant clinical findings and patient history
- previous abnormal biopsy (date of procedure and diagnosis rendered)

Requests For Direct Fluorescence Testing Should Have:

- specimen procurement date
- description / source and location of specimen removed (i.e. mole / left upper arm)

APP-ECP Specimen Collection Manual

Sample Reports

- 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 each container submitted and labeled as A..B..C..D)
- operative diagnosis
- relevant clinical findings and patient history
- previous abnormal biopsy (date of procedure and diagnosis rendered)

Cytology – Pap Test

The National Cancer Institute recommends using the “Bethesda System” of reporting for cervical/vaginal specimens. This system of reporting replaces the traditional Pap class system. The standardizing language of the Bethesda System should provide a better and more consistent means of communication of Pap results between physicians and laboratories.

The Cytology Report will include:

- patient’s name, identifying number, address (if given), date of birth, age, sex, LMP (if given)
- submitting physician’s name
- laboratory accession number
- date specimen collected and received
- type of specimen received
- specimen diagnosis
- statement of specimen adequacy
- signature of cytotechnologist and pathologist (if applicable) reviewing the case
- reporting date
- name of laboratory medical director
- location of submitting physician and request for copies to be submitted to other physicians (if applicable)
- triage area including Pap test date and diagnosis

The Non-Gyn Cytology Report will include:

- patient’s name, identifying number, date of birth, age, and sex
- submitting physician’s name
- laboratory accession number
- date of specimen collected and received
- date specimen reported
- clinical information
- tissue submitted and gross description
- microscopic description
- diagnosis
- pathologist’s signature
- location of submitting physician

APP-ECP Specimen Collection Manual

Sample Reports

The Surgical Pathology Report will include:

- patient's name, identifying number, date of birth, age, and sex
- tissue submitted and gross description
- microscopic description
- submitting physician's name
- diagnosis
- laboratory accession number
- pathologist's comment
- date specimen collected and received
- signature of pathologist and date specimen reported
- submitting physician's location

Ancillary test reports will be issued by the laboratories which perform the tests and passed on to the requesting physician's location. A copy of the reports will be kept by Eastern Carolina Pathology and attached to the patient's record.

APP-ECP Specimen Collection Manual

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 Client Service Representative or Manager. **Please check the appropriate billing box on the test request form.**

Client / Physician Office Billing

Clients will be bill monthly. The physician's office will receive an itemized roster and invoice containing the date, patient's name specimen identification number, CPT code, number of tests for CPT code, 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 contact the Client Billing office at Eastern Carolina Pathology at (252) 234-2841. Any adjustments will appear on the next month's bill.

Insurance / Third-Party Billing

Eastern Carolina Pathology 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 becomes 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 (843)664-4300.

As a service to your patients, Eastern Carolina Pathology will bill your patient's primary insurance company and managed care organization directly when provided with **complete** and **accurate** billing information. Please provide a photo copy of the insurance card including front and back. If a photo copy can not be made, please make sure all appropriate boxes on the test request form are completed. 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.)

- specimen procurement date
- patient's complete name
- 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-9 diagnosis code
- complete name of insurance company and address
- patient member identification number
- group identification number

APP-ECP Specimen Collection Manual

Billing Procedures

Medicare

Eastern Carolina Pathology is a participating supplier with the Medicare program and we are required by CMS to file all claims for laboratory services rendered. Eastern Carolina Pathology 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. **Medicare will pay for one routine screening Pap test every two years.** Pap tests performed more than once every two years must be supported with the appropriate ICD-9 code or clinical description.

CMS and Medicare carriers have developed a system using ICD-9 diagnosis codes to prevent payment of claims that they determine not to be medically necessary. It is critical that a code used for ordering the anatomic pathology service/ test be consistent with the documentation in the patient's medical records. The ICD-9 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 reimbursement is denied due to lack of medical necessity, Medicare rules allow the laboratory to subsequently bill the patient only if the patient has signed and dated the Advanced Beneficiary Notice (ABN) prior to the testing procedure. To comply with HCFA guidelines for Medicare reimbursement, please be certain to include the appropriate ICD-9 code or clinical description on both the test request and in the patient records and always have the patient date and sign the Advanced Beneficiary Notice. This is especially important, when it is believed the service is likely to be denied (ie.. more than one screening Pap test in two years).

If you or the patient have questions regarding third-party billing (private insurance, managed care organizations, Medicare, or Medicaid), please call our Insurance / Third-Party billing office at (843) 664-4300.

The following information must be provided to Eastern Carolina Pathology for Medicare billing:

- patient's full name (as it appears on card)
- patient's complete address
- patient's sex and date of birth
- Medicare Number
- referring physician name
- ICD-9 diagnosis code or clinical description
- signed Advanced Beneficiary Notice (if applicable)

APP-ECP Specimen Collection Manual

Billing Procedures

Medicare

Eastern Carolina Pathology is a participating supplier with the Medicare program and we are required by CMS to file all claims for laboratory services rendered. Eastern Carolina Pathology 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. **Medicare will pay for one Pap screening test every two years.** Pap tests performed more than once every two years must be supported with the appropriate ICD-9 code or clinical description.

CMS and Medicare carriers have developed a system using ICD-9 diagnosis codes to prevent payment of claims that they determine not to be medically necessary. It is critical that a code used for ordering the anatomic pathology service/ test be consistent with the documentation in the patient's medical records. The ICD-9 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 reimbursement is denied due to lack of medical necessity, Medicare rules allow the laboratory to subsequently bill the patient only if the patient has signed and dated the Advanced Beneficiary Notice (ABN) prior to the testing procedure. To comply with HCFA guidelines for Medicare reimbursement, please be certain to include the appropriate ICD-9 code or clinical description on both the test request and in the patient records and always have the patient date and sign the Advanced Beneficiary Notice. This is especially important, when it is believed the service is likely to be denied (ie.. more than one screening Pap test in two years).

If you or the patient have questions regarding third-party billing (private insurance, managed care organizations, Medicare, or Medicaid), please call our Insurance / Third-Party billing office at (843)664-4300.

The following information must be provided to Eastern Carolina Pathology for Medicare billing:

- patient's full name (as it appears on card)
- patient's complete address
- patient's sex and date of birth
- Medicare Number
- referring physician name
- ICD-9 diagnosis code or clinical description
- signed Advanced Beneficiary Notice (if applicable)

APP-ECP Specimen Collection Manual

Billing Procedures

Medicaid

Eastern Carolina Pathology 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 Eastern Carolina Pathology for Medicaid billing:

- patient's full name (as it appears on the card)
- patient's complete address
- patient's sex and date of birth
- patient's Medicaid number
- referring physician's name
- ICD-9 diagnosis code or clinical description

Other

Eastern Carolina Pathology will file claims and accept payment from Champus, Workman's Compensation and Vocational Rehabilitation, etc. Please include all appropriate information on the test request form. Please call (843) 664-4300 if you have any questions.

Questions Regarding Billing

If you or your patients have questions regarding bills the patient has received from the laboratory, please refer them to the client service representative at (252) 234-2841 or our insurance / third-party billing office at (843) 664-4300.

Financial Hardship Patients

Eastern Carolina Pathology recognizes the inability of some patients to pay for necessary anatomic pathology and cytology screening. This also includes patients who do not have insurance coverage for specified anatomic pathology and cytology screening. The laboratory will assume financial responsibility for these cases. The doctor's office personnel must indicate on the test request form the patient's inability to pay for the testing / screening services by writing "HARDSHIP" in the billing information check box area.

APP-ECP Specimen Collection Manual

Important Phone Numbers and Address

Laboratory Main Line	(252) 234-2841
FAX	(252) 234-9270
Pathologists	(252) 399-8157
Cytology	(252) 234-2841
Histology	(252) 399-8723/ (252) 234-2841
Courier Service	(252) 234-2841
Client Billing Representative	(252) 234-2841
Insurance / Third-Party Billing	(843) 664-4300
Client Service Representative	(252) 234-2841
Copy of Final Histology Report	(252) 234-2841
Copy of Final Cytology Report	(252) 234-2841
Request for Courier Pick-up	(252) 234-2841
Request for Supplies	(252) 234-2841
Or FAX supply requests to	(252) 234-9270

Hours of Operation 8:00 am to 4:30 pm Monday through Friday

Mailing Address for Main Laboratory:

**Eastern Carolina Pathology
PO Box 3898
Wilson, NC 27895**

Physical Address for Main Laboratory

**Eastern Carolina Pathology
2693-Suite B Forrest Hills Road**