



**PATHOLOGY
LABORATORIES
OF ARKANSAS, P.A.**

A TRADITION OF PROFESSIONAL EXCELLENCE

**PROVIDING TIMELY, CONVENIENT, ECONOMICAL AND
ACCURATE PATHOLOGY SERVICES FOR
PATIENT CARE**

A Message From The Pathology Laboratories of Arkansas, P.A. (PLA) Staff

Pathology Laboratories of Arkansas, P.A. (PLA) was formed over 30 years ago by four pathologists who shared lofty standards of professional expertise and common ideals of personal and professional integrity.

For many years our practice has been predominantly confined to hospitals in the Central Arkansas region. However, there has been steady growth in the service needs of both hospitals and physician offices. Pathology Laboratories of Arkansas, P.A. (PLA) has expanded to meet the service requirements of Central Arkansas. Today PLA is a thriving, independently owned and operated pathology practice comprised of ten full-time pathologists and 30 staff members. Our strategy of controlled conservative expansion has carefully maintained PLA's tradition of excellence.

The pathologists and staff members of PLA are acutely aware, however, of the shift in service needs toward the outpatient sector. In response, we have committed ourselves to build from our foundation of excellence an organization that is more "user friendly" for physician's offices and other outpatient providers.

This manual is one method of achieving this goal. It provides basic information to help you use our services. If you cannot find the information you need in this manual, please call Tracy A. Smith at the Pathology Laboratories of Arkansas, P.A. Administrative Office at 501-225-2760 or 1-888-809-3730; or call one of our pathologists at 501-202-2888. Your concerns are very important to us. We will make every effort to address your problems in an efficient, timely manner.

Sincerely yours,

PLA Staff

Pathology Laboratories of Arkansas, P.A. Directory of Services

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Staff of Pathology Laboratories of Arkansas, P.A.

Our commitment to excellent and “user friendly” patient care is a team effort and requires a broad range of talented, dedicated individuals.

PATHOLOGISTS:

Rex H. Bell, M.D.
Amy R. Hudson, M.D.
Dianne F. Johnson, M.D.
Gary S. Markland, M.D.
Hal E. Palmer, M.D.
Maria C. Porter, M.D.
Brian D. Quinn, M.D.
Michelle Riddick, M.D.
Rickey O. Ryals, M.D.
Robert O. Shaver, M.D.
Elizabeth N. Schneider, M.D.
L. Gene Singleton, M.D.
John E. Slaven, M.D.
Brent C. Staggs, M.D.

ADMINISTRATOR:

Keith E. Miller

CLIENT SERVICE REPRESENTATIVE:

Tracy A. Smith

PATHOLOGY ASSISTANTS:

Steve Evans, Supervisor
Laurie Willcott, Assistant Supervisor
Steve Herring
Lindsey Hughes
Jessica Loughmiller
Bob Lynch
Amy Rhodes, PA (ASCP)
Makesha Thompson

TISSUE LAB ASSISTANT:

Shirley Bryant

CYTOTECHNOLOGISTS:

Pam Turnage, SCT (ASCP), Supervisor
Deborah Hardin, CT (ASCP)
Richard “Tony” Mitchell, CT (ASCP)
Van Raney, SCT (ASCP)

CYTOLOGY PREPARATION TECHNICIANS:

Susan Moore
Emily Riddling
Adrian Cothrel

COURIERS:

John Stitt
James Shenep

BILLING OFFICE STAFF:

Debbie Coleman
Rita Shepherd
Stacy Hall
Melissa Lambert
Michelle McEuen
Shari Mills
Sandy Parish
Rhonda Snyder
Linda Suggs

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GENERAL INFORMATION— PROFESSIONAL AND TECHNICAL SERVICES

Accreditation and Licensure

Pathology Laboratories of Arkansas, P.A. is dedicated to providing highest quality logistical support, technical services and medical professional services to patients, physician’s office staff, and to physicians. We recognize that our long-term success requires a total commitment to exceptional standards of service and support.

Our desire is that you will recognize, from the initial test requisition to the final report, a service and support team that can only be found in a locally owned and operated physician group.

Pathology Laboratories of Arkansas, P.A. is routinely subjected to the laboratory quality standards of all state and federal inspection agencies. We are licensed, accredited, and/or certified by the following organizations and government entities:

| Organization | Respective Numbers |
|--|--------------------|
| College of American Pathologists | 34112-02 |
| CLIA Number | 04D0467366 |
| Tax ID Number | 71-0410253 |
| Ark Medicare # | 57285 |
| Ark Medicaid # | 104544002 |

General Information

Our pathologists’ professional training is centered around providing daily, consistently excellent, accurate professional services to physicians and patients. In today’s more competitive environment we must respond with improved service to raise the quality, efficiency and availability of the medical care we provide.

The combination of an independently owned local pathology group with deeply rooted traditions of professional excellence is an unparalleled inheritance and will always be the foundation for our continued growth and changing service needs.

Our laboratory is directed by Board certified pathologists. The pathologists are responsible for the laboratory on a full-time basis and are directly involved in ensuring that the laboratory’s performance is meeting the needs of our referring physicians and patients.

Several of our pathologists serve regularly as voluntary members of the College of American Pathologists’ Laboratory Accreditation Program inspection teams. This inspection activity affords the pathologist the opportunity to assure that Pathology Laboratories of Arkansas, P.A. is abreast of the latest developments in laboratory technology and quality assurance.

The laboratory also consists of highly trained technical staff and medical laboratory technologists. Our pathologists, serving as the Laboratory Directors, ensure that our staff is able to provide the level of competency that patients and our referring physicians deserve. A variety of in-house programs and outside continuing educational programs are used to promote consistent, accurate and timely testing results.

Quality controls and preventive maintenance are performed and recorded daily by our technologists. The Laboratory Director reviews these records to ensure accurate and reliable test results.

Monthly quality control meetings in which unusual cases are discussed are just another method utilized to ensure that both our pathologists and technologists are consistent and accurate in their diagnostic skills.

All laboratory reports are reviewed prior to distribution to ensure the transfer of high quality diagnostic and/or therapeutic information to the clinical decision maker. All charges are also reviewed to ensure that only services provided will be reflected on the billing statements

Pathology Reports

Pathology Laboratories of Arkansas, P.A. realizes that the accuracy, clarity and format of our reports are an essential part of our business. Reporting can often vary because of the complexity of the testing process. We have endeavored to keep our reports concise in design with only a minimal amount of modifications through the years.

For your convenience, reports can be delivered by courier, by telecommunication devices (telephone, printers, faxes or other office systems) or by mail. For telephone requests, please call our client support line 225-2760 or 1-888-809-3730.

General Information— Client Support Services

Pathology Consultation

With ten full-time pathologists, Pathology Laboratories of Arkansas, P.A. is able to provide our clients with local pathology consultation services. All pathologists are Board certified and are available for consultations by calling (501) 202-2888 for the Little Rock area or (501) 450-2188 for the Conway area. You may also use our 888 number to avoid long-distance charges if you are not in one of these local areas: (888) 809-3730.

Whether it is to discuss a pathology report or actually sit down with the pathologist and review the slides, we hope you recognize our availability for consultations as a major benefit of using our local services.

Courier Services

An important part of our support service is our courier team. Our couriers are available for daily pick-ups and delivery of reports. We are also able to provide customized courier service in the metropolitan areas with multiple daily pick-ups.

We can schedule once a day pick-ups in the afternoon for clients outside the metropolitan areas. We are committed to providing a dependable, quality courier service for prompt delivery of reports and supplies for specimen procurement.

Client Service

In an effort to better meet the needs of our clients and to provide easier, more efficient access to our services, we have added a

client service representative who is able to respond to any questions which you may have. From supply requests, stat specimen pick-up requests, to obtain pathology or cytology reports, or to schedule a call-in pick-up, our client service phone numbers are all you need to call.

Client services can be reached by calling 501-225-2760 for Little Rock and surrounding areas. You may also use our 888-809-3730 number to avoid any long-distance charges from any location. You will find customer-oriented, responsible client service representatives to provide you with a professional and convenient method to answer questions, request supplies or simply provide you with general information.

Physician Office Laboratory Consulting

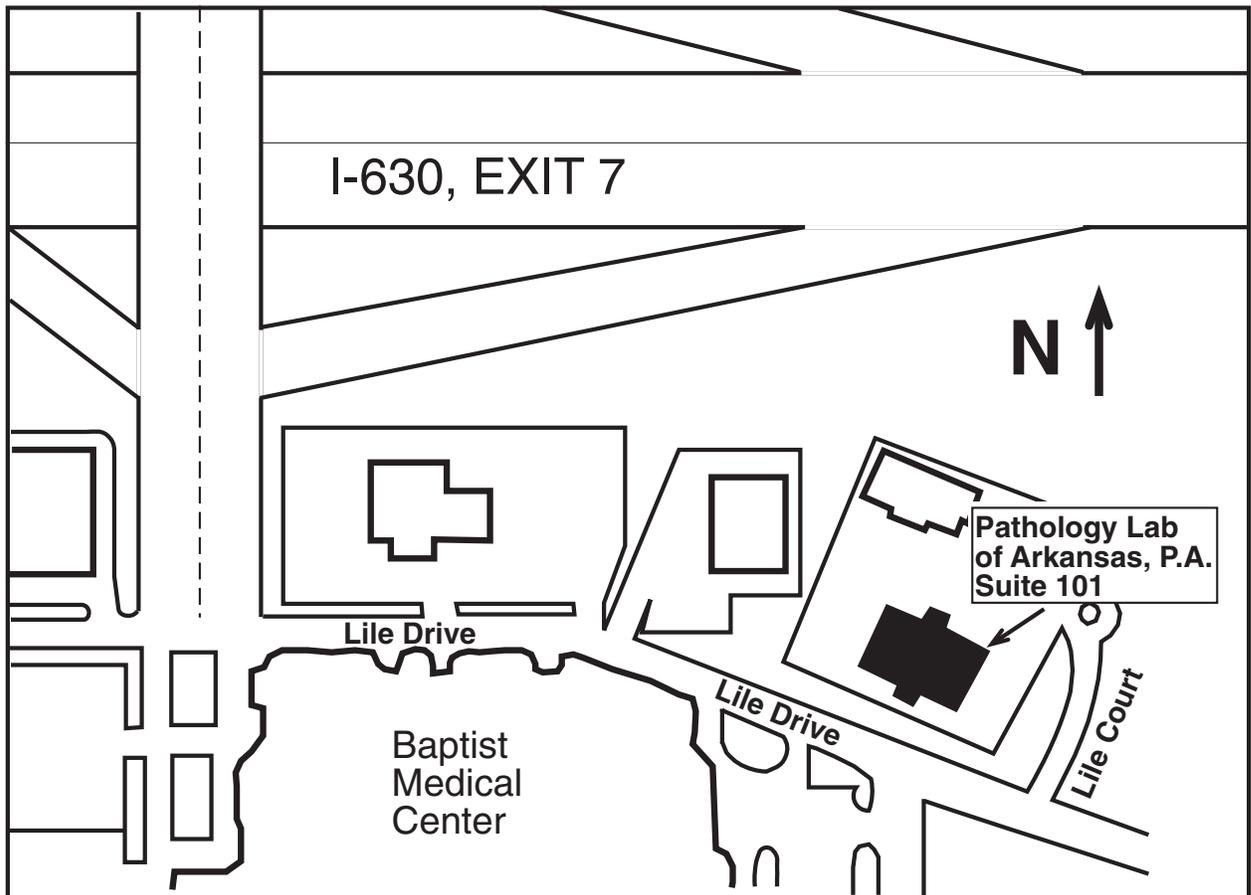
PLA provides services of a designated clinical pathologist to discuss specific lab results or to provide consultation for specific problems your laboratory may be experiencing.

Business Office

Our business office is conveniently located adjacent to Baptist Medical Center, allowing for excellent accessibility from various locations around Central Arkansas (see map). The office hours are from 9:00 AM to 5:00 PM Monday through Thursday and 4:30 PM Friday.

Pathology Laboratories of Arkansas, P.A.

Business Office
#1 Lile Court, Suite 101
Little Rock, AR 72205
501-225-2760
888-809-3730



General Information— Administrative Support Services

Requisition

To simplify our testing services, Pathology Laboratories of Arkansas, P.A. is now using a single test requisition form for all laboratory services. Each requisition is a multi-part form allowing appropriate clinical data, patient information and insurance information to be completed.

The following information is required on the requisition in order to process the specimen and bill for the services rendered:

Patient Information Section

- Patient name, sex, date of birth and other relevant demographic information.

Specimen Information

- Specimen collection date, specimen type and the source of the specimen.
- Provide a written diagnosis or ICD-9 code.
- Indicate special requests and pertinent clinical history.

Billing Information

- Indicate if the billing should be to the referring physician/clinic, to an insurance/HMO/PPO/PCN, to the patient, Medicare or to Medicaid by checking the appropriate box.
- If we will be billing the patient, record the patient's address, telephone number, social security

number, and the responsible party's name in the billing information section.

- If Medicare or Medicaid billing is needed, record the patient's Medicare or Medicaid number in the appropriate section. It is also necessary for Medicare patients to sign the Advance Waiver Statement. This will allow us to bill the Medicare allowable amount to the patient should the testing be considered a non-covered screening service.
- If we are to bill the patient's insurance, record the following information for the primary and, if applicable, the secondary insurance carriers:
 - The patient's home address and telephone number;
 - The patient identification number or social security number;
 - The insurance company(ies) name(s);
 - The insurance group identification number;
 - A responsible party's name, phone number and place of employment.

Testing Requested

- Indicate testing desired with notation of any special requests. Use any test name which is listed in this Service Directory. The special requests may be listed in the area provided.

Monthly Physician Billing

If the client prefers to be billed directly for our laboratory services, an itemized monthly statement will be provided each month detailing the services provided. The itemization will include the date-of-service, patient name, procedure code and charges. Discounts are available to our physician accounts. Please contact our office if you would like to discuss this billing option.

Direct Patient Billing

If the client prefers, Pathology Laboratories of Arkansas, P.A. will bill patients directly for our services. The necessary box should be checked and appropriate billing information recorded on the test requisition. Each test requisition will result in a separate bill from Pathology Laboratories of Arkansas, P.A.. We utilize CPT coding procedures as prescribed by the American Medical Association and recognized by most third-party payors.

Patient billing is due upon receipt and Pathology Laboratories of Arkansas, P.A. will seek payment for any unpaid bills with subsequent monthly statements, letters, and normal collection activity.

Third-Party Billing

Pathology Laboratories of Arkansas, P.A. will directly file insurance to third-party agencies. In most cases the patient will be billed concurrently with the insurance company. The patient will be responsible for payment of total charges which may include denied claims, co-payments, deductibles, and amounts above the company's usual, customary and reasonable (UCR) fee schedule. Contractual exceptions to this include: Medicare, Medicaid, Blue Cross and Blue Shield, FirstSource and Health Advantage.

To ensure proper submission and payment of your patient's insurance claims, please make certain that all necessary billing information is recorded, current and correct. It is particularly important that Medicare and Medicaid numbers be recorded in the spaces provided and that the patient's name be recorded as it appears on their Medicare and Medicaid cards.

In addition, Medicare, Medicaid and most third-party payors are now requiring a written diagnosis or diagnosis code per the ICD-9 terminology before payment can be made. Some testing, such as Pap smears, will not be paid in concurrent years unless the patient has a medical diagnosis supporting the testing.

Note: This form may not be representative of the most current requisition.



**HISTOLOGY/CYTOLOGY
REQUISITION**

#1 Lile Court, Suite 101
Little Rock, AR 72205
501-225-2760
1-888-809-3730

Pathology
Laboratories
Of Arkansas, P.A.

Information Provided By: _____

DOCTOR: _____

For Lab Use

Accession#: _____

Charge Code(s): _____

SHADED FIELDS INDICATE REQUIRED PATIENT INFORMATION. FAILURE TO COMPLETE ALL FIELDS WILL RESULT IN DELAYS OF SPECIMEN PROCESSING.

| PATIENT INFORMATION | | | | | | | |
|---|------|------|---|-----------------|-----------------|-----------------------------|--|
| LAST NAME: | | | FIRST NAME: | | | MIDDLE INITIAL: | |
| ADDRESS: | | | | CITY: | STATE: | ZIP: | |
| DATE OF BIRTH: | AGE: | SEX: | SOC. SEC. NO.: | HOME PHONE NO.: | WORK PHONE NO.: | CHART NO.: | |
| Billing Instructions: | | | CLINICAL HISTORY/SPECIAL REQUESTS: | | | SPECIMEN INFORMATION | |
| <input type="checkbox"/> Bill Dr. Office <input type="checkbox"/> Bill Patient <input type="checkbox"/> Bill Insurance* <small>* Complete Insurance Information Below.</small> | | | | | | DATE COLLECTED: _____ | |

| INSURANCE INFORMATION | | |
|-------------------------------------|--------------------------|----------------------------|
| MEDICARE NO: | MEDICAID NO: | |
| | PRIMARY INSURANCE | SECONDARY INSURANCE |
| Insurance Company Name: | | |
| Insurance Company Street Address: | | |
| Insurance Company City, State, Zip: | | |
| Patient ID No.: | | |
| Group No.: | | |
| Responsible Party and Relationship: | | |
| Employer/Address/Phone No | | |

| GYN CYTOPATHOLOGY TEST REQUEST | |
|---|--|
| Does Patient Have A History of An Atypical Pap Test: Yes/ No If Yes, Please Provide Diagnosis And Date Of Diagnosis: _____ | |
| _____ Liquid Based Pap Smear or _____ Conventional Pap Smear & Number of Slides _____ 1 _____ 2 | |
| SPECIMEN SOURCE: _____ Cervix or _____ Vagina/Hyst | |
| DATE OF LAST MENSTRUAL PERIOD _____ / _____ / _____ or POST MENOPAUSAL _____ | |
| CHECK ALL THAT APPLY: _____ I.U.D. Present _____ Birth Control Pills _____ Hormone Therapy _____ Hyst _____ Gross Lesion | |
| _____ Irradiation Therapy _____ Postmenopausal Bleeding _____ Pregnant _____ Postpartum | |
| OTHER PERTINENT CLINICAL INFORMATION: _____ | |

| TEST REQUEST ON LIQUID BASED PAP GYN SPECIMEN | |
|--|---|
| _____ HPV Testing (DNA Probe) High Risk Only | _____ HPV Testing (DNA Probe) High & Low Risk |
| _____ Chlamydia (PCR) _____ Gonorrhea (DNA Probe) | _____ Herpes Simplex Virus Type 1 & 2 (PCR) |

| NON-GYN TEST REQUEST | HISTOPATHOLOGY TEST REQUEST |
|--|--|
| NON-GYN: <input type="checkbox"/> Bronchial Wash <input type="checkbox"/> Bronchial Brush <input type="checkbox"/> Urine Voided <input type="checkbox"/> Urine Catheterized <input type="checkbox"/> Bladder Wash <input type="checkbox"/> Breast Secretion <input type="checkbox"/> Breast Aspiration-Cyst <input type="checkbox"/> Peritoneal Fluid <input type="checkbox"/> Pericardial Fluid <input type="checkbox"/> Cerebrospinal Fluid <input type="checkbox"/> Sputum <input type="checkbox"/> Fine Needle Aspiration Site _____ <input type="checkbox"/> Other: (Specify): _____ | <input type="checkbox"/> Gross Only <input type="checkbox"/> Bone Marrow <input type="checkbox"/> Gross & Micro <input type="checkbox"/> Flow Cytometry <input type="checkbox"/> Frozen Section <input type="checkbox"/> ER/PR, DNA Preoperative Diagnosis _____ Postoperative Diagnosis _____ SPECIMEN SOURCE: A. _____ B. _____ C. _____ D. _____ E. _____ |
| ICD - 9/DIAGNOSIS* | ICD - 9/DIAGNOSIS* |

Rex H. Bell, M.D., Amy R. Hudson, M.D., Dianne F. Johnson, M.D., Gary S. Markland, M.D., Hal E. Palmer, M.D., Maria C. Porter, M.D., Brian D. Quinn, M.D., Michelle D. Riddick, M.D., Rickey O. Ryals, M.D., Robert O. Shaver, M.D., L. Gene Singleton, M.D., John E. Slaven, M.D., Charles D. Sullivan, M.D.

(Revised 02/06)

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HISTOPATHOLOGY

Pathology Laboratories of Arkansas, P.A. offers a full spectrum of surgical pathology services for physician offices, outpatient surgery centers, hospitals and other health care providers. All of our pathologists are Board certified by the American Board of Pathology and are fellows of the College of American Pathologists.

We welcome the opportunity to provide this important professional health care service to you and your patients. Surgical pathology examinations represent a consultation for the patient and the associated physician and require considerable teamwork between the provider and the pathology department for optimal patient care to be rendered.

If the following information is unclear, or you cannot find instructions regarding the method of handling specific specimens, please call our client service representative at (501) 225-2760 or (888) 809-3730. Furthermore, if the results of the surgical pathology examination are unclear or do not correlate with the clinical findings, you are encouraged to contact our pathologists concerning the patient's report.

SUBMISSION REQUIREMENTS - ROUTINE

Pathology Laboratories of Arkansas, P.A. supplies request forms for surgical pathology examinations. The surgical pathology request form must accompany the specimen(s). Patient data should be filled out as completely as possible, including the patient name, date of birth, sex, address, chart number (if applicable), physician name and address, specimen identification (tissue type and site), collection date, clinical diagnosis, and any applicable history.

For routine specimens each separately identified specimen should be submitted in a plastic screw top container filled with 10% neutral buffered formalin. Containers filled with 10% neutral buffered formalin are available on request from our client service representative (501) 225-2760 or (888) 809-3730.

The container must be labeled with the patient's name and physician's name. Larger specimens may require the use of large containers with enough 10% neutral buffered formalin to completely cover the specimen. Inadequate fixation of larger specimens may result in a delay of specimen processing.

Any special requests (e.g. extra copies of reports to additional physicians, special stain requests, photographs, etc.) should be stated on the request form.

Smaller specimens should be put in the formalin contained in the small plastic screw top containers and placed in the sealable plastic bag provided by PLA. The folded request form should be placed in the pocket on the back of the plastic bag, separated from the specimen container to avoid contamination from unexpected leaking of the specimen container.

Once the specimen has been placed in the proper specimen container and the request form completed properly, please call the Pathology Laboratories of Arkansas, P.A. client service number to obtain prompt courier service to the histopathology laboratory. The specimen will then be promptly processed and submitted to the pathologist for diagnosis.

For procedures and requirements for handling of non-routine specimens (e.g., kidney biopsies, skin biopsies, immunofluorescence studies, muscle biopsies, etc.) please contact the client service representative (501-225-2760 or 888-809-3730) or the tissue laboratory (501-202-1745).

HISTOPATHOLOGIC EXAMINATION AND CHARGES

The pathologist who examines the surgical pathology specimen will determine whether additional studies, such as special stains, are needed.

The fee for surgical pathology services will vary based on the number of specimens submitted, the location and size of the specimens and the additional studies needed for proper evaluation of the specimen.

We utilize CPT codes for surgical pathology based on the Current Procedural Terminology (CPT-4). These codes are updated regularly to conform with the latest edition of the official CPT coding manual.

If you have questions concerning the charges for surgical pathology specimens, please contact the client service representative (501-225-2760 or 1-888-809-3730), or Mr. Keith Miller (501-225-7711 or 1-888-809-3730).

FLOW CYTOMETRY

The technology of flow cytometry and the discovery of a method to produce monoclonal antibodies have made possible the clinical use of flow cytometry for the identification of cell populations.

Light scatter is utilized to identify the cell population(s) of interest, while the measurement of fluorescence intensity provides specific information about individual cells.

Monoclonal antibodies “tagged” with a fluorescent dye are commonly used for the identification of cell surface antigens and fluorescent dyes that directly and specifically bind to certain components of the cell (i.e. DNA) are used for cell cycle analysis.

The flow cytometer is able to rapidly screen large numbers of cells far beyond the capacity of traditional pathological or cytological methods. The information obtained aids in the diagnosis, classification, and prognosis of a variety of diseases.

Common uses for flow cytometry in the routine clinical laboratory include immune status evaluation, especially quantitation of CD4 positive T-Cells in HIV positive patients, immunophenotyping of hematopoietic neoplasms and DNA cell cycle analysis of solid tumors.

IMMUNE STATUS EVALUATION

Subpopulations of lymphocytes are identified and quantitated by the flow cytometer by utilizing monoclonal antibodies to various cell surface antigens.

Patients with acquired or congenital immunodeficiency disease and patients on immunosuppressive drug therapy exhibit characteristic alterations in lymphocyte populations.

IMMUNOPHENOTYPING

Different cell populations that compose the hematopoietic system express distinctly different cell surface antigens at various stages of maturation. By detecting and measuring these expressed antigens, flow cytometry can aid in the classification of the cell lineage of leukemia and lymphoma.

Although not intended to be an independent diagnostic modality, flow cytometry is often able to subclassify hematopoietic malignancies beyond the capabilities of traditional morphologic and cytochemical techniques.

DNA CELL CYCLE ANALYSIS

Nuclear DNA is another parameter measured by flow cytometry. This measurement determines whether an abnormal DNA content is present (aneuploidy) and calculates the percentage of a cell population in each phase of the classic cell cycle. The percentage of cells in the S-phase gives an indication of the proliferative activity of that cell population.

Both of these parameters have been shown to have prognostic significance in various hematopoietic and solid malignancies.

AVAILABLE TESTS

CLINICAL INDICATIONS

Lymphocyte Subsets

Used to evaluate the immune status of individuals and assess disease progression. Meets CDC guidelines for HIV monitoring.

CD4/CD8

Used to monitor HIV positive individuals, to assess their immune status and determine necessity for therapy.

CD4 Lymphocytes only

Used to monitor HIV positive individuals.

CD3 Analysis and Subsets

Used to monitor effectiveness of immunosuppressive therapy in transplant patients.

CD3 Analysis Only

Used to monitor effectiveness of immunosuppressive therapy in transplant patients.

Leukemia/Lymphoma/Plasma Cell Panel

Used to differentiate reactive from neoplastic lesions, to subclassify lymphoma and to define the lineage and developmental stage of hematopoietic neoplasms.

DNA Cell Cycle Analysis

Used to predict ploidy and proliferative activity of certain solid tumors. The finding of DNA aneuploid and/or a high S-phase fraction predicts decreased disease free and overall survival times in many malignancies.

LYMPHOCYTE SUBSETS

WBC
% Lymphocytes
Absolute Lymphocyte Count
Lymphocyte Subsets
(% Positive and Absolute)

| | |
|---------|-----------------------------------|
| CD3 | Pan T lymphocyte |
| CD19 | Pan B lymphocyte |
| CD3/CD4 | Helper-inducer T lymphocyte |
| CD3/CD8 | Suppressor/Cytotoxic thymocyte |
| CD56 | Natural killer cell |
| CD4:CD8 | Helper/Suppressor ratio |

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

CD4 (T4)/CD8 (T8)

WBC
% Lymphocytes
Absolute Lymphocyte Count
Lymphocyte Subsets
(% Positive and Absolute)

| | |
|---------|-----------------------------------|
| CD3/CD4 | Helper-inducer T lymphocyte |
| CD3/CD8 | Suppressor/Cytotoxic thymocyte |
| CD4:CD8 | Helper/Suppressor ratio |

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of

collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

CD4 (T4) ANALYSIS ONLY

WBC
% Lymphocytes
Absolute Lymphocyte Count
(% Positive and Absolute)

| | |
|---------|--------------------------------|
| CD3/CD4 | Helper-inducer T lymphocyte |
|---------|--------------------------------|

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

CD3 (T3) ANALYSIS AND SUBSETS

WBC
% Lymphocytes
Absolute Lymphocyte Count
Lymphocyte Subsets
(% Positive and Absolute)

| | |
|---------|-----------------------------------|
| CD19 | Pan B lymphocyte |
| CD3/CD4 | Helper-inducer T lymphocyte |
| CD3/CD8 | Suppressor/Cytotoxic thymocyte |
| CD56 | Natural killer cell |
| CD4:CD8 | Helper/Suppressor ratio |
| CD3 | Pan T lymphocyte |
| TcR | T-Cell receptor site |

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

| | |
|------|----------------------------------|
| CD13 | Myelocyte/Monocyte |
| CD64 | Monocytes |
| cMPO | Myeloperoxidase |
| c79a | B cells |
| C3 | Cytoplasmic CD3 T Cells |
| cTdT | Immature lymphocytes /thymocytes |

CD3 (T3) ANALYSIS ONLY

| | |
|-----|--|
| CD3 | Pan T lymphocyte Count (Absolute only) |
|-----|--|

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

| | |
|--------|---------------------------------------|
| CD45 | Human leukocytes |
| CD3 | Pan T Lymphocytes |
| CD5 | Pan T Lymphocytes |
| CD7 | Pan T Lymphocytes |
| CD4 | T-helper Lymphocytes |
| CD8 | T-suppressor/ cytotoxic lymphocyte |
| CD10 | B-cells |
| CD19 | Pan B-cells |
| CD20 | Mature B-cells |
| FMC7 | Activated B-cells |
| CD23 | Activated B-cells |
| CD38 | Plasma cells, activated T-cells |
| CD103 | T and B Lymphocytes |
| CD11c | T and B cells, NK cells, monocytes |
| CD25 | Activated B-cells |
| CD22 | B-cells |
| Kappa | Light chains |
| Lambda | Light chains |

LEUKEMIA / LYMPHOMA/PLASMA CELL PANEL

Leukemia Panel*

| | |
|-------------|-------------------------------|
| CD45 | Human leukocytes |
| CD5 | Pan T lymphocytes |
| CD10 | B lymphocytes |
| CD19 | Pan B lymphocytes |
| CD20 | Mature B Cell |
| HLA-DR (I3) | Activated T and B lymphocytes |
| CD34 | Progenitor Cell |
| CD117 | Progenitor Cell |
| CD15 | Monocytes/ Granulocytes |
| CD33 | Myelocyte/Monocyte |
| CD56 | Natural Killer Cells |
| CD14 | Monocyte |

Plasma Cell Panel*

| | |
|---------|---------------------------------|
| CD138 | Plasma cells |
| CD38 | Plasma cells, Activated T-cells |
| CD56 | Natural Killer Cells |
| CD 45 | Human leukocytes |
| cKappa | Cytoplasmic light chain |
| cLambda | Cytoplasmic light chain |

*Other antibodies are utilized if indicated from the basic panel results.

Specimen Required:

BLOOD - Collect one 5 mL lavender (EDTA) tube (minimum 3 mL). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. EDTA collection tubes available upon request. Please call PLA client services for prompt specimen pickup.

BONE MARROW - Collect one 5 mL lavender(EDTA) tube, minimum is 1 mL. Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. Please submit a peripheral blood specimen (lavender), peripheral blood smear and patient history. EDTA collection tubes are available upon request. Please call our client services for prompt specimen pickup.

TISSUE - Submit fresh tissue specimens (approximately 1 gram, or “as large as your thumbnail”) in sterile tissue culture medium (e.g. RPMI). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. RPMI media is available upon request. Please call our client services for prompt specimen pickup.

FINE NEEDLE ASPIRATION - Submit total contents of aspirate in sterile tissue culture medium (e.g. RPMI). Store and transport at room temperature. Specimen must be analyzed within 30 hours of collection. RPMI media available upon request. Please call PLA client services for prompt specimen pickup.

DNA CELL CYCLE ANALYSIS

DNA Content (ploidy)
S-phase Interpretation
Copy of Histogram

Specimen required:

Paraffin embedded tissue block enriched with tumor. Store and transport at room temperature.

Please call PLA client services for prompt specimen pickup or mail to Pathology Laboratories of Arkansas, P.A., # 1 Lile Court, Suite 101, Little Rock, AR 72205.

CYTOPATHOLOGY

INTRODUCTION

The Cytopathology Laboratory at Pathology Laboratories of Arkansas, P.A. (PLA) is a full-service Cytopathology Department providing routine screening and diagnostic cytopathology services, including both gynecologic and non-gynecologic specimen types. Special studies can also be performed on non-gynecologic specimens that include the following: Flow cytometry, UroVysion™ FISH, bladder tumor associated antigen, and immunocytochemical studies.

The Cytopathology Department utilizes leading technology by offering Focal Point automated slide screening (AutoPap® Primary Screening System), SurePath® liquid-based Pap test (AutoCyte PREP System™). Call the Cytopathology Department at (501) 202-1985 for more information concerning the available technologies.

Cytology services are provided through arrangements made with our Client Support Services at (501) 225-2760 or (888) 809-3730. Our Cytopathology Department includes three cytopreparatory technicians, four certified cytotechnologists (two certified as Specialist in Cytotechnology by the American Board of Clinical Pathology) and ten board certified pathologists (two are board certified in Cytopathology by the American Board of Pathology).

Together we strive to provide superior service to our physicians and patients with emphasis on accuracy and timeliness. Our goal is to constantly define and promote excellence in cytopathology and to provide the highest quality of patient care and client service. To achieve this goal we have developed a comprehensive quality

assurance program which is closely overseen by the medical director (a board certified Cytopathologist) and an experienced cytotechnologist supervisor (a specialist in cytology).

AVAILABLE TEST LIST

The following is a list of available tests through PLA Cytopathology Laboratory for diagnostic cytopathologic evaluation for the purpose of determining the presence of malignancy, micro-organisms/infectious agents and other cellular or extracellular materials (e.g. fat, asbestos fibers, colloid, etc.).

Body Cavity fluids (may include):

- Pelvic washings
- Pericardial effusions
- Peritoneal effusions
- Pleural effusions
- Cerebrospinal fluid
- Synovial fluids

Fine needle aspirations

Pap Tests

- Conventional Pap smear
- SurePath™ Liquid-base Pap Test

Pap Ancillary/Reflex Tests performed from Liquid-base Pap vials only in addition to PapTest*

- Chlamydia Trachomatis
- Cystic Fibrosis Mutation Detection
- Herpes Simplex Virus I & II
- Human Papilloma Virus (Low/High Risk Types)
- Neisseria Gonorrhoea

Respiratory/Pulmonary specimens

Bronchoalveolar lavage (BAL)
Bronchial Washing
Bronchial Brushing
Sputum

Smears(s) or brushing(s) may include specimen samples from:

Breast/nipple discharge
Gastrointestinal tract
Larynx
Nasopharynx
Oral cavity
Paranasal sinus
Prostate
Respiratory tract
Trachea

Urine UroVysion™ FISH*

*Indicates Reference Laboratory Tests.

LABORATORY SERVICES/ AVAILABILITY OF TESTING

1. The laboratory is open for receiving specimens daily from 7:00 AM to 5:00 PM, Monday through Friday with the exception of legal holidays. The laboratory is also open Saturday mornings. The anatomic pathologist on call will determine which specimens will be processed on Saturday.

2. If a client desires **STAT** processing of a specimen then contact the laboratory immediately. Ask for the supervisor or the anatomic pathologist on call.

(501)-225-2760
(888)-809-3730
(501)-202-2005 after working hours

TEST RESULT -TURNAROUND TIME

Gynecologic PAP Test and Ancillary Reflex Testing 1-7 days.

Non-Gyn Cytology Specimens 1-day (24 hours). Results are generally available the following workday. Exceptions include cases which require additional testing (e.g. special stains or consultation, etc.).

Refer to individual test section for information on collection and transportation requirements. Consultations are available on all cytologic materials. Submit all materials (slides and blocks) with a copy of the original pathology report, clinical history, and PLA Pathology test request form designating that the case is for consultation.

SPECIMEN SUBMISSION / HANDLING

All fresh specimens should be sent to the cytology laboratory during regular operating hours 7:00 AM-5:30 PM.

Please call Client Services for specimen pickup. **501-225-2760** or **1-888-809-3730**.

In the event of a delay in transporting the specimen to the laboratory add an equal amount of CytoRich Red™ cytology preservative or 50% ethanol to the specimen (see information regarding collection and submission of specific specimen types). The fixative can be obtained from the Cytopathology Department at: **501-202-1985**

With large specimens (that cannot be immediately refrigerated) 50 mL of the specimen should be placed in a small container with 50 mL of CytoRich Red™ cytology preservative or 50% ethanol.

For a smear(s) prepared at the time of procuring the specimen refer to the smear section.

SMEARS

Prepared slides should have material evenly smeared on clear glass slides, labeled with the patient's name in pencil and be **FIXED IMMEDIATELY** in 95% ethanol or with cytologic spray fixative. If spray fixative is used the slides should be allowed to dry before placing in the transport slide holder.

Specimens prepared in this manner may include brushings (e.g. bronchial, gastric, esophageal, urethral, etc.) or breast discharge material. If a bronchial brush is submitted separately, place the brush in a separate container of CytoRich Red™ cytology preservative or 50% ethanol.

Send smears to the laboratory in a cardboard or plastic slide carrier or in a tightly sealed container of 95% ethanol.

Smear(s)/brushing(s) may include but are not limited to specimen samples from the:

- Respiratory tract
- Oral Cavity
- Larynx
- Nasopharynx
- Paranasal sinus
- Gastrointestinal tract
- Breast/nipple discharge

Collection Supplies

Cytology supplies may be obtained from PLA Client Services at (501) 202-1985 or by faxing an order to (501) 202-1420. Additional supply order forms may be requested from Client Services (501-225-7711). Please order supplies at least two weeks in advance of actual need to keep cost at a minimum

because the collection kit for SurePath™ (AutoCyte PREP™) contains flammable liquid limiting the quantity of vials that can be shipped.

All orders are reviewed by the Cytology section to verify that requested supplies match estimated workload to provide optimal availability of supplies and to minimize costs for all clients. PLA provides containers and supplies **ONLY** for the collection and transport of lab specimens intended for PLA Laboratories.

Rotate stock of SurePath™ vials and use vials with closest expiration date first. **No specimen will be accepted in expired solution.**

Specimen Labeling

Label all specimens legibly with the patient's first and last name, specimen source and any other client-specific identifier on all materials submitted for testing. Requisition and specimen container must be labeled with patient name and specimen source. Glass slides need to be labeled on the frosted end of slide in pencil.

Each individual specimen container should be accompanied by a separate requisition. For example, if a bronchoscopy procedure generates both bronchial wash and bronchial brush material, then a separate requisition should accompany each of these two specimens.

Please Note:
Outer shipping container labeling only will NOT be acceptable for specimen identification.

CYTOLOGY TEST REQUEST FORM

Cytology specimens must be submitted with a completed PLA Cytology test request form. The patient's first and last name must be printed on the specimen container label or slides, including specimen type for non-gynecological specimens. The following information must be included on the test request form for accurate specimen preparation, interpretation, result reporting, record keeping, and billing (exclusion of any information may result in specimen rejection and/or processing delays):

Patient Name

Date of Birth

Collection Date

Physician's Name

Source of Specimen Specimen type: Check the space next to the specimen type (e.g. cervical – vaginal smear, gastric brush, bronchial wash or legibly write the source in).

Pertinent Clinical history

This information is required under Federal Regulation CLIA '88. If the above information is not supplied or if slides are received broken, the specimen processing will be delayed and the ordering physician will be notified.

Gynecologic specimens (PAP smears)

Document the following information on the test request form in the GYN History Section for required GYN clinical information.

Menstrual history: postmenopausal or last menstrual period (LMP), pregnancy history, hormonal therapy, clinical findings such as abnormal bleeding or discharge, IUD use and previous history of abnormal diagnosis or procedures such as biopsy or cryotherapy.

Check appropriate box and specify if Pap smear is for **Screening PAP Test** or **Patient is High Risk for Cervical Disease**.

HIGH RISK PATIENT CRITERIA (PAP TEST)

Listed below are clinical features utilized by PLA to determine high-risk status. This list includes, but is not limited to, all high-risk features as defined by the Centers for Medicare & Medicaid Services (CMS).

History of any of the following **ALWAYS** qualifies the specimen as high risk, regardless of the time since any pertinent procedure or diagnosis:

- High-grade squamous intraepithelial lesion (HSIL), carcinoma in situ (CIS), or cervical, endometrial, ovarian or vulvar malignancy of any type, diagnosed by Pap test or tissue studies.
- Chemotherapy, radiotherapy, and/or surgical treatment for cervical, endometrial, ovarian, or vulvar malignancy of any type.
- Cervical biopsy (including LEEP, cone, endocervical curettage), abnormal endometrial biopsy, colposcopy, or cryosurgery.
- Unspecified abnormal or atypical Pap test, including inflammatory atypia, with no other information provided (e.g. how long since occurrence, etc.).
- Friable cervix.
- Pregnancy in-patients younger than 18 years of age.
- All tests on patients 16 years of age and younger.
- Abnormal bleeding at any age.
- Any bleeding in a postmenopausal female.
- D & C in a postmenopausal female.
- Previous or current sexually transmitted disease, including genital herpes, HPV, and HIV infection.

- Question of previous abnormal Pap test or biopsy.
- DES exposure.
- History of early onset of sexual activity (e.g. before 16 years of age).
- Multiple sexual partners (five or more in a lifetime).
- Fewer than three negative Pap tests within the previous seven years.

History of any of the following within five years prior to the current PAP test qualifies the specimen as high risk:

- Low-grade squamous intraepithelial lesion (LSIL) or atypical squamous or glandular cells.
- Any previous unspecified abnormal or atypical Pap test.

History of any of the following does NOT qualify the Pap test as high risk:

- Unspecified previous abnormal or atypical Pap test greater than five years prior to the current Pap test.
- AS/GUS or LSIL greater than five years prior to the current Pap test.
- Carcinoma not primary to the female genital tract, unless metastatic to the female genital tract.
- D & C in a premenopausal female.

For Non-gynecologic specimens, document the clinical information on the test request form under the **Clinical History/Special Request header** and write any pertinent clinical information related to the specimen collected.

Name of the referring physician: Clearly write the name of the referring physician and how that individual may be contacted if additional information is required or results need to be reported by phone.

SPECIMEN REJECTION CRITERIA FOR UNACCEPTABLE SPECIMENS

Specimens to which the following conditions apply will be rejected, returned to the originating site or specimen processing delayed. The physician office will be notified.

1. Specimen is submitted without a test request form.
2. Specimen is not labeled with the patient's full name (for slides, the frosted end must be labeled with the patient's first and last name in pencil).
3. The patient name (or other identifying information) on the specimen and test request form do not correspond.
4. The specimen is labeled appropriately, but the test request form is not labeled.
5. Specimen is submitted from an unauthorized source. (Specimens are accepted only from physicians or other authorized persons recognized under Arkansas state law).
6. No source or test marked on the test request form.
7. Incorrect specimen submitted for test requested.

Submitted specimens not meeting the criteria listed below may be discarded after notifying the submitting physician. A supervising technologist or pathologist will be contacted to determine the disposition of all specimens in this category. The submitting physician/nursing station will be notified to recollect the specimen. In the event of a specimen that is difficult to recollect (i.e. specimen is impossible to recollect), the test will be run with approval of the cytopathologist and the submitting physician will be notified of the inadequacy of the specimen which will be documented in the final report.

1. Incorrectly labeled specimens, mismatched specimen/patient name, any specimens not properly labeled with patient's name, specimen source and unique patient identifying number.
2. The specimen and/or slide(s) is (are) irreparably broken or damaged.
3. The specimen is submitted frozen.
4. Incorrect specimen submitted for test requested.

CYTOLOGY SPECIMEN ADEQUACY CRITERIA

The adequacy of Pap test collection is determined by:

1. Accurate patient and specimen identification.
2. Pertinent clinical history.
3. The presence of an adequate squamous component.
4. The presence of an adequate endocervical component (in premenopausal females with a cervix).
5. The absence of obscuring entities, including inflammation, blood and contaminants such as talc or lubricant.
6. Adequate cellular preservation.

The adequacy of Non-gynecological specimen collection is determined by:

1. Accurate patient and specimen identification.
2. Pertinent clinical history.
3. The presence of adequate site-specific cellular material and/or diagnostic cellular material.
4. Adequate cellular preservation.

RESULT REPORTING

Pap Tests: Please note that the Pap test is a screening test for cervical cancer and its precursors with an inherent false-negative rate.

Turnaround Time: 1-7 days

Pathology Laboratories of Arkansas, P.A. utilizes the Bethesda system terminology for reporting of cervical/vaginal cytology smear results (see Table 1). Our gynecologic cytology reports utilize the following format:

1. A general categorization of the diagnosis:
 - Negative for Intraepithelial Lesion or Malignancy.
 - Other: See Interpretation/Result (e.g. endometrial cells in a woman 40 \geq years of age).
 - Epithelial Cell Abnormality: See Interpretation/Result).
2. A statement regarding specimen adequacy.
3. Pathologist qualifying statement and recommendation, if applicable.

SUBMITTING PHYSICIAN PAP SMEAR MONTHLY SUMMARY REPORT

Each month the cytology department will forward to each submitting physician a list of all patients who have had abnormal PAP smear results signed out during the previous month. This report serves as an adjunctive quality assurance mechanism to help track patients that may require clinical follow-up.

CLIENT ALERT NOTIFICATION OF PATIENT ABNORMAL PAP RESULT

Our technical staff will verbally notify your office when a patient has a PAP smear that is diagnosed as a High-grade Squamous Intraepithelial lesion (HGSIL) or when a malignant diagnosis is rendered.

Table 1 Revised BETHESDA SYSTEM 2001

SPECIMEN TYPE: *Indicate conventional smear (Pap smear) vs. liquid-based vs. other*

SPECIMEN ADEQUACY

- Satisfactory for evaluation (*describe presence or absence of endocervical/transformation zone component and any other quality indicators, e.g. partially obscuring blood, inflammation, etc.*)
- Unsatisfactory for evaluation ... (*specify reason*)
- Specimen rejected/not processed (*specify reason*)
- Specimen processed and examined, but unsatisfactory for evaluation of epithelial abnormality because of (*specify reason*)

GENERAL CATEGORIZATION

- Negative for Intraepithelial Lesion or Malignancy
- Epithelial Cell Abnormality: See Interpretation/Result (*specify 'squamous' or 'glandular' as appropriate*)
- Other: See Interpretation/Result (*e.g. endometrial cells in a woman > 40 years of age*)

AUTOMATED REVIEW

If case examined by automated device, specify device and result. (i.e., Focal Point® TriPath Imaging™ Primary Screening System)

ANCILLARY TESTING

Provide a brief description of the test methods and report the result so that it is easily understood by the clinician.

INTERPRETATION/RESULT

- **NEGATIVE FOR INTRAEPITHELIAL LESION OR MALIGNANCY** (*When there is no cellular evidence of neoplasia, state this in the General Categorization above and/or in the Interpretation/Result section of the report, whether or not there are organisms or other non-neoplastic findings*)

ORGANISMS:

- *Trichomonas vaginalis*
- Fungal organisms morphologically consistent with *Candida* spp
- Shift in flora suggestive of bacterial vaginosis
- Bacteria morphologically consistent with *Actinomyces* spp.
- Cellular changes consistent with Herpes simplex virus

OTHER NON-NEOPLASTIC FINDINGS (*Optional to report; list not inclusive*):

- Reactive cellular changes associated with inflammation (includes typical repair)
- Radiation
- Intrauterine contraceptive device (IUD)
- Glandular cells status post hysterectomy
- Atrophy

- **OTHER**

Endometrial cells (*in a woman > 40 years of age*)
(*Specify if 'negative for squamous intraepithelial lesion'*)

- **EPITHELIAL CELL ABNORMALITIES**

SQUAMOUS CELL

- Atypical squamous cells
 - of undetermined significance (ASC-US)
 - cannot exclude HSIL (ASC-H)
- Low grade squamous intraepithelial lesion (LSIL)
 - Encompassing: HPV/mild dysplasia/CIN 1
- High grade squamous intraepithelial lesion (HSIL)
 - Encompassing: moderate and severe dysplasia, CIN 2 and CIN 3/CIS with features suspicious for invasion (*if invasion is suspected*)
 - Squamous cell carcinoma

GLANDULAR CELL

- Atypical
 - Endocervical cells (NOS or *specify in comments*)
 - Endometrial cells (NOS or *specify in comments*)
 - Glandular cells (NOS or *specify in comments*)
- Atypical favor neoplastic
 - Endocervical cells, favor neoplastic
 - Glandular cells, favor neoplastic
 - Endocervical adenocarcinoma *in situ* (A/IS)
- Adenocarcinoma
 - Endocervical
 - Endometrial
 - Extrauterine not otherwise specified (NOS) **OTHER MALIGNANT NEOPLASMS:** (*specify* **EDUCATIONAL NOTES AND SUGGESTIONS** (*optional*))

LABORATORY REQUEST FOR PATIENT FOLLOW-UP

Periodically the PLA Cytopathology Department will send a form requesting follow-up on certain abnormal smears (ASC-H r/o HSIL, LSIL, HSIL) for which there is no corresponding clinical follow-up information or tissue biopsy in the PLA laboratory records for correlation with the cytology results. This follow-up is an integral part of our quality assurance program and is one way to help ensure that we are providing the clinician with consistent accurate diagnostic reports that meet the highest standards for quality patient care.

BILLING AND CODING FOR CYTOPATHOLOGY TESTING

All Cytopathology tests will have the CPT code and associated billing charges assigned after completion of the testing. CPT codes are assigned in accordance with the actual processing of the test. For inquiries relating to CPT codes or billing, contact Client Services at (501) 225-7711.

FOCAL POINT™ (AUTOPAP™ SCREENING SYSTEM)

All conventional and SurePath™ cervicovaginal specimens (Paps) will be processed on the Focal Point™ (AutoPap™ Primary Screening System). This automated microscope and image processing device analyzes specimens stained by a modified Papanicolaou method utilizing image interpretation algorithms.

All conventional specimens are classified into one of the four following categories:

1. No Further Review (CPT 88147): requires no manual screening.
2. Review (CPT 88148): requires manual screening.

3. QC Review (CPT 88148): requires manual screening and rescreening.
4. Process Review (CPT 88164 or 88165): instrument cannot process these slides, they require manual screening and rescreening.

Note: Pathology Review: all cases requiring final interpretation by a pathologist will have an additional CPT code (CPT 88141).

PREPSTAIN™ (AUTOCYTE PREP™ SYSTEM)

The PrepStain™ (AutoCyte PREP™ System) is a liquid-based cell preparation system used for gynecological specimens collected in the SurePath™ (CytoRich™ GYN Preservative) vial. It converts a liquid suspension of cells into a discretely stained, homogeneous thin layer maintaining diagnostic cell clusters. This technique includes cell preservation, randomization, enrichment, sedimentation, automated pipetting and staining to create the SurePath™ (AutoCyte PREP™) slide.

GYN Liquid-Based CPT coding:

1. Cervical/vaginal collected in preservative fluid, automated thin-layer preparation; manual screening under physician supervision (CPT 88142).
2. Cervical/vaginal collected in preservative fluid, automated thin-layer preparation; manual screening with subsequent rescreening under physician supervision (CPT 88143).
3. Cervical/vaginal collected in preservative fluid, automated thin-layer preparation; screened by automated system, under physician supervision (CPT 88174).
4. Cervical/vaginal collected in preservative fluid, automated thin-layer preparation with screening by automated system and manual rescreening, under physician supervision (CPT 88175).

NON-GYNECOLOGIC Liquid-Based CPT coding:

Cytopathology, selective cellular enhancement technique with interpretation (e.g. liquid based slide preparation method) except cervical or vaginal. (CPT 88112)

Note: Pathology Review: all cases requiring final interpretation by a pathologist will have an additional CPT code (CPT 88141).

BODY CAVITY FLUID (S)

Test indication: Any excess amount of fluid, an effusion is always an indication of a pathologic process. Thus the presence of an effusion indicates that the patient has a disease. Laboratory investigation of the effusion fluid including examination of the exfoliated cells may provide the key to the patient's diagnosis. Body cavity fluids are commonly evaluated for the presence of malignant cells from metastatic disease. These fluids include pleural, peritoneal, pericardial, synovial and pelvic washing.

Specimen types: Body fluids (Pericardial, Peritoneal, Ascites, and Pleural fluids, Paracentesis, Thoracentesis)

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

TAT: 1 day (24 hours).

Specimen requirements: 10 mL (or more) of fluid for small fluid accumulations the entire specimen is submitted for laboratory evaluation. For larger effusions, 50-200 mL of well-mixed fluid should be sent for cytologic evaluation. However the entire specimen is acceptable.

Supplies: Non-sterile specimen container, test requisition, biohazard bag.

Collection procedure: Using standard aseptic technique by needle puncture, saline washing and/or aspiration to obtain a fluid specimen from the desired body cavity. If necessary, move the patient into multiple positions to suspend cellular material in the fluid. A minimum of 10 mL of specimen is desirable for optimal cytologic evaluation. If other studies are required, withdraw a fraction of the specimen and submit it to the appropriate laboratory separately following their guidelines for specimen collection. Heparin may be added to the specimen to reduce clotting. Place 3 units of heparin per mL capacity of the collection container. Agitate the container to coat the sides with heparin. Label the container with the patient's first and last name, date of birth, specimen type and collection date. Submit the specimen to the Cytopathology Laboratory along with the completed Cytology test request form.

Fixation: Submit fresh sample (no fixative preferred). If delay in transportation to laboratory, refrigerate 4°C (or 39°F) up to 72 hours. The exception is cerebrospinal fluid, which begins to degrade shortly after collection if stored at room temperature or refrigerated. Add 50% ethanol equal to the volume of specimen if transport is delayed or use proprietary transport medium supplied by the manufacturers of liquid based medium systems. Any fixative added should be noted on the requisition.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen in a biohazard transport bag. The paper requisition(s) that accompanies the specimen should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect

or expired fixative, specimen from unauthorized person.

Specimen stability: Varies; if some delay is unavoidable (12-24 hours) body fluids may be refrigerated at 4°C (or 39°F) up to 72 hours.

Reference interval: By report

CPT code(s): 88108 Concentration and interpretation, or 88112 Selective cellular enhancement with interpretation and 88312 x3. Special stains. Additional CPT codes may apply if special studies are required.

References:

1. DeMay Richard M. "Fluids" The Art & Science of Cytopathology. Chicago:ASCP Press, 1996
2. Non-gynecological Cytology Practice Guidelines; American Society of Cytotechnology, CytoPathology Practice Committee, Adopted by: ASC Executive Board, March 2, 2004. <http://www.cytopathology.org/guidelines/nongynecological.php>

BREAST NIPPLE SECRETION/ DISCHARGE

Test indication: Detection of malignant cells in nipple discharge specimen.

Specimen type: Direct smear of nipple discharge.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

TAT: 1 day.

Specimen requirement: Direct smear of nipple discharge.

Supplies: Two clean glass slides (single-end frosted), fixative (spray fixative or 95% ethanol), test requisition form, biohazard bag, slide mailer or clean non-sterile leak proof container.

Collection procedure: Label the two slides with the patient's first and last name, date of birth and specimen site in pencil on the frosted end. Collect a small amount of nipple secretion directly onto one of the slides. Oppose a second glass slide onto the first, allowing the collected material to provide surface tension between the two slides, and then gently and quickly pull the two slides apart in a horizontal motion to distribute the material in a thin film over both slides.

Fixation: The slide should be fixed immediately. Immediate fixation of cellular sample is necessary to prevent air-drying which obscures cellular detail and compromises specimen evaluation. Fixation can be done by:

1. Immersion: Place the smear into 95% ethanol. If the specimen is immersed in alcohol, it may remain in the alcohol for transport to the laboratory or alternatively the specimen can be immersed in alcohol for 20-30 minutes, removed and allowed to air dry, then placed in a container/mailer to be transported to the laboratory.

2. Spray fixation: If spray fixed, only quality controlled cytology fixative should be used. The manufacturer's instructions should be followed. Hold spray 6-10 inches (15-25 centimeters) from the glass slide when applied.

Transport: Fixed smears should be submitted in slide mailer(s), clearly labeled with patient name and specimen site(s). Slides in fixative should be submitted in leak proof containers that protect against breakage and clearly labeled with patient name and specimen site(s). Paper requisitions that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative. Submit the specimen and the completed test request form to the Cytopathology Department.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fixed slides: Indefinitely.

Reference interval: By report.

CPT code(s): 88104 smears and interpretation

BRONCHOALVEOLAR LAVAGE (BAL)

Test indications: For the detection and characterization of microbiologic pathogens (primarily *Pneumocystis*, viral, fungal, and bacterial) in immunocompromised patients; for detection and characterization of malignancy, interstitial lung disease, transplant rejection, pulmonary hemorrhage, acute inflammatory diseases and disorders in which lymphocyte predominant.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday. ***STAT** Performed on weekends, holidays or after hours for rapid evaluation of opportunistic pulmonary infection.

TAT: 1 day (24 hours).

Specimen requirement: Lavage obtained by bronchoscopy (preferably at least 20 mL) of the distal airways and alveoli. **Note:** BAL specimens sent for culture **MUST** be split from the main cytologic specimen prior to transport. The Cytopathology Laboratory does not have the proper facilities for the sterile handling of BAL specimens necessary for culture procedures.

Supplies: Standard bronchoscopy equipment. 120 mL clean plastic specimen containers, test requisition and biohazard bag

Collection procedure: Using standard bronchoscopy BAL technique, lavage the lung distribution in question with sterile, normal saline (or other physiologic solution). Collect the lavage specimen in a clean specimen container. Label the container with the patient's first and last name and specimen type. Submit the specimen, along with the completed Cytology test request form, to the Cytopathology Laboratory. If transport will be delayed, refrigerate the specimen.

Fixation: Do not add fixative to the specimen. BAL specimens are submitted fresh because microbiologic studies, immunologic studies or chemical analyses may be requested.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen in a biohazard transport bag. The paper requisition(s) that accompanies the specimen should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Varies; if some delay is unavoidable (12-24 hours) body fluids may be refrigerated.

Reference interval: By report.

CPT code(s): 88108 Concentration and interpretation, or 88112 Selective cellular enhancement with interpretation and/88312

x3 Special stains. Additional CPT codes may apply if special studies are required.

Note: BAL specimens sent for culture **MUST** be split from the main specimen prior to transport. The Cytopathology Laboratory does not have facilities for the sterile handling of BAL specimens necessary for culture procedures.

BRUSHING(S)

Test indication: For the detection and characterization of visible premalignant/malignant lesions; for the identification of some microbiologic pathogens (primarily viral and fungal).

Specimen types: Brushing specimens may be taken from any surface of the body including, but not limited to, the following sites: Gastrointestinal tract, Larynx, Nasopharynx, Oral Cavity, Paranasal sinus, Prostate, Respiratory tract and Trachea.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

TAT: 1 day.

Specimen requirement: Direct brush sampling of identified lesion.

Supplies: Two clean glass slides (single-end frosted), fixative (spray fixative, 95% ethanol, 50% ethanol, Saccomanno or proprietary transport medium, test requisition form, biohazard bag, slide mailer or clean non-sterile leak proof container).

Collection procedure: Using standard technique, identify the lesion in question and obtain a brushing. Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of sterile saline or fixative. Do not apply the brush directly to the slides. If possible, detach the brush and leave it in the vial/container of fixative (either CytoRich Red™ cytology preservative, 50% ethanol or proprietary transport medium). The brush may

be submitted in the 50% ethanol equal to the volume of the specimen or in a proprietary transport medium supplied by manufacturers of liquid based systems. The brush may be submitted in the solution or discarded after vigorously removing the adherent cellular material into the medium. The container must be clearly labeled with the patient's name. The container should be leak proof with enough fluid to cover the brush if submitted. If direct smears are prepared prior to the procedure label the two slides with the patient's first and last name, date of birth and specimen site in pencil on the frosted end. Oppose a second glass slide onto the first, allowing the collected material to provide surface tension between the two slides, and then gently and quickly pull the two slides apart in a horizontal motion to distribute the material in a thin film over both slides. Alternatively, air-dried brushing smears may be submitted for staining with one of the Romanowsky stains or for rehydration prior to Papanicolaou staining. Mark smears clearly indicating they are air-dried.

Fixation: The slide(s) should be fixed immediately. Immediate fixation of cellular sample is necessary to prevent air-drying which obscures cellular detail and compromises specimen evaluation. Fixation can be done by detaching the brush and leaving it in the vial/container of liquid transport medium (CytoRich Red™ cytology preservative, 50% ethanol or proprietary transport medium). The brush may be submitted in the 50% ethanol equal to the volume of the specimen or in a proprietary transport medium supplied by manufacturers of liquid based systems.

Immersion: Place the smear(s) into 95% ethanol. If the specimen is immersed in ethanol, it may remain in the ethanol for transport to the laboratory or alternatively the specimen can be immersed in ethanol for 20-30 minutes, removed and allowed to air dry, then placed in a container/mailer to be transported to the laboratory.

Spray fixation: If spray fixed, only quality controlled cytology fixative should be used. The manufacture's instructions should be followed. Hold spray 6-10 inches (15-25 centimeters) from the glass slide when applied.

Transport: Fixed smears should be submitted in slide mailer(s), clearly labeled with patient name and specimen site(s). Slides in fixative should be submitted in leak proof container(s) that protect against breakage and clearly labeled with patient name and specimen site(s). Paper requisitions that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fixed slides: Indefinitely. Liquid preservative up to 72 hours, fresh refrigerated specimen time varies. If transport time will be less than 24 hours or fixative is not available, the specimen should be refrigerated at 4°C (or 39°F) or kept on wet ice until transport to the lab.

Reference interval: By report

CPT code: 88104 smears with interpretation

CEREBROSPINAL FLUID (CSF)

Test indication: Detection and characterization of malignant cells in the central nervous system. In cytology, cerebrospinal fluid is most commonly evaluated to detect and characterize malignancy which may have gained access to the central nervous system. While in most individuals CSF specimens are relatively easy to obtain, in some individuals, collection may require radiographic guidance. In addition, due to lack of nutrients in this fluid, cells may rapidly degenerate rendering morphologic evaluation less than optimal if adequate care is not taken.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

TAT: 1 day.

Specimen required: Minimum of 3 mL cerebrospinal fluid (CSF). 10 ml CSF (minimum) of required for immunologic marker studies.

Supplies: Standard cerebrospinal fluid collection equipment. Clean, clear 10 mL collection container for CSF. Fixative: 50% ethanol or CytoRich Red™ cytology preservative.

Collection procedure: Using standard CSF procedure collect 3 mL of CSF. In general, morphology of cells within the CSF can be adequately maintained with prompt refrigeration for 24 hours.

Fixation: Although a fresh specimen is preferred, if a longer time period between collection and processing is anticipated, the specimen may be preserved by adding an equal volume of 50% ethanol or CytoRich Red™ cytology preservative to the specimen. Label the container with the patient's first and last name, date of birth, specimen type and collection date. Submit

the specimen to the Cytopathology Laboratory along with the completed Cytology test request form.

Note: Do not add fixative. Specimens submitted for immunocytochemical testing must be submitted fresh.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen in a biohazard transport bag. The paper requisition(s) that accompanies the specimen should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Stability: Refrigerated: 24 hours.

Reference interval: By report.

CPT code(s): 88108 Concentration and interpretation or 88112 selective cellular enhancement with interpretation. Additional CPT codes may apply if special studies are required.

CONJUNCTIVAL SCRAPING

Test indication: Detection and characterization of inflammatory/infectious processes of the conjunctiva.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Specimen required: Direct smear of material collected from the conjunctival surface.

Supplies: Two clean glass slides, fixative (95% ethanol), conjunctival scraping spatula and test request form.

Collection procedure: Label the slides with the patient's first and last name and specimen source, in pencil, on the frosted end and place in a container filled with 95% ethanol so that the slides are completely covered. Gently scrape the area of abnormality. Remove one of the slides from the fixative. Quickly and evenly smear the collected material on one of the glass slides. Immediately re-immerses the slide in fixative. For better diagnostic yield we recommend that the process be repeated with a second slide. Submit the specimen and the completed request form to the Cytopathology Laboratory.

Transport: Fixed smears should be submitted in slide mailer(s), clearly labeled with patient name and specimen site(s). Slides in fixative should be submitted in leak proof container(s) that protect against breakage and clearly labeled with patient name and specimen site(s). Paper requisitions that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fixed slides: Indefinitely. Liquid preservative up to 72 hours, fresh refrigerated specimen time varies. If transport time will be less than 24 hours or fixative is not available, the specimen should be refrigerated at 4°C (or 39°F) or kept on wet ice until transport to the lab.

Reference interval: By report.

CPT code(s): 88160.

FINE NEEDLE ASPIRATION COLLECTION

Test indication: Fine needle aspiration of mass lesions is commonly utilized in the detection and characterization of a variety of malignant diseases. Obtaining an adequate specimen requires attention to good aspiration technique as well as processing of material obtained. It is highly desirable that several direct smears be prepared (preferably air-dried) for all fine needle aspiration specimens submitted to Cytopathology Laboratory.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Collection of FNA Specimens

Patient Preparation

- a) Examine the patient with review of clinical history.
- b) Determine the gross characteristics of the mass to be aspirated including location relative to other structures, estimated depth, consistency and any evidence of pulsation or bruit.
- c) If the lesion is not palpable, then fine aspiration procedure can also be done using ultrasound fluoroscopy or CT scan guidance by radiology.

Specimen required: Adequate cellular material for cytologic evaluation obtained from an appropriately performed fine needle aspiration. This will depend on the specimen site and character of the lesion being aspirated. In general, this requires that there be enough material for the examiner to at least determine that the aspiration needle sampled the targeted mass lesion.

Supplies: 10 mL syringe. Syringe pistol (optional). 22 to 25 gauge needle of appropriate length. Single-end frosted glass slides labeled with the patient's first and last name and specimen source (for preparation of direct smears). Alcohol skin preparation pad. Fixative (either CytoRich Red™ cytology preservative or 95% ethanol).

Collection procedures: Please note that the following collection procedure is a suggested guideline. Aspiration techniques vary widely based on personal preferences and specific clinical circumstances must be taken into account when deciding on the method of aspiration utilized.

Identification and Localization of a Mass Lesion

Mass lesions usually come to attention either by simple identification of the development of a palpable mass (usually superficially) or by the development of symptoms directly or indirectly caused by the lesion. In order to be able to sample the identified lesion, some means of accurate localization must be available. If the mass is superficial, simple isolation of the mass by palpation using the thumb and index fingers of the non-aspirating hand is usually sufficient. For deeper masses, ultrasound or radiographic techniques are usually required for accurate guidance and localization of the aspirating needle.

FNA -Obtaining Specimen

For superficial aspirates, alcohol preparation technique suffices for cleansing of the skin surface. Local anesthetic usually is not necessary. If multiple passes of deep seated lesions are anticipated, anesthetic is recommended. However, be certain not to contaminate the lesion with a large volume of anesthetic solution. Local anesthetic may interfere with the ability to palpate and localize superficial lesions. Sterile technique for deep aspirates is required for cleansing of

the skin and local anesthetic is usually required.

- a) Assemble the syringe pistol with attached needle and lay out several glass slides with alcohol fixative.
- b) Clean the skin at the puncture site with an alcohol pad.
- c) Lay the needle point on the skin over the puncture site and determine the angle of approach to the mass. A “fine needle”, 22 gauge or smaller diameter (e.g. 23, 25 gauge) is used.
- d) Hold the lesion firmly stationary with the free hand and insert the needle in one swift motion.
- e) Determine that the mass has been penetrated either by noting the resistance encountered on puncture or by moving the syringe slightly from side to side while feeling the mass move beneath the finger of the palpating hand.
- f) Apply full vacuum pressure to the syringe with the pistol finger.
- g) Move the needle back and forth within the mass at slightly different angles while full pressure is maintained.
- h) Observe the hub junction of the needle and syringe for the appearance of any sample or continue to make multiple back and forth passes within the mass lesion.
- i) Conclude the aspiration at the first appearance of any sample within the syringe or after multiple passes by releasing the trigger of the syringe pistol. Vacuum pressure is applied to the syringe **ONLY** when the needle is within the mass. If vacuum pressure is applied while withdrawing the needle air and sample will be pulled into the syringe where it will dry and be difficult to retrieve.
- j) Withdraw the needle from the mass and place pressure on the puncture with a sterile gauze pad to minimize blood. No vacuum pressure should be applied to the syringe during withdrawal of the needle.

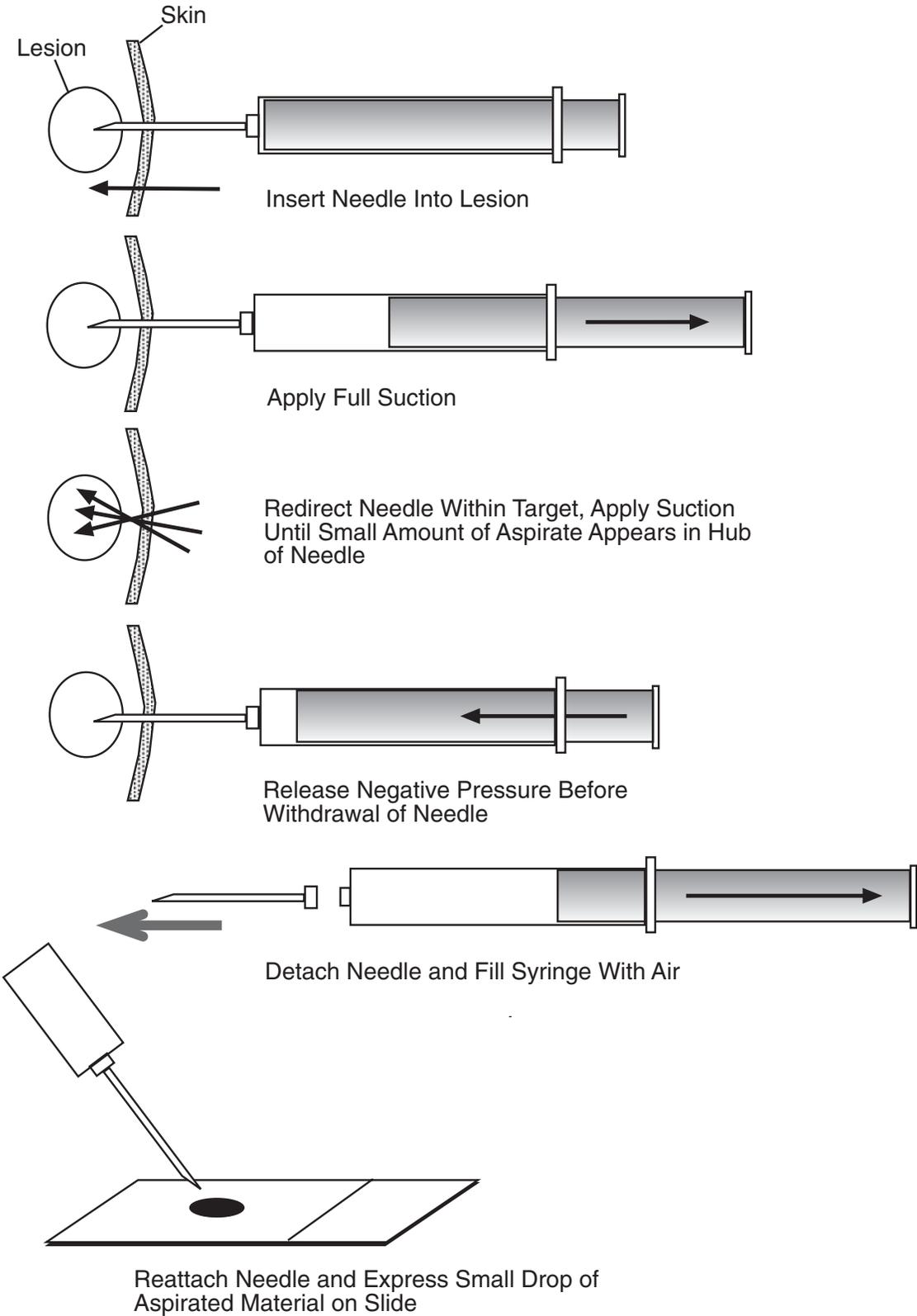
- k) Once the needle has been removed from the patient, the needle is detached from the syringe so that the syringe can be filled with air. The needle is then reattached (see Figure 1), and sample is expressed for the needle onto the glass slide. The sample is then delicately smeared between two glass slides (Figure 2).

Aspiration of Superficial Masses procedural notes

Assemble the aspirating equipment. If direct smears are to be made, label the slides prior to the aspiration. With the target of aspiration fixed with the non-dominant hand between the thumb and index finger and the syringe or syringe pistol in the dominant hand, the needle is placed against the skin. The needle should approach the skin at approximately a 30-degree angle if the lesion is very superficial. If the mass is deep, the needle should approach the skin at a perpendicular angle. A quick motion should be used in passing the needle through the skin. The needle is then advanced through the subcutaneous tissue into the mass. If the mass is small the needle should be aimed toward the center; if it is large the needle should be aimed toward the periphery (because the center of larger masses may be necrotic). A noticeable difference in the consistency of the tissue should be noted when the needle penetrates the mass. With the needle in the mass the needle tip should be moved in short motions initially to loosen cells within the mass. Negative pressure is then applied by pulling back on the plunger of the syringe. When blood or material appears in the hub of the needle the aspiration should be stopped. Prior to withdrawal of the needle negative pressure must be released to prevent suction of the material into the barrel of the syringe when the needle exits the skin.

Figure 1

Aspiration of Palpable Masses



Aspiration of Deep Lesions-Procedure Notes

While the basic aspiration procedure is similar for deep lesions, specialized equipment of imaging, specialized needles and set-ups for aspiration and emergency equipment for handling major complications are required. Specific techniques are highly variable, according to personal preferences.

FNA-Preparation of Direct Smears

For preparation of smears, single-end frosted slides should be utilized. Slides should be labeled with patient's first and last name and specimen source in pencil prior to aspiration. Some investigators recommend to first gently express a drop of aspirated fluid onto a slide, while others recommend forcefully expelling the material onto the slide. The actual method will be determined in part by the nature of the material present. A drop may be easily expressed without force if the aspirated material is abundant and fluid. If the material is scant, or more viscous or solid, the material must often be forcefully expelled. The latter method can result in splattering of material off of the slide and will utilize most of the specimen resulting in the preparation of a minimal number of smears necessitating more passes if additional material is required for additional studies. The former method allows for better control of the smear process.

Once the specimen is on the slide, it must be smeared. The simplest way to accomplish this is to place a second glass slide onto the first (Figure 2).

a) To prepare smears, place the bevel of the needle directly on the glass slide near the frosted end. Express the aspirated material using the air-filled syringe to blow out material through the needle onto a slide in one drop. Do not spray the specimen through the air onto the slide.

b) A second or spreader slide is then used to make the smear. The spreader slide is gently lowered, crosswise, over the droplet, which will then spread out slightly by capillary action. The spreader slide is then gently pulled straight back in one smooth motion, down the length of the diagnostic slide. Little or no diagnostic material should remain on the spreader slide.

c) Repeat the above procedure with additional drops of material to make approximately 4-6 slides. Any material that remains can be expressed into CytoRich Red™ cytology preservative (unless lymphoma is suspected and then place material in RPMI media). We prefer that air-dried smears be prepared from thyroid fine needle aspirations specimens. Do not prepare air-dried smears from other specimens sources unless discussed first with the Cytopathology Department. Follow the same procedure for preparing slides, as outlined above, when preparing air-dried smears except for the fixation step. For thyroid aspirations we recommend several unfixed slides be prepared in addition to several fixed smears. In addition, material may be submitted in CytoRich Red™ cytology preservative.

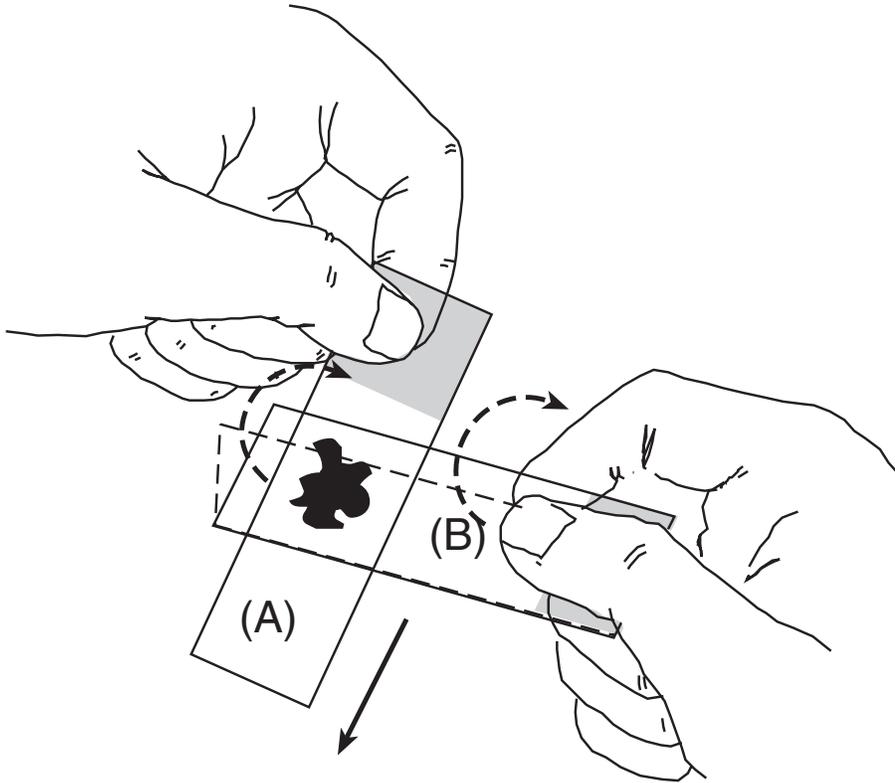
Fixation:

The smears should be:

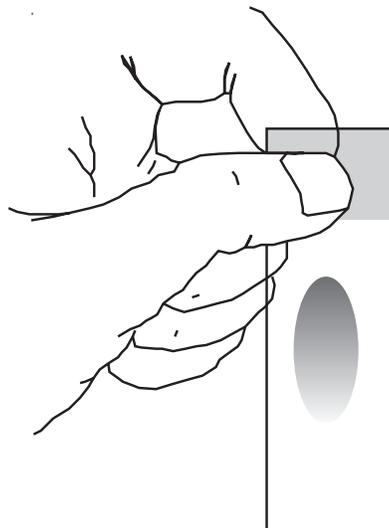
- 1) Immediately fix the slides in 95% ethanol for Papanicolaou staining (delineate with an "F", for fixed, on the frosted end of the slide).
- 2) Air-dried smears for Diff-Quick staining should be prepared for thyroid specimens only (delineate with an "A", for air-dried, on the frosted end of the slide).
- 3) If spray fixative is used, spray 10-12 inches from slide immediately after the smear is made. Additional smears may be prepared if material remains in the hub of the needle or the material may be entirely rinsed into a specimen container containing either fixative CytoRich™ Red, CytoLyt or a physiologic solution such as normal saline (or RPMI if lymphoma is suspected). All of the aspirated material should be flushed into a physiologic solution if smears are not prepared. The advantage of submitting material

Figure 2

One-Step Method



Hold stationary slide (A) firmly in one hand. With the other hand rest edge of spreader slide (B) that is closer to operator on stationary slide and tilt spreader slide until the aspirated material is beginning to spread. Then move spreader slide toward you, applying slight pressure to aspirated material. Do not lift either end of spreader slide until smear preparation is complete.



in CytoRich Red™ cytology preservative is that cell block material can be prepared which facilitates utilization of special stains in evaluating the specimen. Please submit material in RPMI solution if lymphoma is suspected (arrange with the laboratory in advance by calling 202-2888 and request the clinical pathologist on call or the Tissue Laboratory at 202-1745).

Transport: Submit the specimen (smears and/or material rinsed into solution) to the Cytopathology Laboratory along with the completed test request form. The specimen should be submitted in fixative if transport of specimen in fluid will be delayed more than 24 hours.

Specimen stability: If transport time of fluid specimen will be less than 24 hours or fixative is not available then refrigerate the specimen (or keep on wet ice) until transport to the Cytopathology Department.

Reference interval: By report.

CPT code(s): 88173 This CPT code may also be reported in conjunction with aspiration of the specimen (10021) and/or immediate on-site evaluation of the specimen (88172). Additional CPT codes may be reported depending on the preparation methods, such as 88106, 88108, and/or 88305.

GASTROINTESTINAL SPECIMEN(S)

Test indication: For detection and characterization of endoscopically visible gastrointestinal lesions; for the identification of some microbiologic pathogens (e.g. herpes, CMV, and *Candida*, etc.).

Specimen types: Brushings (Esophageal, GI Junction, Gastric, Duodenal, Bile Duct, Other).

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Specimen requirement: Endoscopically-directed brushing sample of the identified lesion.

Supplies: Standard endoscopy equipment. One (or more if necessary) 5 to 10 mL vial or tube of sterile normal saline or fixative (either CytoRich Red™ cytology preservative or 50% ethanol).

Collection procedure: Instruct the patient to fast overnight or for a minimum of six hours prior to the procedure. Identify the lesion in question and obtain a brushing sample of the lesion using standard endoscopy technique.

Note: It is important to brush the edges of an ulcer, as well as the floor, in order to obtain diagnostic material. Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of saline or fixative. **DO NOT APPLY THE BRUSH DIRECTLY TO SLIDES.** If possible, detach the brush and leave in the vial. Label the vial with the patient's first and last name and specimen source. Submit the specimen along with the completed Cytology test request form to the Cytopathology Laboratory.

Fixation: Preferred specimen: Fresh, no fixative. If transport will be delayed more than 4 hours the specimen should be partially fixed by adding an equal amount of 50% ethanol or CytoRich Red™ cytology preservative to the specimen or submit the specimen in a proprietary transport medium used for liquid based systems supplied by the laboratory (e.g. Cyto-Rich Red™, CytoLyt)

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: 4 hours fresh refrigerated (4°C or 39°F), all GI specimens tend to deteriorate rapidly in the fresh state due to enzymatic activity endogenous to the GI tract.

CPT Code(s) 88104

(GI) ESOPHAGEAL, GASTRIC WASHINGS

Test indication: For detection and characterization of endoscopically visible gastrointestinal lesions; for the identification of some microbiologic pathogens (e.g. herpes, CMV, and *Candida*, etc.).

Specimen required: Endoscopically obtained washing (preferably at least 10 mL) of the region of the suspected lesion.

Supplies: Standard endoscopy equipment. 120 mL clean plastic specimen container(s). Fixative (either CytoRich Red™ cytology preservative or 50% ethanol), biohazard transport bag.

Collection procedure: Instruct the patient to fast overnight or for a minimum of six hours prior to the procedure. Lavage the area of interest with physiologic solution using standard endoscopy technique. Aspirate the solution and place in a clean specimen container. Label the container with the patient's first and last name, date of birth and specimen source. Submit the specimen and the completed Cytology test request form to the Cytopathology Laboratory.

Fixation: Preferred specimen: Fresh, no fixative. If transport will be delayed more than 4 hours, the specimen should be partially fixed by adding an equal amount of 50% ethanol or CytoRich Red™ cytology preservative to the specimen or submit specimen in a proprietary transport medium used for liquid based systems supplied by the laboratory (e.g. Cyto-Rich red™, CytoLyt™).

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen Stability 4 hours fresh refrigerated (4°C or 39°F), all GI specimens tend to

deteriorate rapidly in the fresh state due to enzymatic activity endogenous to the GI tract.

Reference interval: By report.

CPT code(s): 88108 Concentration and interpretation, 88112 Selective cellular enhancement with interpretation. Additional CPT codes may apply if special studies are required.

(GI) BILE DRAINAGE

Test indications: For the detection of malignant cells arising within the hepatobiliary system.

Specimen required: 10 mL or more of collected bile drainage.

Supplies: Standard transcutaneous or endoscopic biliary drainage equipment. Clean plastic specimen container of an appropriate size, biohazard transport bag, patient requisition.

Collection procedure: Using appropriate sterile technique, collect as much bile drainage through the drainage apparatus as possible into a clean plastic specimen container. Label the container with patient's first and last name, date of birth, and specimen source. Place specimen in biohazard transport bag. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Fixation: Preferred specimen: Fresh, no fixative. If transport will be delayed for more than one (1) hour, add an equal amount of 50% ethanol to the specimen. The specimen should be refrigerated or kept on wet ice until transport to the lab if transport time will be less than one (1) hour or fixative is not available.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: 1 hour, fresh sample. Bile specimens will degenerate very rapidly due to enzymatic activity and bile salts. Therefore, a 24-hour bile collection is not suitable for cytopathologic evaluation.

Report interval: By report.

CPT code(s): 88108 Concentration and interpretation, 88112 Selective cellular enhancement with interpretation. Additional CPT codes may apply if special studies are required.

ORAL SCRAPING

Test indications: Detection and characterization of malignancy and infectious processes in the oral cavity.

Methodology: Routine cytopathology evaluation.

Performed: Monday-Friday.

Reported: 1 day (unless special studies are required).

Specimen type: Oral Scrapings.

Specimen required: Direct smear of material collected from the oral mucosa.

Supplies: Two (or more) clean glass slides, fixative (95% ethanol) or spray fixative, oral

scraping spatula, lead pencil, biohazard transport bag and test request form

Collection procedure: Label the frosted end of the slides or vial with the patient's first and last name and specimen source in pencil. If slides are used, place in a container filled with 95% ethanol so that the slides are completely covered. Gently scrape the area of the abnormality. Remove one of the slides from the fixative. Quickly and evenly smear the collected material on one of the glass slides. Immediately re-immerses the slide in fixative. Repeat the process with the second slide if necessary for better diagnostic yield. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Fixation immersion: Place the smear(s) into 95% ethanol. If the specimen is immersed in alcohol, it may remain in the alcohol for transport for to the laboratory or alternatively the specimen can be immersed in alcohol for 20-30 minutes, removed and allowed to air dry then place in a container/mailler to be transported to the laboratory.

Spray fixation: If spray fixed only quality controlled cytology fixative should be used. The manufacture's instructions should be followed. Hold spray 6-10 inches (15-25 centimeters) from the glass slide when applied.

Transport: Fixed smears should be submitted in slide mailer(s), clearly labeled with patient name and specimen site(s). Slides in fixative should be submitted in leak proof container(s) that protect against breakage and clearly labeled with patient name and specimen site(s). Paper requisitions that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fixed slides: Indefinitely.

Reference interval: By report.

CPT Code(s): Depending on collection method: 88108 Concentration and interpretation or 88112 Selective cellular enhancement with interpretation or 88104 Smears with interpretation. Additional CPT codes may apply if special studies are required.

ORAL BRUSHINGS

Test indication: Detection and characterization of malignancy and infectious processes in the oral cavity.

Methodology: Routine cytopathology evaluation.

Performed: Monday-Friday.

Reported: 1 day (unless special studies are required).

Specimen required: Brushing sample of the identified lesion.

Supplies: One 5 to 10 mL vial or specimen container of sterile normal saline or fixative. (CytoRich Red™ cytology preservative or 50% ethanol).

Collection procedure: Identify the lesion in question and obtain a brushing sample of the lesion.

Note: It is important to brush the edges of an ulcer, as well as the floor, in order to obtain diagnostic material. Agitate the brush vigorously in a 5 to 10 mL vial of saline or fixative. DO NOT APPLY THE BRUSH

DIRECTLY TO SLIDES. If possible, detach the brush and leave it in the fixative vial/container. Label the vial with patient's first and last name, date of birth and specimen source. Submit specimen along with the completed test request form to the Cytopathology Laboratory. The specimen should be submitted in fixative if transport of the specimen will be delayed more than 4 hours. If transport time will be less than four hours or if fixative is not available the specimen should be refrigerated or kept on wet ice until transport to the lab.

Fixation: The slide(s) should be fixed immediately. Immediate fixation of a cellular sample is necessary to prevent air-drying which obscures cellular detail and compromises specimen evaluation.

Fixation can be done by: Detaching the brush and leaving it in the vial/container of liquid transport medium (CytoRich Red™ cytology preservative, 50% ethanol or proprietary transport medium). The brush may be submitted in 50% ethanol equal to the volume of the specimen or in a proprietary transport medium supplied by manufacturers of liquid based systems.

Immersion: Place the smear(s) into 95% ethanol. If the specimen is immersed in alcohol it may remain in the alcohol for transport for to the laboratory or alternatively the specimen can be immersed in alcohol for 20-30 minutes, removed and allowed to air dry, then placed in a container/mailer to be transported to the laboratory.

Spray fixation: If spray fixed only quality controlled cytology fixative should be used. The manufacture's instructions should be followed. Hold spray 6-10 inches (15-25 centimeters) from the glass slide when applied.

Transport: Fixed smears should be submitted in slide mailer(s), clearly labeled with patient name and specimen site(s). Slides in fixative should be submitted in leak proof container(s) that protect against

breakage and clearly labeled with patient name and specimen site(s). Paper requisitions that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fresh specimen is stable for 4 hours. Fixed slides are stable indefinitely. Liquid preservative up to 72 hours, fresh refrigerated specimen stability varies. If transport time will be less than 24 hours, or fixative is not available, the specimen should be refrigerated (4°C or 39°F) or kept on wet ice until transport to the Cytopathology Laboratory.

Reference interval: By report.

CPT code(s): Depending on collection method: 88108 Concentration and interpretation or 88112 Selective cellular enhancement with interpretation or 88104 Smears with interpretation. Additional CPT codes may apply if special studies are required.

PAP SMEAR TEST(S)

Test indication: The Pap smear is used as a screening test for the evaluation of the lower female genital tract to detect the presence of inflammatory/infectious conditions, benign proliferative conditions, unsuspected or confirmation of suspected atypia, pre-malignant, or malignant changes, follow-up of patients with known and/or treated pre-malignant or malignant lesions.

Specimen types: Vaginal, cervical or cervical/endocervical sample(s) collected using conventional or liquid base Pap test collection method.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1- 7 days.

Reference interval: By report.

GENERAL PATIENT PREPARATION INSTRUCTIONS

To optimize collection, a woman should:

1. Schedule an appointment approximately two weeks (10-18 days) after the first day of her last menstrual period (obtain specimens during the second half of the menstrual period to avoid contamination by obscuring blood).
2. Not douche 48 hours prior to test.
3. Not use tampons, birth control foams, jellies or other vaginal creams or vaginal medications for 48 hours prior to the test.
4. Refrain for intercourse 48 hours prior to the test.

General procedural instructions (See below for specific instructions)

1. Label the slide(s) with the patient's first and last name, and specimen source directly on the frosted end of the glass, in pencil, before

beginning the procedure. **THE LABORATORY WILL NOT ACCEPT UNLABELED SLIDES.**

Please note that a Pap smear folder labeled with the patient's name is not adequate for patient identification. The patient information must appear on the slide.

2. Obtain all specimens prior to bimanual examination.
3. Place the patient in the lithotomy positions. Using an un-lubricated vaginal speculum (saline may be used as a lubricant) visualize the cervix as fully as possible.
4. Do not use a cotton-tip applicator, it provides less cellular sample due to material being trapped in the fibers.
5. After collection and proper fixation of specific specimens as outlined in specific collection procedure as follows place slide(s) in a cardboard slide folder or submit in liquid-base Pap test vial to the Cytopathology Laboratory, along with the completed test request form.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Fixed slides are stable indefinitely. SurePath™ Pap Test liquid preservative specimens stable up to 28 days.

CPT codes: CPT codes vary based on testing performed.

CONVENTIONAL PAP-ROUTINE CERVICAL/VAGINAL

Supplies: Vaginal speculum, plastic extended-tip spatula, cytobrush*** and fixative (spray fixative or bottle of 95% ethanol), clean glass slide (single end frosted), black lead pencil and test request form. Pap kits are available from PLA.

Collection procedures:

- a) Label one (1) slide with patient's first and last name and specimen source.
- b) Use an un-lubricated speculum (saline or warm water may be used).
- c) After visualization of the cervix is accomplished insert the spatula into the cervix. Rotate the spatula 360 degrees to perform a scraping. This will allow a specimen to be obtained from the transformation zone where neoplasia occurs. In post menopausal patients, it is desirable to obtain a sample from the vaginal pool (posterior fornix) with the rounded end of the spatula.
- d) Make a smear lengthwise along one side of a previously labeled glass slide. Smear slide thinly and evenly.
- e) If a cytobrush is used, insert the cervical brush into the cervical os with gentle pressure and rotate only 90 to 180 degrees to minimize bleeding.
- f) Quickly make an adjacent lengthwise smear on the same slide spreading material quickly and evenly. The endocervical mucus will prevent air-drying during collection of the subsequent cervical component.
- g) "Broom", another collection instrument for taking Pap smears, is a plastic "broom-like" brush which simultaneously samples the endocervix and ectocervix at the same time. To use the broom insert the long central bristles into the cervical os until the lateral bristles bend against the ectocervix and rotate in a clockwise direction 360° in the same direction five (5) times while maintaining gentle pressure. The broom is removed and with a single paint stroke motion the cellular sample is transferred down the long axis of the labeled slide surface. The broom is turned over the paint stroke motion is repeated over the same area.
- h) Fix immediately (spray with fixative holding the spray bottle approximately 10-12 inches from the slide or drop slide into 95% ethanol fixative).

- i) Complete the Cytology test request form, including relevant clinical information. Submit the specimen to the Cytopathology Laboratory.

CONVENTIONAL PAP-ROUTINE VAGINAL SMEAR

Indications: Can be used in conjunction with routine cervical/endocervical smears in individuals with a uterus or alone in patients with prior hysterectomy.

Specimens required: Lateral vaginal wall smear or smear of sample from a clinically concerning area.

Supplies: Vaginal speculum, one or more plastic cervical spatulas, fixative** (spray fixative or 95% ethanol), one or more clean glass slides (single-end frosted), black lead pencil lab pencil and test request form. Pap kits are available from PLA.

Collection procedure:

- a) If only a routine lateral vaginal wall sample will be obtained, label one slide with patients first and last name, and source of specimen. If vaginal sample will be obtained in conjunction with a cervical and endocervical component, make sure that the slides are also appropriately labeled according to site.
- b) If smears from separate vaginal areas are also to be obtained, label the sites accordingly as to specific site (e.g. left lateral vaginal wall, posterior vaginal wall, etc.).
- c) Obtain specimen prior to bimanual evaluation. Use an un-lubricated speculum (saline or warm water may be used).
- d) Scrape the desired region of the vaginal mucosa with the spatula.
- e) Withdraw the spatula and spread the material quickly and evenly onto the glass slide (if cervical/endocervical smears are also obtained, or smears from other areas of the vagina are obtained, make certain that each

smear is performed on the corresponding labeled slide).

f) Fix immediately, (spray with fixative holding the spray bottle approximately 10-12 inches from the slide or drop slide into 95% ethanol fixative).

g) Complete the Cytology test request form, including relevant clinical information. Submit the specimen to the Cytopathology Laboratory.

CONVENTIONAL PAP-VAGINAL SMEAR, DES EXPOSURE

Indications: Evaluation of potential changes associated with in utero DES exposure.

Specimens required: Lateral vaginal wall sample, cervical sample, endocervical sample.

Supplies: Vaginal speculum, one or more cervical spatulas, one extended-tip spatula, cytobrush^{***}, fixative^{**} (spray fixative or 95% ethanol), two or more clean glass slides (single end frosted), black lead lab pencil, and test request form. Pap kits are available from PLA.

Collection procedures:

- Label two slides with patient's first and last name, date of birth and specimen source.
- Label one slide "C" and one "LVW". Label others as necessary (see below).
- Obtain specimens prior to bimanual examination. Use an un-lubricated speculum (saline or warm water may be used). After visualization of the upper 1/3 of the vagina is accomplished use the spatula to scrape the upper 1/3 of either lateral vaginal wall. Withdraw the spatula and spread the material quickly and evenly onto the slide clearly marked "LVW."
- Fix immediately (drop slide into fixative or spray with fixative holding the spray bottle approximately 10-12 inches from the slide).

e) Scrape additional areas of the vagina that appear abnormal. Label slides accordingly (prior to sampling) and spread and fix as above.

f) Obtain routine cervical and endocervical specimens as outlined in the respective procedures. These smears should be collected on the slide labeled "C." Complete the Cytology test request form, including relevant history. Submit the specimen to the Cytopathology Laboratory.

*Procedures for collection of the cervical and endocervical components on either one or two sides are provided.

**Most hair sprays no longer contain adequate amounts of alcohol for appropriate fixation.

***Endocervical sampling devices other than a cytobrush may be used. Refer to specific specimen collection procedures provided with these devices for more information.

SUREPATH™ LIQUID-BASED PAP TEST

(AutoCyte Prep™ System) with Reflex to Human Papillomavirus (HPV) DNA Probe, High Risk

Test indication: The SurePath™ (formerly AutoCyte Prep™ system) liquid-based Pap test produces slides that are intended as replacements for conventional gynecologic. The Pap smear is use in the screening and detection of cervical cancer, precancerous lesions, atypical cells and all other cytologic categories as defined by the Bethesda System for Reporting Cervical Cytology.

Specimen required: Cervicovaginal/ endocervical sampling.

Methodology: PrepStain™ Slide Processor, FocalPoint™ (computer assisted pap screening analysis), routine cytopathologic evaluation, Hybrid Capture® II DNA Test (Nucleic acid, hybridization assay with signal amplification)

Supplies: This test requires a SurePath™ special collection kit, which includes a SurePath™ preservative fluid collection vial and the sampling device(s). Kits may be ordered separately through PLA Client Services at (501) 225-7711. Also required is a PLA Cytology test request form and a permanent marker.

Collection procedure:

- a) Obtain cervical specimen prior to bimanual examination. Use an un-lubricated speculum (saline or warm water may be used). Vaginal discharge or secretion, when present in large amounts, should be removed before obtaining the cervical sample so as not to disturb the epithelium (e.g. cellulose swab). Small amounts of blood will not interfere with the cytologic evaluation; however, large amounts of blood as present during menses may interfere with cytologic evaluation because cells may be obscured by blood. Use of liquid-based specimen collection minimizes the interference from these factors. If testing for sexually transmitted disease is indicated, the cervical cytology sample should be Cervex-Brush™ or the Pap Perfect® plastic spatula and Cytobrush® Plus GT or ROVER'S CERVEX-BRUSH™
- b) To use the broom, insert the long central bristles into the cervical os until the lateral bristles bend against the ectocervix and rotate 360° in a clockwise direction five (5) times in the same direction while maintaining gentle pressure.
- c) The device should be twisted slowly. While maintaining gentle pressure hold the stem between the thumb and the forefinger and rotate the brush five times in a clockwise direction. The direction must be consistent. Do not alter or vary the direction of the broom during sampling.
- d) Transfer the entire sample by placing your thumb against the back of the brush pad, and simply disconnect the entire brush from the stem into the SurePath™ preservative vial.

Using other sampling devices with SurePath™

- a) To obtain an adequate sampling, scrape the ectocervix using the Pap Perfect® plastic spatula. Disconnect the spatula head into the SurePath™ Preservative vial.
- b) Insert the Cytobrush® Plus GT into the cervix until only the bottom most fibers are exposed. Slowly rotate or turn one half turn in one direction. **DO NOT OVER-ROTATE.** Disconnect the brush head and place in the SurePath™ preservative vial.
- c) Recap the vial and tighten. Record the patient's first and last name, date of birth, specimen source and date collected on the vial. Record the patient's information and medical history on the PLA Cytology test request form.
- d) Place the vial and test request form in a biohazard specimen bag for transport to the laboratory. PLA Laboratories will not accept samples in expired SurePath™ preservative.

NOTE:

Samples received without the collection devices in the vial are reported in the Specimen Adequacy statement as: Satisfactory, but limited if cellularity is adequate. The specimen is processed and examined but limited due to the absence of the Cervex-Brush (broom-like device), cytobrush or spatula head in the specimen collection vial. Failure to follow recommended procedures for SurePath™ collection may compromise performance. Use of the SurePath™ Test without the Cervex-Brush is not FDA approved and is considered off label testing by TriPath Imaging.

Specimen requirements: This test requires a SurePath™ special collection kit that must be ordered separately through PLA Client Services at (501) 225-7711. Collect and transport in Path™ Liquid-Based Pap Test vial (AutoCyte Prep™ System).

Remarks: This test includes a Cytology, SurePath™ Liquid-Based Pap Test (AutoCyte Prep™, FocalPoint™ computer assisted screening analysis, Routine cytopathologic evaluation and a Human Papillomavirus (HPV) DNA Probe, recommended High Risk ONLY if the SurePath™ Liquid-Based Pap Test is interpreted as atypical squamous cells of undetermined significance (ASC-US).

Unacceptable conditions: Frozen, older than 28 days, samples not collected in a SurePath™ special collection kit provided by lab, Expired SurePath™ vials will not be processed.

Stability: Ambient: 1 month; Refrigerated: 1 month; Frozen: Unacceptable.

SurePath test reference interval: By Report.

Note: Store SurePath™ preservative fluid without cytologic samples at 15-30°C in this vials provided. Do not use SurePath™ solution beyond expiration date marked on the vial. Rotate stock of SurePath™ and use vials with closest expiration date first. No specimen will be accepted in expired solution.

Warning: SurePath™ preservative contains denatured ethanol which may be fatal if swallowed. Vapor is harmful if inhaled. May cause blindness. SurePath™ is flammable. Keep away from fire, heat, sparks, and flames. Other solutions must not be substituted for SurePath™ preservative.

CPT code(s): Refer to the earlier information given in Cytopathology section of this Directory of Services.

HPV DNA reference interval: High-risk HPV: Not detected.

Hybrid capture II Interpretative Data: Women with atypical squamous cells of undetermined significance (ASC-US) should be managed using a program of either repeat cervical cytology testing, immediate colposcopy or DNA testing for high-risk types of Human Papillomavirus (HPV). Testing for HPV DNA is the preferred approach when liquid-based cytology is used for screening. All women who test positive for high-risk HPV DNA should be referred for colposcopic evaluation. Women with ASC-US who test negative for high-risk HPV DNA can be followed up with repeat cytologic testing at 12 months (2001 ASCCP Guidelines –JAMA 2002; 287:2120-2129).

A positive high risk HPV test result indicates that the patient may be infected with one or more of the following HPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68; which are associated with cervical cancer and its precursor lesions. However, cross-reactions with other genotypes may occur. Results should be correlated with cytologic/histologic findings.

Note: A negative result does not rule out the presence of an HPV genotype absent from the test panel, a low level infection or specimen sampling error.

CPT code(s): CPT Codes vary based on testing.

CHLAMYDIA TRACHOMATIS

Test Code: 3333

Method: Polymerase chain reaction (PCR)-Qualitative

Specimen requirements: SurePath™: 1.0 mL (0.50 mL) minimum, ambient temperature.

Collection and transport: SurePath™: Store and ship at ambient temperature up to 28 days. ThinPrep™: Store and ship at ambient temperature up to 3 months/ 90 days.

Causes for rejection: SurePath™: Less than 0.50 mL and/ or more than 28 days.

Specimen stability: SurePath™: Stable for up to 28 days at room temperature.

Reference range: Not Detected.

TAT: 1-5 days.

CPT code: 8749, *Chlamydia trachomatis* amplified probe technique.

Clinical significance: *Chlamydia trachomatis* infections are among the most common sexually transmitted bacterial infections in the United States with approximately 4 million new cases occurring annually. The speed and enhanced sensitivity of the Roche amplified DNA probe methodology enables early, accurate detection of *Chlamydia trachomatis*, resulting in timely administration of therapy. Several publications involving multiple centers have demonstrated a sensitivity of greater than 96.6% in the detection of *Chlamydia* and a specificity greater than 99%.

References

1. Center for Diseases control and Prevention: Recommendations for the prevention and management of *Chlamydia trachomatis*, 1993, MMWR.
2. Vincellet J, Sehirm J, Bogard M, Rosenstraus M; Multicenter evaluation of the fully automated COBAS AMPLICOR PCR test for the detection of *Chlamydia trachomatis* in urogenital specimens. *J. Clinic Microbiol* 1999; 37(1): 74-80.
3. Puolakkainen M, Hiltunene-Back E, Reunala T, Paavonen ; Comparison of performances of two commercially available tests, a PCR assay and a ligase chain reaction test, in detection for urogenital *Chlamydia trachomatis* infection: *J Clin Microbiol* 1998 June, 36(6): 1489-93.

CYSTIC FIBROSIS MUTATION DETECTION BY PCR-OLA

Test code: 6262

Method: Polymerase chain reaction (PCR)-oligonucleotide ligation assay (OLA).

Specimen instructions: It is the Health Care Provider's responsibility to obtain consent from the patient prior to collecting/submitting a sample for CF testing.

Specimen requirements: SurePath™: 1.0 mL (0.50 mL) minimum. ThinPrep™: 1.0 mL (0.5 mL) minimum, ambient temperature.

Collection and transport: SurePath™: Store and ship at ambient temperature up to 28 days.

Causes for rejection: SurePath™: Less than 0.50 mL and/ or more than 28 days.

Specimen stability: SurePath™: Stable for up to 28 days at room temperature.

Reference range: Interpretative report.

TAT: 7 Days.

CPT code: 83891 Isolation or detection of highly purified nucleic acid 83901 Amplification of patient nucleic acid, multiplex, each multiplex reaction 83896x55 Nucleic acid probe, each 83894 Separation by gel electrophoresis 83912 Interpretation and Report.

Clinical significance: This assay is used to determine affected or carrier status of the 33 most common Cystic Fibrosis (CF) mutations and associated polymorphism. It detects >90% of CF mutations in the Northern European caucasian populations. There may be higher or lower detection efficiency for different ethnic groups.

The American College of Obstetricians and Gynecologists (ACOG) now recommends that OB-GYN physicians make DNA screening for CF available to all couples seeking preconception or prenatal care not just those with a personal family history of carrying the CF gene, as previously recommended. ACOG recommends a screening panel of 25 common CF mutations and associated polymorphism (Genetics in Medicine 3:149-154, 2001).

Cystic Fibrosis is one the most common inherited diseases in the United States, affecting one infant out of every 3,000 live births. If both parents are carriers, then their child has a 25% (or one in four) chance of being born with CF. There is a 50% chance that the child will not have CF, but will be a carrier. Finally, there is a 25% chance the child will not be a carrier. Those affected have high levels of sodium and chloride in their sweat. More importantly, a thick, sticky mucous in the lungs causes persistent coughing wheezing and frequent lung infections, including pneumonia.

CF detection is done using a multiplex PCR-multiplex oligonucleotide ligation assay. The PCR OLA assay is followed by the loading of ligation products into one electrophoresis gel lane for separation, detection and data by analysis.

HERPES SIMPLEX VIRUS (HERPES SIMPLEX VIRUS) TYPE 1 & 2 DNA BY REAL-TIME (PCR)- QUALITATIVE

Test code: 900.

Method: Real-time polymerase chain reaction (PCR)-Qualitative.

Specimen requirements: SurePath™: 1.0 mL (0.50 mL) minimum.

Collection and transport SurePath™ or ThinPrep™ solution: In addition to the cervix, a thorough brushing of the vaginal wall is necessary to ensure adequate sample source.

Causes for rejection: SurePath™: Less than 0.50 mL and/or more than 28 days.

Specimen stability: ThinPrep™: Stable for up to 3 months at room temp. SurePath™: Stable for up to 28 days room temp.

Reference range: Not detected.

TAT: 1-5 days.

CPT codes: 87529x2: Herpes simplex virus Type 1 & 2, amplified probe technique.

Clinical significance: Herpes simplex virus I & II (HSV) is one of the most prevalent viruses found in the general population today. It is estimated that more than 107 million people worldwide are infected with herpes and only 21.4 million are diagnosed. Type 1 infections usually involve non-genital areas, whereas type 2 infections are primarily found in genital areas although there can be overlap between the two types. The clinical courses of acute first episode genital herpes among patients with Herpes simplex virus I and Herpes simplex virus II infections are similar and both can cause symptomatic or asymptomatic rectal and perianal infections. HSV infections may not be apparent because symptoms do not always follow a typical pattern.

By utilizing Real-time polymerase chain reaction (PCR)-Qualitative, HSV has been demonstrated in asymptomatic patients on 28% of days tested versus 8.1% by viral isolation. As a result, the rate of detection for Real-time polymerase chain reaction (PCR)-Qualitative is 3.5 times that of a traditional viral culture in asymptomatic patients. Asymptomatic shedding was shown on 60% of

days where HSV DNA was measured by Real-time polymerase chain reaction (PCR)-Qualitative. Patients with ulcerative lesions have positive Real-time polymerase chain reaction (PCR)-Qualitative results on 15 of 17 days (88.2%) versus positive culture results on 3 of 17 days (17.6%). Culture isolation or immunologic analysis of HSV from cerebrospinal fluid (CSF) is limited.

These techniques lack sensitivity and specificity and do not yield results quickly. Real time polymerase chain reaction (PCR)-Qualitative offers a rapid and sensitive way to test for HSV. In Conclusion, the detection of HSV DNA by Real-time polymerase chain reaction (PCR)-Qualitative has been proven to be the most specific, rapid and sensitive means to diagnosis anogenital and CNS infections.

References

1. Marchant J, Roe A. Genital herpes: Recognizing and addressing patients' needs. *Herpes J* 1997; 4:36:41.
2. Walt A. Subclinical shedding of herpes simplex virus in genital tract: implications from transmission *Herpes J* 1997;4:20-35
3. Cone Wyatt, Richard, et al. Extended duration of herpes simplex virus DNA in genital lesion detected by the polymerase chain reaction. *J Infect Dis* 1991 Oct;146(4):757-60.

HPV DNA ASSAY BY HYBRID CAPTURE II

Test code: 395H High Risk only (Recommended).

Method: Hybrid Capture® II.

Specimen requirements: SurePath™: 1.0mL (0.50 mL) minimum. ThinPrep™: 8.0 mL; (4.0 mL) minimum, Ambient temperature.

Cervical Biopsy: Cervical biopsy should be fresh tissue. Use the Digene cytology brush specimen collection kit (available from Genetic Assays). Remove and discard cytology brush and suspend fresh tissue in media within the collection tube. Biopsies

should be frozen at -20°C until they are shipped. Cervical biopsies processed with histological fixatives cannot be tested.

Collection and transport: SurePath™: Store and ship at ambient temperature up to 28 days. ThinPrep™: Store and ship at ambient temperature up to 3 months/90 days. Cervical biopsies are frozen and placed in styrofoam cooler with dry ice.

Causes for rejection: SurePath™: Less than 0.5 mL and/or exceeds 28 days. ThinPrep™: Less than 4.0 mL and/or exceeds than 3 months/90 days. Cervical biopsies processed with histological fixatives.

Specimen stability: SurePath™: Stable for up to 28 days at room temperature. ThinPrep™: Stable for up to 3 month at room temperature. Cervical biopsy stable indefinitely at -20°C.

Reference range: Not detected.

TAT: 1-7 days.

CPT code: 87621, papillomavirus human, amplified probe technique (low risk); 87621, papillomavirus human, amplified probe technique (high risk).

Clinical significance: HPV is a family of over 70 viruses of which 18 are associated with anogenital lesions, representing a spectrum of disease ranging from common genital warts to cervical cancer. The HPV DNA test is used for clarification and confirmation of cytologic diagnosis and may be used in triaging patients for possible referral for colposcopy.

The American Society for Colposcopy and Cervical Pathology developed consensus management guidelines that suggest testing for oncogenic/high risk types of HPV DNA to determine the management of "Atypical

squamous cells of undetermined significance” when the test can be performed using a liquid-based Pap (already available sample).

This recommendation was based on results from ALTS and other large studies demonstrating that HPV testing was as sensitive as colposcopy in identifying women with an underlying cervical intraepithelial neoplasia (CIN 2 or 3), but reduced the number of referrals by nearly 50 % and data demonstrating the optimal cost-effectiveness of this approach.

The U.S. Food and Drug Administration has approved HPV ancillary testing for management of “Atypical squamous cells of undetermined significance and in March 2003, approval was extended to include primary screening in conjunction with cytology among women 30 years of age and older. Testing should be restricted to oncogenic/high-risk types when possible.

Interpretative data: Women with atypical squamous cells of undetermined significance (ASC-US) should be managed using a program of either repeat cervical cytology testing, immediate colposcopy, or DNA testing for high-risk types of Human Papillomavirus (HPV). Testing for HPV DNA is the preferred approach when liquid-based cytology is used for screening. All women who test positive for high-risk HPV DNA should be referred for colposcopic evaluation. Women with ASC-US who test negative for high-risk HPV DNA can be followed up with repeat cytologic testing at 12 months (2001 ASCCP Guidelines –JAMA 2002; 287:2120-2129)

A positive high risk HPV test result indicates that the patient may be infected with one or more of the following HPV genotypes: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68; which are associated with cervical cancer and its precursor lesions. However, cross-reactions with other genotypes may occur.

Results should be correlated with cytologic/histologic findings.

Note: A negative result does not rule out the presence of an HPV genotype absent from the test panel, a low level infection, or specimen sampling error.

References:

1. Cox Tanner, James, Lorinez AT, Schiffman Henry, Micheal G., Sherman ME, Cullen A, Kurman RJ: Human Papillomavirus testing by hybrid capture appears to be useful in triaging women with a cytologic diagnosis of atypical squamous cells of undetermined significance. *Am.J.Obstet. Gynecol.* 1995;172:946-954
2. Wright TC Jr., Cox fJT, Massad LS, Twiggs LB, Wilkinson EJ. 2001 management guidelines for the management of women with cervical cytologic abnormalities. *JAMA* 2002; 287:287 2120-2129
3. The ALTS Group. Results of a randomized trial on the management of cytology interpretations of atypical squamous cells of undetermined significance. *Am J Obstet Gynecol* 2003;188:1383-1392.
4. Manos MM, Kinney WK, Hurley LB, et al. Identifying women with cervical neoplasia: using human papillomavirus DNA testing for equivocal Papanicolaou results. *JAMA* 1999;281: 1605-1610.

NEISSERIA GONORRHOEAE AMPLIFIED PROBE TECHNIQUE (PCR)

Test code: 180.

Method: Polymerase chain reaction (PCR)-Qualitative.

Specimen requirements: SurePath™: 1.0 mL (0.50 mL) minimum. ThinPrep™: 1.0 mL; (0.5 mL) minimum.

Collection and transport: SurePath™: Store and ship at ambient temperature up to 28 days.

Causes for rejection: SurePath™: Less than 0.25 mL and/or more than 28 days.

Specimen stability: SurePath™: Stable for up to 28 days at room temperature.

Reference range: Not detected.

TAT: 1-7 days.

CPT code: 87591, *Neisseria gonorrhoeae*, amplified probe technique.

Clinical significance: The speed and enhanced sensitivity of the Roche amplified DNA probe methodology enables early, accurate detection of *Neisseria gonorrhoeae*, resulting in timely administration of therapy. Several publications involving multiple centers have demonstrated a sensitivity of greater than 97% sensitivity in the detection of gonorrhea. The specificity is greater than 99%.

References:

1. Paldino, S., et al (1999). Diagnosis of Chlamydia trachomatis and *Neisseria gonorrhoeae*. Genitourinary infections in males by the Amplicor PCR assay of urine. *Diag Micro Infect Dis* Mar;33(3):141-6
2. Bassiri, M, Mardh, P.A., and Domeika, M. (1977). Multiplex AMPICOR PCR Screening for Chlamydia trachomatis and *Neisseria gonorrhoeae* in women attending non-sexually transmitted disease clinics. *J Clin Microbiol* Oct;35 (10):2556-60
3. Crotchfeit, K.A. et al. (1997). Detection of Chlamydia trachomatis and *Neisseria gonorrhoeae* in genitourinary specimens from men and women by a coamplification PCR assay. *J Clin Microbiol* Jun;35(6):1536-40

RESPIRATORY-PULMONARY SPECIMEN COLLECTION

The adequacy of a sputum specimen is determined primarily by the presence of alveolar (pulmonary) macrophages indicating that the specimen obtained is a deep cough specimen producing material from the lower airways. In addition, the specimen should not be obscured by oral or upper airway contaminants. Adequate bronchial brushing and washing specimens should contain large numbers of well-preserved bronchial lining cells with as little contaminating oral and upper airway material as possible. For bronchoalveolar lavage specimens, refer to Cytology, Bronchoalveolar lavage specimen collection.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

SPUTUM COLLECTION

Indications: For the detection and characterization of premalignant/malignant pulmonary lesions.

Specimen required: 5 mL (about one teaspoon), or more if possible, of sputum obtained from a deep cough specimen submitted on three to five successive mornings.

Supplies: 120 mL clean plastic specimen container; fixative (either CytoRich Red™ cytology preservative or 50% ethanol).

Collection procedures: Sputum specimens should be obtained as follows when clinically feasible. The optimum time for specimen collection is within 15 to 30 minutes after waking and before eating breakfast. Brushing of teeth or rinsing of the mouth thoroughly with water will reduce contamination by saliva. Instruct the patient to inhale and exhale deeply, forcing air from the lungs using the diaphragm. Repeat until the patient coughs and is able to produce a sputum specimen. Collect the specimen in the container attempting to obtain at least one teaspoon of sputum. Specimen should be a deep cough specimen and not saliva. Saliva is of no diagnostic value.

Fixation: Submit specimens fresh and unfixed if at all possible (see below).

If this is not possible then either:

1. Refrigerate specimen (4°C) or (39°F) up to 24 hours.
2. Add an equal amount of CytoRich Red™ cytology preservative to specimen.
3. Add an equal amount of 50% ethanol alcohol to specimen.
4. Submit specimen in a proprietary transport medium used for liquid based systems supplied by laboratory (e.g. Cyto-Rich Red™, CytoLyt).

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Up to 24 hours for a fresh specimen with no fixative added and refrigerated (4°C) or (39°F). Fixative added to specimen at room temperature stable indefinitely

Reference interval: By report.

Note: If a good specimen is not obtainable by this method, or if the patient is unable to comply, obtain an induced sputum or tracheal aspirate. The Cytopathology Laboratory will not accept induced or any other sputum samples for the cytologic detection of *Pneumocystis*, fungi or acid-fast bacilli. If a bronchoalveolar lavage cannot be obtained, the preferred methodology for detection of *Pneumocystis* is by fluorescent antibody testing. Sputum specimens for fungi and acid-fast bacilli may also be submitted to the Microbiology or Mycology Laboratories for rapid detection procedures of these organisms.

Post-Bronchoscopy sputum: Collect one (1) good, deep cough specimen at any time during the 24-hour period following bronchoscopy, as outlined above. Submit the specimen to the Cytopathology Laboratory, along with the completed Cytology test request form.

CPT code(s): 88108 Concentration and interpretation; 88305 cell block. Additional CPT codes may apply if special studies are required.

BRONCHIAL BRUSHINGS COLLECTION

Indications: For the detection and characterization of bronchoscopically visible premalignant/malignant pulmonary lesions; for the identification of some microbiologic pathogens (primarily viral and fungal).

Specimen required: Bronchoscopically directed brushing of the identified lesion.

Supplies: Standard bronchoscopy equipment. One (or more if necessary) 5 to 10 mL vial or tube of sterile normal saline or fixative (either CytoRich Red™ cytology preservative or 50% ethanol).

Collection procedures: Using standard bronchoscopy technique identify the lesion in question and obtain a brushing sample of the lesion. Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of sterile saline or fixative. **DO NOT APPLY THE BRUSH DIRECTLY TO SLIDES.** If possible, detach the brush and leave it in the vial. Label the vial with patient's first and last name, date of birth and specimen source. Submit the specimen along with the completed Cytology test request form to the Cytopathology Laboratory. If transport of the specimen will be delayed more than 4 hours the specimen should be submitted in CytoRich Red™ cytology preservative or 50% ethanol. If transport time will be less than 4 hours, or fixative is not available, the specimen should be refrigerated or kept on wet ice until transport to the Cytopathology Laboratory.

Fixation: Submit specimens fresh and unfixed if at all possible (see below). If this is not possible then either:

1. Refrigerate specimen (4°C) or (39°F) up to 24 hours.
2. Add a equal amount of CytoRich Red™ cytology preservative to specimen.
3. Add a equal amount of 50 % ethanol to specimen.
4. Submit specimen in a proprietary transport medium use for liquid based systems, supplied by laboratory (e.g. CytoRich Red™, CytoLyt).

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Up to 24 hours for a fresh specimen, no fixative added and refrigerated (4°C) or (39°F). Fixative added to specimen at room temperature indefinitely

Reference interval: By report.

CPT code: 88104.

BRONCHIAL WASHINGS COLLECTION

Indications: For the detection and characterization of bronchoscopically ill-defined or invisible premalignant/malignant pulmonary lesions; for the identification of some microbiologic pathogens (primarily viral or pneumocystis).

Specimen required: Bronchoscopically obtained washing (10 mL is preferred, fresh

no fixative) of the bronchi in the region of the suspected lesion.

Supplies: Standard bronchoscopy equipment. 120 mL clean plastic specimen container(s).

Collection procedures: Using standard bronchoscopy technique, lavage the distribution of the bronchus to be sampled. Collect the wash in a clean container. Label the container with patient's first and last name, date of birth, and specimen source.

Fixation: Submit specimens fresh and unfixated if at all possible (see below).

If this is not possible then either:

1. Refrigerate fresh specimen (4°C) or (39°F) up to 24 hours.
2. Add a equal amount of CytoRich Red™ cytology preservative to specimen.
3. Add a equal amount of 50 % ethanol to specimen.
4. Submit specimen in a proprietary transport medium use for liquid based systems, supplied by laboratory (e.g. CytoRich Red™, CytoLyt).

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Up to 24 hours for fresh specimen, no fixative added and refrigerated (4°C) or (39°F). Fixative added to specimen at room temperature indefinitely.

Reference interval: By report.

Note: For Bronchoalveolar Lavage Specimens refer to Cytology, Bronchoalveolar Lavage.

CPT code(s): Depending on methodology: 88112 Selective cellular enhancement with interpretation or 88108 Concentration and interpretation or 88104 Smears with interpretation or 8806 Cytopathology, filter. Additional CPT codes may apply if special studies are required.

SKIN SCRAPING/ TZANCK SMEAR

Test indications: Detection and characterization of inflammatory/infectious processes of the skin, especially herpetic infections.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Specimen required: Direct smear of material collected from a skin lesion, usually a vesicle.

Supplies: Two (or more) clean glass slides fixative (95% ethanol), skin scraping spatula, and Cytology test request form.

Collection procedure:

1. Label the slides with the patient's first and last name, date of birth and specimen source in pencil on the frosted end and place in a container filled with 95% ethanol so the slides are completely covered.
2. Gently scrape the area of abnormality. If the abnormal lesion is a vesicle, remove the covering and scrape both at the base of the vesicle and around the rim.

3. Remove one of the slides from the fixative. Quickly and evenly smear the collected material on one of the glass slides.
4. Immediately re-immerse the slide in fixative. Repeat the process with the second slide, if necessary, for better diagnostic yield.
5. Repeat the process for additional area if necessary. After collection, leave the slides in the 95% ethanol.
6. Submit the specimen and the completed test request form to the Cytopathology Laboratory.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Unacceptable conditions: Air-dried smears.

Stability: Fixed slides: Indefinitely.

Reference interval: By report.

CPT code: 88160

URINE (VOID OR CATHETERIZED)

Test indication: Detection and characterization of malignant cells and other urologic abnormalities in symptomatic (usually hematuria) patients; screening for malignancy in selected individuals at high risk for the development of urologic malignancy; detection and characterization of some non-neoplastic renal diseases in symptomatic (usually hematuria) patients.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

TAT: 1 day.

Specimen type: Voided/Catheterized urine.

Special required: 50 mL of an appropriately collected voided or catheterized urine specimen. Early morning and 24 hour samples are not recommended for cytologic evaluation.

Supplies: Clean collection container of appropriate size. Standard catheterization equipment (for catheterized urine). Fixative (50% ethanol).

Collection procedure: For purposes of obtaining the greatest yield of diagnostic material, a second-morning voided urine specimen should be obtained, if possible. A midstream, clean-catch specimen is recommend to avoid vaginal contamination in female patients. If the patient must be catheterized to obtain the specimen, this should be noted on the test request form as catheterization can lead to artifacts which may be misinterpreted without the knowledge that the specimen was catheterized. Label the vial with the patient's first and last name, date of birth, and specimen source. Submit the specimen to the Cytopathology Laboratory along with the completed Cytology test request form.

Fixation: If transport of the specimen will be delayed more than 24 hours, add an equal volume of 50%-70% ethanol (if sample size is too large to accommodate this volume, a well mixed aliquot (50 mL) of the specimen with an equal volume of fixative may be utilized). If transport time will be less than 24 hours, or fixative is not available, the specimen should be refrigerated or kept on wet ice until transport to the lab.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen inside a biohazard transport bag. Paper requisition(s) that accompany the specimen or slides in fixative should be placed in the outside pocket of the biohazard bag to avoid exposure to any leakage of fixative.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen in incorrect or expired fixative, specimen from unauthorized person.

Stability: Ambient temperature up to 24 hour fresh, refrigerated 72 hours add fixative 50-70% ethanol.

Reference interval: By report.

CPT code(s): 88108 Concentration and interpretation or 88112 Selective cellular enhancement with interpretation and/or 88106 Cytopathology, filter. Additional CPT codes may apply if special studies are required.

UROVYSION FISH BLADDER CANCER DETECTION BY VYSIS® UROVYSION

Test Indication: The Vysis Urovysion® Bladder Cancer FISH assay should be used as a noninvasive method to monitor urothelial carcinoma.

Method: Fluorescence in situ hybridization (FISH).

Specimen requirements: 50 ml (minimum). Note: First voided urine or bladder wash increases specimen cellularity.

Specimen type: Voided urine, bladder wash catheter urine, renal wash, ileal conduit, post cystotomy wash.

Collection and transport: Patients should be well hydrated prior to collection. Refrigerate specimen until preserved. Add an equal amount of 50% ethanol or CytoRich Red™ cytology preservative to 50-100 ml urine or washing/conduit specimen collected. Store at room temperature once preserved.

Fixation: 48 hours 2-8°C (without preservation) or 48 hour at room temperature with preservative, equal amounts 50-70% ethanol or CytoRich Red™ cytology preservative.

Causes for rejection: Specimen is 3 days (72 hours) or older (from date of collection), or specimen is less than 50 mL.

Specimen stability: Optimal 24-48 hours, (specimen cell viability is optimally high), 99% sensitivity & reliable reportable results for assay within this time frame. Suboptimal- after 48 hours, (specimen cell viability is decrease), there is a higher probability of no reportable result for this assay due to insufficient cell viability.

Reference range: Normal profile.

Interpretative data: The Vysis Urovysion® Bladder Cancer FISH assay should be used as a noninvasive method to monitor urothelial carcinoma. These findings should be interpreted in association with other clinical and pathological findings. The Vysis® Bladder Cancer Recurrence assay has been cleared by the U.S. Food and Drug Administration for voided urine samples from patients with transitional cell carcinoma of the bladder.

TAT: 2-3 days.

Test performed at US Labs, CLIA & CAP certified for High complexity testing CLIA I.D. #05D0923321 S

ICD9 code: Required on all patient requisitions.

OTHER UROLOGIC SPECIMENS

Indications: Detection of suspected malignancy utilizing lavage and brushing specimens obtained cystoscopically bladder washing, renal pelvis washing/brushing, ureteral washing/brushing or urethral washing); staging of urologic malignancies.

Specimen required: 10 ML (or more) of an appropriately-collected, cystoscopically-derived specimen.

Supplies: Standard cystoscopy equipment. Clean collection container of appropriate size. Fixative (50% ethanol).

Collection Procedure:

Washing: Using standard cystoscopy technique, obtained washing specimens, carefully denoting specific specimen sites for each specimen on the test request form. Submit the specimen fresh to the Cytopathology Laboratory along with the completed Cytology test request form. If transport of the specimen will be delayed more than 24 hours, add an equal volume of 50% ethanol alcohol. If transport time will be less than 24 hours, or fixative is not available, the specimen should be refrigerated or kept on wet ice until transport to the lab.

Brushing: Using standard cystoscopy technique, identify the lesion in question and obtain a brushing sample of the lesion.

Note: It is important to brush the edges of an ulcer, as well as the floor, in order to obtain diagnostic material. Upon withdrawing the brush, agitate the brush vigorously in a 5 to 10 mL vial of saline or fixative. DO NOT APPLY THE BRUSH DIRECTLY TO SLIDES. If possible, detach the brush and leave it in the vial. Label the vial with the patient's first and last name, date of birth and specimen source. Submit the specimen along with the

completed Cytology test request form to the Cytopathology laboratory.

If transport of the specimen will be delayed more than four hours, the specimen should be submitted in CytoRich Red™ cytology preservative or 50% ethanol. If transport time will be less than four hours, or fixative is not available, the specimen should be refrigerated or kept on wet ice until transport to the lab.

VITREOUS FLUID

Test indication: Detection and characterization of malignant cells in the eye. In cytology, vitreous fluid is most commonly evaluated to detect and characterize malignancy which may have gained access to the eye. Vitreous fluid specimens require special collection procedures under the direction of an ophthalmologist. In addition, due to lack of nutrients in this fluid, cells may rapidly degenerate rendering morphologic evaluation less than optimal if adequate care is not taken.

Methodology: Routine cytopathologic evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Specimen required: For vitreous fluids, there is no minimum amount, but collect as much as possible.

Supplies: Standard vitreous aspiration equipment, a clean collection container for vitreous fluid, a fresh specimen is preferred, (Fixative 50% ethanol if delay transport to laboratory is greater than 24 hour).

Collection procedure: Using standard vitreous collection procedures, collect an appropriate amount of vitreous fluid. Label the specimen with patient's first and last name, date of birth and specimen source. Submit the specimen to the Cytopathology

Laboratory along with the completed Cytology request form.

Note: Specimens submitted for immunocytochemical testing must be submitted fresh. If necessary, on-call personnel can be utilized during the evening or on weekends for processing of urgent specimens or those which need to be processed rapidly to avoid degeneration.

Fixation: A fresh specimen is preferred, if a longer time period between collection and processing is anticipated, the specimen may be preserved by adding an equal volume of 50% ethanol to the specimen.

Specimen stability: Refrigerated: 3 days.

Reference interval: By report.

CPT code(s): 88108 concentration and interpretation or 88112 Selective cellular enhancement with interpretation and/or 88106 Cytopathology, filter. Additional CPT codes may apply if special studies are required

WASHING(S)

Test indication: The detection and characterization of ill-defined or invisible premalignant/malignant cells.

Specimen required: Washings can be collected from various body sites including but not limited to the following sites: Respiratory tract (bronchial washings), Abdominal/Pelvic washings, Gastrointestinal tract, Larynx, Nasopharynx, Oral Cavity, Paranasal sinus, Prostate, Renal/Ureteral washing.

Methodology: Routine cytopathology evaluation.

Performed: Monday-Friday.

Reported: 1 day.

Specimen requirement: 10 mL-50 mL aliquots of balanced saline solution washed over a directly visualized area. Preferable submit sample unfixed to the laboratory in clean container labeled with patients name and source of specimen accompanied by a patient requisition with pertinent clinical information. If the specimen cannot be delivered to the laboratory immediately then a fixative should be added to the sample.

Supplies: Clean container, patient requisition, fixative (if specimen cannot to sent to lab immediately) and biohazard specimen bag.

Collection procedure: Using standard technique and equipment locate the suspect area and rinse small aliquots directly over visualized area and remove immediately with suction and place in clean container, submit unfixed to the laboratory. If a delay is expected, then sample may be partially fixed in 50% ethanol equal to the volume of the specimen, or in a proprietary transport medium supplied by the lab. Any added fixative should be noted on the requisition.

Fixation: Preferable, fresh unfixed sample. If transport time to the lab will be less than 24 hours, or fixative is not available, the specimen should be refrigerated or kept on wet ice until transport to the lab. If a longer delay (greater than 24 hours) is expected than the sample may be partially fixed in 50% ethanol equal to the volume of the specimen, or in a proprietary transport medium supplied by the lab. Any added fixative should be noted on the requisition.

Transport: Each specimen should be placed in a clearly labeled container that is leak proof. Place specimen in a biohazardous transport bag. The paper requisition(s) that accompanies the specimen should be place in the outside pocket of the biohazard bag to avoid exposure to any leakage.

Causes for rejection: Incomplete patient requisitions, unlabeled/incorrectly labeled specimen, frozen specimen, incorrect test ordered for specimen, specimen submitted in incorrect or expired fixative, specimen from unauthorized person.

Specimen stability: Up to 72 hours for a fresh specimen, no fixative added and refrigerated (4°C) or (39°F). Fixative added to specimen at room temperature indefinitely.

Reference interval: By report.

CPT code(s): 88108 Concentration and interpretation; 88305 Cell block. Additional CPT codes may apply if special studies are required

BONE MARROW- ASPIRATION AND BIOPSY

The bone marrow is one of the body's largest organs, representing 3.5 to 4.5% of the total body weight and averaging about 1500 grams in adults. The hematopoietic bone marrow is organized around the vasculature of the bone cavity. The bone marrow can be sampled relatively easily using either a needle aspirate or needle biopsy technique.

The main function of the bone marrow is to supply mature hematopoietic cells for circulating blood in a steady-state donation, as well as, to respond to increased physiologic or pathologic demands.

The bone marrow aspiration and bone biopsy are usually performed concurrently. Bone marrow studies aid in the diagnosis, staging, and monitoring of several diseases.

Hematologic diseases affecting primarily the bone marrow causing an increase or decrease of any of the cellular blood elements are among the most common indications for a bone marrow study. The conditions typically include:

1. Anemias, erythrocytosis, polycythemia;
2. Leukopenia and unexplained leukocytosis;
3. Appearance of immature and abnormal cells in the circulation;
4. Thrombocytopenia and thrombocytosis.

Systemic diseases may affect the bone marrow secondarily and require bone marrow studies for diagnosis and monitoring of the patient's condition. These may include:

1. Solid tumors arising elsewhere in the body, such as lymphomas, carcinomas,

and sarcomas, may metastasize to the bone marrow.

Patients having any of these solid tumors may undergo bone marrow studies when the initial diagnosis is established for evaluation of the degree of tumor spread and/or clinical staging of the patient's disease.

2. Infections manifested clinically as "fever of unknown origin" may exhibit granulomas, focal necrosis, or histiocytic proliferation with intracytoplasmic organisms within the marrow.
3. Hereditary and acquired histiocytosis occasionally involve the bone marrow. Examples include Gaucher's disease, sea-blue histiocytosis and hemophagocytic syndrome.

Bone marrow aspirations and/or bone marrow biopsies can be performed in physicians' offices, outpatient clinics and/or hospital settings. It is extremely important, however, to deliver the bone marrow sample to the proper anticoagulants or fixative for optimal preservation of the cellular detail and optimal interpretation of the patient's findings. Generally speaking, testing of the bone marrow sample must be performed within 24 hours.

SUPPLIES:

Appropriate supplies for preservation and delivery of bone marrow samples to the pathology laboratory can be obtained from the client service representative at PLA (501-225-2760 or 888-809-3730).

Supplies available from PLA include the following:

1. Small biopsy 10% formalin containers.
2. Lavender top vacutainer blood collection tubes.
3. Green top vacutainer blood collection tubes.
4. PLA requisition slip.
5. BioHazard specimen transport bags.

OUTPATIENT BONE MARROW SPECIMEN REQUIREMENTS

| TEST | CONTAINER | MINIMUM | STORAGE |
|-----------------------------------|---|-----------------|----------------|
| Path Evaluation of BM aspirate | EDTA (Purple) | 1 mL | Room Temp |
| Path Evaluation of BM Biopsy | 10% formalin | 1 cm | Room Temp |
| Leukemia Profile (Flow Cytometry) | EDTA (Purple) | 1 mL Aspirate | Room Temp |
| Lymphoma Profile (Flow Cytometry) | EDTA (Purple) | 1 mL Aspirate | Room Temp |
| Culture | Heparin (Green), Sterile *use a second syringe if collecting a culture | 1 mL Aspirate | Room Temp |
| Fungus Culture | Heparin (Green), Sterile | 1 mL Aspirate | Room Temp |
| Chromosome Analysis | Heparin (Green), Sterile *draw in heparinized syringe | 3-5 mL Aspirate | Room Temp |

Heparin used in sample collection for culture or chromosome analysis testing should be preservative free.

Include with the specimen:

1. A peripheral smear or a peripheral blood specimen in an EDTA tube;
2. PLA requisition (fill out completely, including insurance information), check Bone Marrow under Histopathology Test Request section;
3. Description of procedure (location and type of specimen);
4. Patient history and/or probable diagnosis;
5. Results of the most recent CBC, platelet count, and reticulocyte count preferably performed within 24 hours.

NOTE: Mix all tubes at collection by inverting a least 10-15 times. Place specimens and forms in BioHazard bag and call PLA client service representative to arrange for immediate transportation to the pathology laboratory.

Hematology and flow cytometry testing **must be completed** before specimen is 24 hours old. If the bone marrow is collected after 4:30 PM on Friday, weekends, or holidays, please make arrangements for appropriate transportation and receipt of the bone marrow biopsy and/or aspirate with the clinical pathologist on call.

This pathologist can be reached by calling (501-202-2000) and requesting the pager number of the clinical pathologist on call.

COLLECTION OF BONE MARROW SPECIMEN IN PHYSICIAN OFFICE

Bone Marrow Aspirate Place the aspirate in a lavender top tube. Mix well by inversion. Label tube with patient's name, date, and specimen type.

Bone Marrow for Flow Cytometry Place 5 mL of aspirate in a lavender top tube (1 mL minimum).

Mix well by inversion. Label tube with patient's name, date and specimen type.

Bone Marrow for Culture Place 1-2 mL of aspirate in a green top tube. Mix well by inversion. Label tube with patient's name, date and specimen type.

Bone Marrow for Cytogetic study Aspirate 3-5 mL into a heparinized syringe containing 1/10 cc of sodium heparin. Mix well. Place specimen in a green top tube. Mix well by inversion at least 20 times.

Bone Biopsy Place specimen in a small biopsy formalin container. Label container with patient's name, date and specimen type.

Please include a copy of a recent CBC, platelet count and reticulocyte count (if available) or include an appropriately drawn sample of peripheral blood in a lavender top blood collection tube. Please label this specimen as peripheral blood and submit it with the remaining portions of the bone marrow examination.

A completed PLA tissue examination requisition must be submitted with each bone marrow aspirate and/or biopsy.

FEE LIST AND CPT CODE GUIDE

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**PATHOLOGY LABORATORIES of ARKANSAS, P.A
SERVICE FEE LIST—(Professional Component Only)**

Call for current price list

Client support line (225-2760 or 1-888-809-3730)

CPT CODE BY TISSUE GROUPS

LEVEL I CPT Code 88300

Gross Exam Only

LEVEL II CPT Code 88302

Appendix, incidental
Fallopian tube, sterilization
Fingers/toes, amp, trauma
Foreskin, newborn
Hernia sac, any location
Hydrocoele sac
Nerve, x/biopsy
Skin, plastic repair
Sympathetic ganglion
Testis, castration
Vaginal mucosa, incidental
Vas deferens, sterilization

LEVEL III CPT Code 88304

Abortion, induced
Abscess
Aneurysm, artery/ventric
Appendix, x/incidental
Artery, atheromatous plaque
Bone frag(s), x/path fracture
Carpal tunnel tissue
Cartilage, shavings
Cholesteatoma
Colon, colostomy stoma
Conjunctiva, biop/pterygium
Cornea
Cyst
Diverticulum, esoph/ sm bowel
Femoral head, x/fracture
Fissure/fistula
Foreskin, x/newborn
Gallbladder
Hematoma
Hemorrhoids
Hydatid of Morgagni
Intervertebral disc
Joint, loose body
Meniscus
Mucocoele, salivary
Neuroma, Morton's/trauma
Pilonidal cyst/sinus
Polyp, inflam, nasal/sinus
Skin, cyst/tag/debride
Soft tissue, debridement
Soft tissue, lipoma
Spermatocoele
Tendon/tendon sheath
Testicular appendage
Thrombus or embolus
Tonsil and/or adenoids
Varicocoele
Vas deferens, x/steriliz
Vein, varicosity

LEVEL IV CPT Code 88305

Abortion, spontan/misseed
Artery, biopsy
Bone, exostosis
Breast, biopsy
Breast, reduc mammoplasty
Bronchus, biopsy
Cell block, any source
Cervix, biopsy
Colon, biopsy
Duodenum, biopsy
Endocervix, curet/biopsy
Endometrium, curet/biopsy
Esophagus, biopsy
Extremity, amputat, trauma
Fallopian tube, biopsy
Fallopian tube, ectopic pregnancy
Femoral head, fract
Fingers/toes, amp, x/trauma
Gingiva/oral mucosa, biopsy
Heart valve
Joint, resection
Kidney, biopsy
Larynx, biopsy
Leiomyoma(s), myomec, w/o uter
Lip, biopsy/wedge resect
Lung, transbronch biopsy
Lymph node, biopsy
Nasal mucosa, biopsy
Nasopharynx/oropharynx, biopsy
Nerve, biopsy
Muscle, biopsy
Odontogenic/dental cyst
Omentum, biopsy
Ovary, biopsy/wedge resect
Ovary w/wo tube, x/neoplasm
Parathyroid gland
Peritoneum, biopsy
Pituitary tumor
Placenta, x/3rd trimester
Pleura/pericardium, bx/tissue
Polyp, x/nasal/sinus
Prostate, needle biopsy
Prostate, TUR
Salivary gland, biopsy
Skin, x/cyst/tag/debrid/plas
Small intestine, biopsy
Soft tissue, x/tumor/mass/lpma/dbrd
Spleen
Stomach, biopsy
Synovium
Testis, x/tumor/biop/castrat
Thyroglossal duct/cleft cyst
Tongue, biopsy
Tonsil, biopsy
Trachea, biopsy
Ureter, biopsy
Urethra, biopsy
Urinary bladder, biopsy

Uterus, w/wo adnex, prolap
Vagina, biopsy
Vulva/labia, biopsy

LEVEL V CPT Code 88307

Adrenal, resection
Bone, biopsy, curettage
Bone frag(s), path fracture
Brain, biopsy
Breast mastect, part/simple
Cervix, conization
Colon, seg resect, x/tumor
Extremity, amputat, x/trauma
Kidney, nephrectomy
Larynx, resect, w/o nodes
Liver, biopsy, needle/wedge
Liver, part resect
Lung, wedge biopsy
Lymph nodes, region resect
Mediastinum, mass
Myocardium, biopsy
Odontogenic tumor
Ovary w/wo tube, neoplasm
Pancreas, biopsy
Placenta, 3rd trimester
Prostate, x/resect/TUR/biop
Salivary gland
Small intest, resect, x/tumor
Soft tissue mass x/lpma, bx/smp exc
Stomach, resect, x/tumor
Testis, biopsy
Thymus, tumor
Thyroid, total/lobe
Ureter, resection
Urinary bladder, TUR
Uterus, w/wo adnex, x/neo/prol

LEVEL VI CPT Code 88309

Bone, resection
Breast, mastect, w/nodes
Colon, seg resect, tumor
Colon, total resection
Esophagus, part/total resect
Extremity, disarticulation
Fetus, w/dissection
Larynx, resect, w/nodes
Lung, total/lobe/seg resection
Pancreas, tot/subtot resect
Prostate, radical resection
Small intest, resect, tumor
Soft tissue tumor, exten resec
Stomach, resect, tumor
Testis, tumor
Tongue/tonsil, resect, tumor
Urinary bladder, resection
Uterus, w/wo adnex, neoplasm
Vulva, resection

CPT CODE — ALPHABETICAL

| CPT | DESCRIPTION | CPT | DESCRIPTION |
|------------|-------------------------------------|------------|------------------------------------|
| 88304 | Abortion, induced | 88304 | Femoral head, x/fracture |
| 88305 | Abortion, spontan/misssed | 88309 | Fetus, w/dissection |
| 88304 | Abscess | 88302 | Finger/toes, amputation, trauma |
| 88307 | Adrenal, resection | 88305 | Finger/toes, amputation, x/trauma |
| 88304 | Aneurysm, artery | 88304 | Fissure/fistula |
| 88304 | Anus, tag | 88302 | Foreskin, newborn |
| 88302 | Appendix, incidental | 88304 | Foreskin, x/newborn |
| 88304 | Appendix, x/incidental | 88304 | Gallbladder |
| 88304 | Artery, atheromatous plaque | 88304 | Ganglion cyst |
| 88305 | Artery, biopsy | 88305 | Gingiva/oral mucosa, biopsy |
| 88304 | Bartholin's gland cyst | 88300 | Gross exam only |
| 88307 | Bone, biopsy, curettage | 88305 | Heart valve |
| 88305 | Bone, exostosis | 88304 | Hematoma |
| 88309 | Bone, resection | 88304 | Hemorrhoids |
| 88307 | Bone frag, pathologic fracture | 88302 | Hernia sac, any location |
| 88304 | Bone frag, x/pathologic fracture | 88304 | Hydatid of Morgagni |
| 88307 | Brain, biopsy | 88302 | Hydrocele sac |
| 88305 | Brain/meninges, other than tumor | 88304 | Intervertebral disc |
| 88307 | Brain/meninges, tumor resection | 88304 | Joint, loose body |
| 88305 | Breast biopsy | 88305 | Joint, resection |
| 88307 | Breast, mastectomy, partial/simple | 88305 | Kidney, biopsy |
| 88309 | Breast, mastectomy, w/nodes | 88307 | Kidney, nephrectomy |
| 88305 | Breast, reduction mammoplasty | 88305 | Larynx, biopsy |
| 88305 | Bronchus biopsy | 88307 | Larynx, resection, w/o nodes |
| 88304 | Bursa/synovial cyst | 88309 | Larynx, resection, w nodes |
| 88304 | Carpal tunnel tissue | 88305 | Leiomyoma(s), myomec, w/o uterus |
| 88304 | Cartilage, shavings | 88305 | Lip, biopsy/wedge resection |
| 88305 | Cell block, any source | 88307 | Liver, biopsy, needle/wedge |
| 88305 | Cervix, biopsy | 88307 | Liver, partial resection |
| 88307 | Cervix, conization/LEEP | 88305 | Lung, transbronchial biopsy |
| 88304 | Cholesteatoma | 88309 | Lung, total/lobe/segmental resect |
| 88305 | Colon, biopsy | 88307 | Lung, wedge biopsy |
| 88304 | Colon, colostomy stoma | 88305 | Lymph node biopsy |
| 88309 | Colon, segmental resection, tumor | 88307 | Lymph nodes, regional resection |
| 88307 | Colon, segmental resection, x/tumor | 88307 | Mediastinum, mass |
| 88309 | Colon, total resection | 88304 | Meniscus |
| 88304 | Conjunctiva, biopsy/pterygium | 88304 | Mucocele, salivary |
| 88304 | Cornea | 88305 | Muscle, biopsy |
| 88304 | Cyst | 88307 | Myocardium, biopsy |
| 88304 | Diverticulum, esoph/small bowel | 88305 | Nasal mucos, biopsy |
| 88305 | Duodenum, biopsy | 88305 | Nasopharynx/oropharynx, biopsy |
| 88304 | Dupuytren's contracture | 88305 | Nerve, biopsy |
| 88305 | Endocervic, curet/biopsy | 88302 | Nerve, x/biopsy |
| 88305 | Endometrium, curet/biopsy | 88304 | Neuroma, Morton's/trauma |
| 88305 | Esphagus, biopsy | 88307 | Odontogenic tumor |
| 88309 | Esophagus, partial/total resection | 88305 | Odontogenic/dental cyst |
| 88305 | Extremity, amputation, trauma | 88305 | Omentum, biopsy |
| 88307 | Extremity, amputation, x/trauma | 88305 | Ovary, biopsy/wedge resection |
| 88309 | Extremity, disarticulation | 88307 | Ovary w/wo tube, neoplasia |
| 88307 | Eye, enucleation | 88305 | Ovary w/wo tube, x/neoplasia |
| 88305 | Fallopian tube, biopsy | 88307 | Pancreas, biopsy |
| 88305 | Fallopian tube, ectopic pregnancy | 88309 | Pancreas, total/subtotal resection |
| 88302 | Fallopian tube, sterilization | 88305 | Parathyroid gland |
| 88305 | Femoral head, fracture | 88305 | Peritoneum, biopsy |

| CPT | DESCRIPTION |
|------------|---------------------------------------|
| 88304 | Pilonidal cyst/sinus |
| 88305 | Pituitary tumor |
| 88307 | Placenta, 3rd trimester |
| 88305 | Placenta, x/3rd trimester |
| 88305 | Pleura/pericardium, biopsy/tissue |
| 88304 | Polyp, inflammatory, nasal/sinus |
| 88305 | Polyp, x/nasal/sinus |
| 88305 | Prostate, needle biopsy |
| 88309 | Prostate, radical resection |
| 88305 | Prostate, TUR |
| 88307 | Prostate, x/resect/TUR/biopsy |
| 88307 | Salivary Gland |
| 88305 | Salivary Gland, biopsy |
| 88305 | Sinus, paranasal, biopsy |
| 88304 | Skin, cyst/tag/debridement |
| 88302 | Skin, plastic repair |
| 88305 | Skin, x/cyst/tag/debridement/plastic |
| 88305 | Small intestine, biopsy |
| 88309 | Small intestine, resection, tumor |
| 88307 | Small intestine, resection, x/tumor |
| 88304 | Soft tissue, debridement |
| 88304 | Soft tissue, lipoma |
| 88307 | Soft tissue mass, x/lipoma/smp exc |
| 88309 | Soft tissue, tumor, extensive excis |
| 88305 | Soft tissue, x/tumor/mass/lipoma/dbrd |
| 88304 | Spermatocele |
| 88305 | Spleen |
| 88305 | Stomach, biopsy |
| 88309 | Stomach, resection, tumor |
| 88307 | Stomach, resection, x/tumor |
| 88302 | Sympathetic ganglion |
| 88305 | Synovium |
| 88304 | Tendon/tendon sheath |
| 88304 | Testicular sppendage |
| 88307 | Testis, biopsy |
| 88302 | Testis, castration |
| 88309 | Testis, tumor |
| 88305 | Testis, x/tumor/biop/cast |
| 88304 | Thrombus or embolus |
| 88307 | Thymus, tumor |
| 88305 | Thyroglossal duct/cleft cyst |
| 88307 | Thyroid, total/lobectomy |
| 88309 | Tongue, tonsil, resection, tumor |
| 88305 | Tongue, biopsy |
| 88305 | Tonsil, biopsy |
| 88304 | Tonsil and/or adenoids |
| 88305 | Trachea, biopsy |
| 88305 | Ureter, biopsy |
| 88307 | Ureter, resection |
| 88305 | Urethra, biopsy |
| 88305 | Urinary bladder, biopsy |
| 88309 | Urinary bladder, resection |
| 88307 | Urinary bladder, TUR |
| 88309 | Uterus, w/wo adnexa, neoplasm |
| 88305 | Uterus, w/wo adnexa, prolapse |
| 88307 | Uterus, w/wo adnexa, x/neo/prolapse |
| 88305 | Vagina, biopsy |

| CPT | DESCRIPTION |
|------------|-------------------------------|
| 88302 | Vaginal mucosa, incidental |
| 88304 | Varicocele |
| 88302 | Vas deferens, sterilization |
| 88304 | Vas deferens, x/sterilization |
| 88304 | Vein, varicosity |
| 88305 | Vulva/labia, biopsy |
| 88309 | Vulva, resection |

TISSUE EXAM ADD-ON:

| | |
|-------|-----------------------------|
| 88311 | Decalcification |
| 88312 | Special Stain-microorganism |
| 88313 | Special Stain-other |
| 88342 | Immunoperoxidase |
| 88346 | Immunofluorescence |

FROZEN SECTION WORK:

| | |
|-------|-----------------------------------|
| 88329 | OR Consult (No Frozen) |
| 88331 | OR Consult with frozen |
| 88332 | OR Consult with additional frozen |

OUTSIDE SLIDE CONSULT:

| | |
|-------|----------------------|
| 88321 | Slides only, limited |
| 88323 | Slides, with tissue |

CYTOPATHOLOGY

| | |
|-------|-----------------------------|
| 88108 | Cytospin |
| 88151 | PAP with pathologist review |
| 88160 | Other source |
| 88162 | Extended study |
| 88104 | Cytopath, fluids/washings |

FINE NEEDLE ASPIRATIONS:

| | |
|-------|----------------------|
| 88172 | Immediate study |
| 88173 | Smear interpretation |
| 88305 | Cell block |

BONE MARROW STUDIES

| | |
|-------|----------------------------|
| 85097 | Aspirate interpretation |
| 88305 | Aspirate clot/cell block |
| 85102 | Core biopsy extraction |
| 88305 | Core biopsy interpretation |
| 88313 | Iron stain |
| 88311 | Decalcification |