

Hematopathology • *Associates*, LLC

Expertise • Reliability • Service



Hematopathology • Associates, LLC

COMPANY OVERVIEW:

One of the most difficult and long-term challenges a reference laboratory faces is earning the confidence of its physicians and practitioners. Companies that devote considerable energies to building new interactions and relationships focusing on high quality services with personal physician to physician interaction offer a professional service others don't.

HematoPathology Associates, LLC was founded in 2001 with the commitment to provide efficient, economical, high quality, state-of-the-art flow cytometric services. HematoPathology Associates, LLC is a privately owned and operated laboratory. In 2005 we developed the relationships to provide cytogenetic and molecular diagnostic services allowing us to expand our value proposition.

MISSION:

To provide fast and reliable laboratory testing services. Our major thrust is to be part of the clinician's team by developing a personal relationship and interaction with our faculty which will aid them in providing optimal care for their patients. We can do this by timely communication of abnormal results as soon as they are identified coupled with expert analysis and interpretation.

EXPERTISE:

Our technical experience in flow cytometry spans 25 years. This includes clinical and research based cytometry methods. Our technical and clinical teams have been involved in establishing many of the routinely used flow cytometry techniques. All of our hematopathologists are board certified and have a strong background in morphology and flow cytometry. All of our team has extensively published in peer-reviewed journals and continue to participate in international meetings and accreditation agencies (CAP).

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Test for Diagnosis of Specific Diseases

Acute Leukemia Panel

This panel is designed to identify and characterize the presence of leukemic blasts in acute leukemias and leukemic transformations of myelodysplastic and myeloproliferative processes. A specific panel of leucocyte markers is used to detect lineage-specific antigens.

Lymphoproliferative Panel

The Lymphoproliferative panel is designed to detect and monitor the presence of clonal expansions of lymphoid cells in tissues (lymphomas), blood (chronic lymphoid leukemia), body fluids, etc.

Acquired Cellular Immune Disorder

This profile quantitates total B-cells, T-cells, T-cell subsets (CD4/CD8), NK's cells and activated T-cells.

T-cell Helper/Suppressor Evaluation

T-cell Helper/Suppressor (CD4/CD8) counts are useful in monitoring the immune status of known HIV positive patients. This panel reports the absolute count of CD4 and the CD4/CD8 ratio.

Additional Tests

DNA ploidy and cell cycle analysis

Terminal Deoxynucleotidyl Transferase (TdT)

Myeloperoxidase Stain

Hematopathologist:

Ricardo E. Duque M.D.

Marcelino L. Alvarez, M.D.

Flow Cytometry Technical Staff:

Jose A. Iturraspe MT (ASCP)

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Flow Cytometry

Turnaround times: Our laboratory is very efficient and operates 24/7 days a week. We phone in reports on weekends and holidays. Our web-presence reporting allows the clinician to cut and paste final reports directly in to the patient's record or forward results to other colleagues.

Diagnosis and sub-classification of

- leukemia and lymphoma
- Identifying plasma cell clonality or B cell clonality
- Aid to diagnosis of myelodysplastic syndrome and blast crisis (as either lymphoid or myeloid)
- Monitoring of residual disease after therapy

Flow cytometric analysis is performed on fresh material which includes peripheral blood, bone marrow, lymph nodes, body fluids, CSF fluids, and tissues. Flow cytometry at HematoPathology Associates Labs utilizes a state-of-the-art Becton-Dickinson FACS-caliber flow cytometer containing two lasers and four fluorescence detectors providing state of the art flow cytometric evaluation.

All data is collected in list mode and can be re-reviewed and re-gated to improve sensitivity. This efficiency improves case turnaround time and is of particular benefit when only a small amount of material is available. The referring physician is notified of the results by telephone at the time abnormalities are identified. HematoPathology Associates' flow cytometry reports include both a detailed comment describing the key findings leading to the final diagnosis, as well as flow cytometric histograms ('dot-plots') showing the relevant histograms on which these findings were based.

We operate seven days a week. Verbal reports will generally be given within 24 hours from the time we receive the sample. Final written reports will be mailed within three days.

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FISH-Leukemias and Lymphomas

Hematopathology Associates, LLC has a mutually beneficial peer to peer relationship with a cytogenetics/FISH lab, Hemacon Laboratories, for additional characterization of hematolymphoid malignancies performed using portions of the specimens submitted for flow cytometry studies.

Leukemia and lymphomas are characterized by few clonal alterations, especially balanced reciprocal translocations, and these alterations are relative stable over the course of disease.

Rational for Molecular Testing

- Diagnosis
- Stratification/prognosis
- Therapy
- Minimal residual disease

Most important genetic mutations in leukemias and lymphomas can be identified by molecular FISH testing.



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WHY CHOOSE HEMATOPATHOLOGY ASSOCIATES, LLC:

- We are small company that can devote attention to all our samples and provide accurate and reliable diagnoses.
- We have a professional relationship with our clients and are available 24/7 days a week for further discussion of reports.
- Having all come from academics with over 25 years experience in hematopathology uropathology, cytogenetics and molecular FISH. We have high standards for specimen handling and reporting.
- Turn-around time: Our routine cytogenetics assay is done in 7 days. A karyotype is included in all reports with abnormal findings. For all STAT abnormal results we provide a 3-4 days preliminary verbal report. For FISH analysis, blood or bone marrow specimens once received are read in 24hours. If abnormal, a verb report is made to the pathologist, urologist or oncologist.
- Billing: HematoPathology Associates Laboratories accepts all insurance. We bill the patient for the appropriate co-pay or deductible. Our office accepts many national networks for insurance, including Medicare and direct patient billing.

CLIENT BILLING

Hematopathology Associates will work with our clients to establish the most appropriate and effective billing process. We have the ability to directly bill clients, accept insurance from the patient, and we are a participating Medicare provider. Our team will be happy to work with you to determine the best approach.

If you have any questions, please notify the client billing department at 352.372.7114.

INSURANCE AND THIRD PARTY ADMINISTRATION

Hematopathology Associates LLC. can bill the patient's insurance company or third party administrator directly. Please ensure the patient's insurance information and all applicable diagnostic codes in the ICD -9 format are provided.

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Professional Biographies

Ricardo E Duque, MD is a Hematopathologist with over 25 years experience in the diagnosis of hematologic neoplasia, particularly utilizing multiparameter flow cytometric techniques. As an Anatomic Pathologist, Dr. Duque has expertise in the correlation of flow cytometric data with the morphologic expression of hematologic malignancies.

Dr. Duque is a Graduate of the Universidad Nacional de Colombia, Bogota, Colombia. He trained in Anatomic and Clinical Pathology at Orlando Regional Medical Center. He completed a fellowship in Immunopathology at the Department of Pathology, The University of Michigan Medical School. He was appointed Assistant Professor in the Department of Pathology with clinical responsibilities in the Diagnostic Flow Cytometry facility. He later joined Dr Raul Braylan in the Division of Hematopathology at The University of Florida College of Medicine where he was appointed Director of Diagnostic Hematopathology and operated a major referral operation for the Southeast United states. Dr. Duque has been in private practice in Lakeland, Florida since 1993.

Jose A. Iturraspe, M.T. Flow cytometry Specialist for HematoPathology Associates. Mr. Iturraspe has over 25 years experience in clinical flow cytometry. Mr. Iturraspe began his career working in the newly formed flow cytometry laboratory at the University of Florida, Gainesville, FL, under the direction of its new Director, Dr. Raul Braylan. Mr. Iturraspe was at ground zero when many of the current routine techniques used in flow cytometry today were developed. He is truly a pioneer in this area and continues to collaborate with scientists at the University of Florida in developing state of the art assays for immunology and oncology. Mr. Iturraspe received his M.T. degree from the University of Florida where he went on to become the Laboratory manager for UF and also Life South Blood Bank and CEO of Hematopathology Associates. Mr. Iturraspe has over 35 peer-reviewed publications in journals.

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FLOW Specimen Collection

Peripheral Blood

1. 3-5 ml collected in EDTA. Heparin is acceptable, EDTA is preferred. Ship with a **refrigerated** gel pack within 24 hours of collection.
2. Include a freshly made smear and, if possible, WBC and differential count.

Bone Marrow

1. Collect 3-5 ml of marrow and place in an EDTA vacutainer tube. Heparin is acceptable, EDTA is preferred.
Ship with a **refrigerated** gel pack within 24 hours of collection
2. Include a freshly made smear and, if possible, WBC and differential count.

Bone Marrow or Tissue Core Biopsy

1. Collect FRESH (unfixed) biopsy and place in culture media or saline. Ship sample in an insulated container on wet ice or **refrigerated** gel packs within 24 hours of collection.

Fluids

1. Needle aspirates should be collected in culture medium or saline. Ship sample in an insulated container on wet ice or **refrigerated** gel packs within 24 hours of collection.
2. Include a freshly made smear.

Tissues

1. Submit an unfixed representative fragment (0.3 cm³ or larger) in a 15 ml conical centrifuge tube, cover the tissue fragment with RPMI. Verify that the cap is securely tightened and cover with parafilm.
2. Ship sample in an insulated container on wet ice or **refrigerated** gel packs within 24 hours of collection.
3. Include frozen section, if available.
4. Whenever possible, please submit a representative portion of the biopsy, fixed in formalin.

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Cytogenetics/FISH Specimen Collection

Peripheral Blood

1. 3-5 ml collected in sodium Heparin is acceptable. DO NOT use lithium heparin it is toxic to cells. Ship with a **refrigerated** gel pack within 24 hours of collection.
2. Include a freshly made smear and, if possible, WBC and differential count.

Bone Marrow

1. Collect 3-5 ml of marrow and place in sodium Heparin. DO NOT use lithium heparin it is toxic to cells. Ship with a **refrigerated** gel pack within 24 hours of collection
3. Include a freshly made smear and, if possible, WBC and differential count.

Handling and Transport Specimen Transport

1. Place the biohazard bag inside a suitable shipping box. Multiple samples may be placed in the same box.
FED EX Account # 260392824
2. Call FedEx at 1-800-GOFEDEX (1-800-463-3339) or DHL at 1-800-247-2676 to schedule a pick up.
3. All specimens must be placed in a biohazard bag, include all paperwork in the outer sleeve of the biohazard bag. Verify that all caps and lids are securely tightened.
4. Enclose a **refrigerated** gel pack in the shipping box with the specimen(s). Place a paper towel or something similar between the gel pack and the specimens so the gel pack does not come into direct contact with the specimens.
5. The box should then be placed in a FedEx or DHL specimen transport envelope. If Saturday is needed place a **SATURDAY DELIVERY** sticker on the envelope and check the "Sat Delivery" box on the air bill.

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Account Name: _____

Consultation request

PATIENT NAME (last, first) _____ Sex : Male Female

DATE OF BIRTH: _____ SOC. SEC.# _____

REQUESTING PATHOLOGIST: _____ Telephone #: _____

OTHER REQUESTING PHYSICIAN: _____ Telephone #: _____

Send Reports to: PATHOLOGIST REQUESTING PHYSICIAN Other _____

Bill to: Hospital Insurance Patient Medicare Medicaid Physician group

Billing Address: _____

(Please attach Face Sheet)

SPECIMEN INFORMATION

Date collected: _____ Time collected: _____

Specimen type :

Bone Marrow Biopsy _____ Bone Marrow Smears _____ Peripheral BI Smears Clot

Peripheral Blood (No. of Heparin tubes _____) (No. of EDTA tubes _____)

Bone Marrow aspirate (No. of Heparin tubes _____) (No. of EDTA tubes _____)

Tissue: type/site _____ Other _____

*****NOTE: Please submit other pertinent diagnostic materials (fixed tissue, H&E slides, frozen sections, smears, CBC w/diff. , etc.).
These materials are required for quality control.*****

TREATMENT STATUS: Pretreatment sample Post therapy sample Sample for staging

RELEVANT CLINICAL FINDINGS (Provisional Diagnosis) ICD 9 Code _____

(Please CHECK specific reasons for consultation)

Anemia Leukopenia Thrombocytopenia Leukocytosis Lymphocytosis Thrombocytosis

Lymphadenopathy History of Lymphoma History of Chronic Leukemia History of Acute Leukemia

Skin Lesion Bone Lesion Splenomegaly Hepatomegaly Mass Abnormal Cells on Smear

Plasma cell dyscrasia (Multiple Myeloma) MGUS Hodgkin's disease MDS

Test Requested:

Bone Marrow Interpretation Morphological evaluation

Flow Cytometric testing to:

R/O Lymphoproliferative process R/O Acute leukemia

Acquired Cellular Immune Disorder Evaluation T-cell Helpers / Suppressor Evaluation (HIV Monitoring)

Cytogenetic Studies

Chromosome Analysis only

Chromosome Analysis with reflex FISH

PHOTOCOPY AS NEEDED

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www.HPFlow.com