



Client Resource Guide



For Hematopathology

Miraca Life Sciences
6655 N. MacArthur Blvd.
Irving, TX 75039

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General Information

Serving more than 5,500 patients each day, Miraca Life Sciences is a leading provider of expert pathology services in the fields of breast pathology, dermatopathology, gastrointestinal pathology, hematopathology, and urologic pathology.

In addition to pathology services, Miraca Life Sciences provides consulting services and technology solutions. Hundreds of practices have worked with Miraca to address everything from workflow efficiency to regulatory measures and compliance. Contact your Sales Director or our Client Services team for more information.

Contact Information

Laboratory Site Address

4207 E. Cotton Center Blvd.
Phoenix, AZ 85040

Hematopathology Client Services

Toll-free 855.856.0656
Fax 855.856.0655
Email Hemeclientservices@miracaLS.com

Patient and Client Billing

Phone 972.331.3150
Toll-free 888.344.1160
Fax 972.331.3148 or 972.331.3149

Lab IDs

CLIA 03D1064744
CAP 7201651
NYS PFI 8362



Laboratory Hours of Operation (Phoenix)

Sunday, 12:00 a.m. to Saturday, 7:00 p.m. (Arizona time)

Please note that Arizona is in the Mountain time zone but the state does not observe Daylight Savings Time—during this part of the year, Arizona is on Pacific time.

Client Services

Client Services representatives are available Monday through Friday, 8:00 a.m. to 7:00 p.m. (Central time). Representatives also are on call after hours, and on weekends and holidays to process urgent requests for specimen pickup.

Consultations

The hematopathologists at Miraca Life Sciences will provide consultation or second opinion on referral cases for which an expert review is desired. A copy of the outside pathology report, patient billing information, and pertinent clinical history should accompany the glass slides and paraffin blocks. Please include unstained smears, if they are available. Contact Client Services (see Contact Information section above) for additional information.

Medical Records/Slide Release

For the release of medical records, please contact Client Services (see page one) and forward the patient's signed Release of Medical Records. Miraca Life Sciences only will release the patient's records to the person(s) named on the release form (physician/pathologist, legal counsel, insurance company).

Client Resource Guide for Hematopathology

For the release of slides or other pathology materials, Miraca requires a signed Record of Loan Form, which may be obtained from Client Services (see page one). Slides and other materials are released only to a patient's clinician or medical institution. Release of slides/materials requires the approval of a Miraca pathologist.

Allow 72 hours for laboratory processing before materials are shipped. Standard delivery is ground. For expedited delivery, requesters may provide a FedEx or UPS label or their carrier's account number. All materials must be returned intact within 14 days unless expressly allowed by Miraca Life Sciences in advance.

The slides/blocks are the property of Miraca Life Sciences and cannot be released to a third party without prior permission. The recipient must agree to take full responsibility and assume chain of custody of the specimen material until the materials are returned to Miraca Life Sciences.

Microbiologic Testing

Miraca Life Sciences does not perform microbial cultures or antimicrobial sensitivity testing. Specimens requiring microbiologic cultures and/or antimicrobial sensitivity testing must be referred to a local clinical laboratory or reference laboratory specializing in microbiologic testing to assure optimal specimen viability and turnaround time. Special histology stains for microbes can be performed on fixed tissues at Miraca Life Sciences.

Specimens Requiring Cultures

Miraca Life Sciences is an anatomic pathology laboratory. Specimens for cultures should be referred to a clinical reference laboratory specializing in microbiology. Miraca does not accept specimens requiring cultures, including stool samples, sputum and insulin/proinsulin testing.

Accidental Receipt of Specimens

Miraca occasionally receives time-sensitive specimens for testing that we do not perform, such as cultures and CLO testing. We will try to contact you for direction, but if we cannot reach you, we will send the specimen to an appropriate lab to preserve viability for your patient.

Radioactive Materials

Miraca Life Sciences does not accept tissue containing radioactive materials.

Turnaround Time

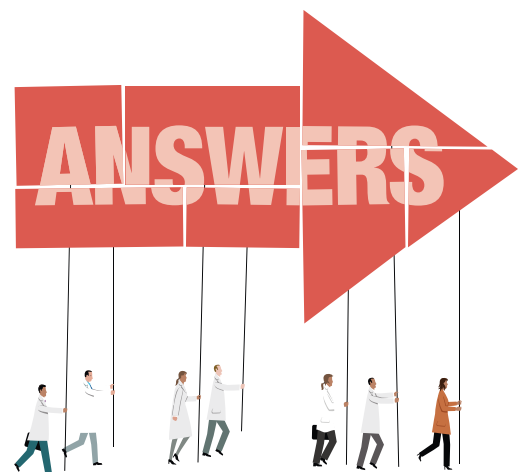
Miraca Life Sciences aims to provide the most rapid turnaround time possible without compromising diagnostic quality. Turnaround time varies with testing modality. Please refer to the expected turnaround time for each test. The turnaround time is measured from the time the specimen is accessioned into our laboratory information system to the time the report is released to the client.

Reporting Results

Any specialized testing performed may delay release of the final report. Reports are delivered electronically (to our online portal, to your fax, secure printer, or EMR interface) and will transmit to client offices after release. If requested, hard-copy reports can be sent via overnight carrier and will arrive the following day.

Specimen Collection, Labeling, and Submission

Miraca Life Sciences is committed to providing the client and patient with the highest quality service through all phases of the laboratory experience. This section describes client supplies, required patient requisition information, required specimen container labeling, and important packaging and shipping instructions.



Specimen Collection and Shipping Supplies

Miraca Life Sciences will supply specimen shippers, UPS/FedEx supplies, lab pack bags, return service labels, and UN3373 (Biological Substance) labels. Please allow 4–5 business days from the time of request for supplies to arrive.

Collection Materials Provided

- Hematopathology Shipper for Bone Marrows (including all required vials and materials)
- Peripheral Blood Shippers (including all required vials and materials)
- RPMI media containers for lymph nodes and other tissues that must be received unfixed for flow cytometric testing
- Urine kits for UroVysion FISH testing

Requisitions for All Specimens

All specimens received by Miraca Life Sciences must be accompanied by a completed test requisition form providing the following information required by regulatory agencies (such as the College of American Pathologists and New York State Department of Health):

- Patient's first and last names (no nicknames, no initials)
- Date of birth
- Patient gender
- Address
- Date of collection
- Specimen source
- Time of collection, when appropriate
- Quantity of unstained slides and/or number of tubes
- Pertinent clinical history (office notes)
- Test Requested
- ICD code
- Name and address of ordering clinician
- Authorized physician or legally authorized person requesting the test
- The identity of the person collecting the sample, if different from the physician or legally authorized person requesting the test

Incomplete information will delay processing of a patient's specimen. A Client Services Advocate will call your practice to resolve any discrepancies; however, a Discrepancy Resolution Form may be needed in order to complete specimen processing.

Labeling Specimen Containers

Use chemical resistant marker for all labeling. DO NOT label the container lid. Label the body of the container and/or specimen tube(s) with the following:

- TWO unique identifiers, one of which should be the patient's first and last name (no nicknames, no initials)
- Date of birth
- Medical record number
- Unique specimen requisition number (labels provided on requisition)

Specific specimen site information must be on the containers; however, this is NOT considered a unique identifier).

Slides and smears must be labeled with PENCIL (not pen or marker) on the frosted end of the slide. Per CAP guidelines, two unique patient identifiers are required on each slide.

Specimen processing will be delayed if the required elements are not on the specimen containers. A Discrepancy Resolution Form may need to be completed in order to complete specimen processing.

DOT Packaging

This guide outlines the requirements for shipping biological specimens. In addition, all shipments must comply with applicable local, state, and federal laws governing the packing, marking, and labeling of shipments containing biological specimens. Blood, urine, other body fluids, and other specimens containing or suspected to contain infectious substances must be shipped according to applicable government, International Air Transport Association (IATA), and International Civil Aviation Organization (ICAO) regulations. For the purposes of this guide, clinical samples are generally defined as non-infectious human or animal materials including, but not limited to, excreta, secreta, tissue and tissue fluids, blood and FDA-approved pharmaceuticals that are blood products.

General Packaging Requirements

Four layers of packaging must be included for all liquid clinical samples:

1. Primary watertight inner container

For all liquid samples, use watertight containers with a positive closure (such as a screw-on, snap-on, or push-on lid). If multiple fragile primary containers are placed into a single secondary container, each must be individually wrapped or separated to prevent contact between them during shipping.

Acceptable watertight inner containers:

- plastic container
- glass or plastic jar
- glass or plastic vial

2. Absorbent material

Place absorbent material between the primary and secondary containers, using enough material to absorb the entire contents of all primary containers in the event of leakage. Note that biohazard bags available from Miraca include absorbent material.

Acceptable absorbent material:

- cellulose wadding
- cotton balls
- super-absorbent packets
- paper towels

3. Secondary watertight inner container

Place the inner container and absorbent material in a secondary watertight container.

Acceptable secondary containers:

- sealed plastic bag—note that biohazard bags available from Miraca have an outer sleeve where you can insert the requisition form
- plastic canister
- screw-cap can

Collect and secure all individual secondary containers into a Miraca-branded Lab Pack bag. The Lab Pack bag ensures that your specimens will reach Miraca, even if the pack comes out of the outer box.

4. Sturdy outer packaging

Use rigid outer packaging constructed of corrugated fiberboard, wood, metal or plastic, appropriately sized for the contents.

Chipboard or paperboard boxes are unacceptable.



Specimen Packaging and Submission

Miraca Life Sciences has special transportation agreements with FedEx and UPS to ensure rapid and safe shipping of specimens. To ensure the viability of the specimens and the timeliness of testing, all specimens are shipped Priority Overnight/Next Day Air, including Saturday delivery.

If shipping UPS, you must use the yellow and white shipping labels. This indicates to UPS that the box is being shipped to a Miraca lab. This label helps with tracking and research of misplaced packages. Affix a UN3373 label on the outside of the box if not already present. The courier requires this label in order to comply with DOT regulations.

Prior to sealing the box, you may include a Specimen Log that lists all enclosed specimens, and fax or email the Specimen Log to Miraca Life Sciences. This optional step helps to avoid missing shipments so that our Client Services team can begin tracking immediately if expected shipments or specimens are not received. Your EMR may have the capability to create and send a specimen log electronically to Miraca. Contact Client Services (see page one) to request a supply of Specimen Log forms.

Note: In order to maintain specimen viability, it is important to contact Miraca's Client Services team (see page one) via phone or email for every shipment, so that our staff can track the specimen and resolve any potential shipping issues.

Specimen Storage

Specimens that are not in fixative must be refrigerated after collection. This includes body fluids and specimens in RPMI media for flow cytometry. All specimens in fixative (such as 10% neutral buffered formalin) can be stored at room temperature. On rare occasions, weather or other conditions may prohibit routine courier transportation of specimens. The same storage requirements apply until routine courier systems resume.

During hot summer months, May 1 to September 30, store and ship all specimens, blocks and slides on ice, particularly paraffin blocks. Additionally, blocks should not be shipped on Fridays during these summer months, May through September. These requirements are critical for specimens shipped to our Phoenix lab.

Specimen Pick-Up

Specimens from clinicians will be arranged to be picked up by UPS, FedEx or a local courier. Contact Client Services (see page one) for assistance in scheduling a specimen pick-up.

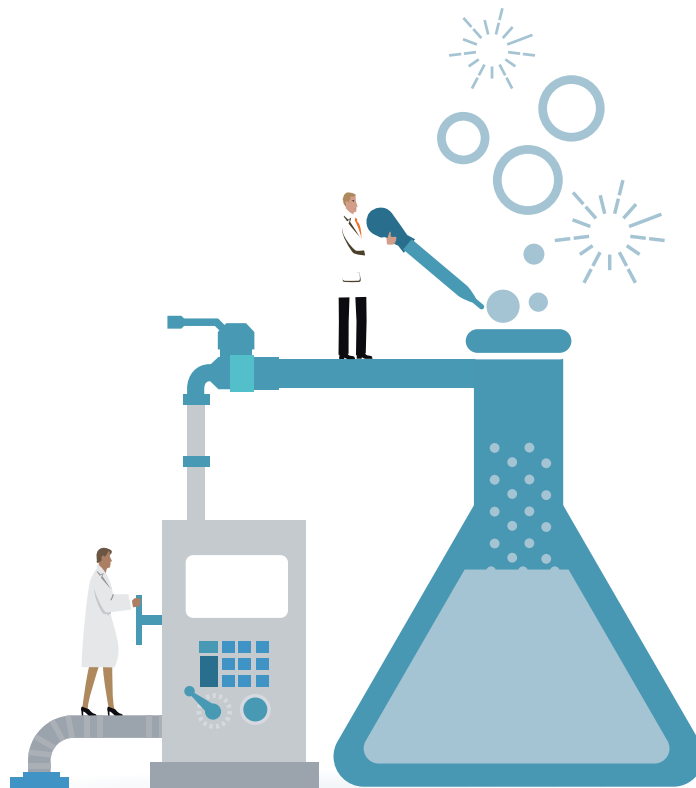


Baylor Genetics

Genetic testing is provided by our sister company, Baylor Genetics—a joint venture between Baylor College of Medicine and Miraca Holdings. Initially launched as Baylor Miraca Genetics Laboratories, this venture was built on Baylor’s existing Medical Genetics Laboratories, which engages in clinical laboratory genetic testing. Baylor has provided diagnostics services for more than 35 years and is the no. 1 National Institutes of Health-funded genetics program. For more information, contact your Miraca Life Sciences sales representative.



When ordering any genetic tests by Baylor Genetics, please first contact our Client Services team (see page one).



Test Menu by Technology

Technology

Morphology

Immunohistochemistry

Flow Cytometry (Multiparameter)

Cytogenetic Analysis

Fluorescence in situ hybridization (FISH)

Molecular Testing



Test

Bone Marrow Comprehensive Diagnostic Evaluation
 Bone Marrow Morphologic Evaluation
 Peripheral Blood Comprehensive Diagnostic Evaluation
 Peripheral Blood Morphologic Evaluation
 Tissue Morphologic Evaluation/Consultation (such as lymph node or slides prepared elsewhere)

Immunohistochemistry (IHC) Fixed Tissue
 Immunohistochemistry (IHC) Paraffin Blocks

Bone Marrow Aspirate
 Peripheral Blood
 Fresh Tissue (such as lymph node or other tissue)
 Fine Needle Aspirate (FNA)
 Body fluids, including cerebrospinal fluid (CSF)
 ZAP-70 for CLL (peripheral blood only)
 Paroxysmal Nocturnal Hemoglobinuria (PNH)

Bone Marrow Aspirate Karyotype
 Peripheral Blood Karyotype

B-cell Acute Lymphoblastic Leukemia Panel
 Acute Myeloid Leukemia Panel
 B-cell Chronic Lymphocytic Leukemia Panel
 Chronic Myeloid Leukemia Panel
 Eosinophilia Panel
 Myelodysplastic Syndrome Panel
 Plasma Cell Neoplasm Panel
 B-cell Non-Hodgkin Lymphoma Panel
 Follicular Lymphoma
 Burkitt Lymphoma
 Mantle Cell Lymphoma
 Anaplastic Large Cell Lymphoma
 HER2
 Malignant Melanoma
 UroVysion

Acute Myeloid Leukemia Prognostic Panel
 KIT (D816V)
 PML/RARA (quantitative)
 BCR-ABL Major p210/Minor p190 (quantitative)
 BCR-ABL Kinase Domain Point Mutation (T315I)
 JAK2 V617F (qualitative)
 JAK2 Exon 12 (qualitative)
 MPL W515L/K (cMPL)
 Calreticulin (CALR)
 B-cell Clonality (Gene Rearrangement Testing)
 T-cell Clonality (Gene Rearrangement Testing)
 IgVH Mutation Analysis for CLL/SLL
 BCL-1 (qualitative)
 MYD88 L265P
 Hematologic Malignancy Gene Mutation Panel

Test Menu by Evaluation Type

Comprehensive Analysis

Bone Marrow Comprehensive Diagnostic Evaluation

Specimen(s) required	<p>Bone marrow core biopsy: Attempt to obtain at least one 1.5 cm core. Place in 10% neutral buffered formalin. If no aspirate, obtain two (2) additional cores and place in RPMI. RPMI should be pinkish orange in color; do not use RPMI if cloudy or yellow. If RPMI is not available, use normal saline.</p> <p>Touch preparations: Four slides prepared from the unfixed core biopsy (before placed into formalin).</p> <p>Bone marrow aspirate smears: Prepare at least 10 at bedside from initial bone marrow aspirate pull from tube WITHOUT sodium heparin. Do not expose smears to formalin fumes. Allow all smears to completely dry before packaging to prevent artifact.</p> <p>Bone marrow aspirate: 2–3 ml in green-top (sodium heparin) tube AND 1–2 ml in purple-top (EDTA) tube.</p> <p>Bone marrow clot: Place in 10% neutral buffered formalin.</p> <p>Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube and a current CBC (a CBC will be performed if not submitted).</p> <p>Peripheral blood smear: Two freshly prepared smears are preferred, but same-day instrument smear is acceptable. Smears can be prepared by fingerstick method if necessary. Allow all smears to completely dry before packaging to prevent artifact.</p>
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes. Testing is determined by hematopathologist based on clinical data and morphologic findings, and may include immunohistochemistry, special histology stains, cytogenetic and/or FISH analysis, and molecular testing. Morphologic evaluation and flow cytometric analysis are routinely performed on all adequate samples.
Turnaround time	<p>Component reports:</p> <p>Flow cytometry; 1–2 days</p> <p>Morphology; 2–3 days</p> <p>Cytogenetics; 5–7 days</p> <p>FISH; 3–5 days</p> <p>Molecular; 5–7 days</p> <p>Summary report; 6–8 days</p>

Peripheral Blood Comprehensive Diagnostic Evaluation

Specimen(s) required	<p>Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube and current CBC report. A CBC will be performed if a recent report is not submitted. A green-top (sodium heparin) tube is required if cytogenetic testing may be needed.</p> <p>Peripheral blood smear: Two freshly prepared smears preferred. Two (2) ml of blood in a purple-top (EDTA) tube is required if smear is not provided.</p>
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Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes. Testing is determined by hematopathologist based on clinical data and morphologic findings, and may include cytogenetic and/or FISH analysis, and molecular testing. Morphologic evaluation and flow cytometric analysis, and morphology examination are routinely performed on all adequate samples.
Turnaround time	Component reports: Flow Cytometry; 1–2 days Morphology; 2–3 days Cytogenetics; 5–7 days FISH; 3–5 days Molecular; 5–7 days Summary Report; 6–8 days

Morphology Examination

Bone Marrow Morphology Evaluation (bone core biopsy, aspirate clot section, touch preps, aspirate smears, and aspirate)

Specimen(s) required	<p>Bone marrow core biopsy: Attempt to obtain at least one 1.5 cm core. Place in 10% neutral buffered formalin. If no aspirate, obtain two (2) additional cores and place in RPMI. RPMI should be pinkish orange in color; do not use RPMI if cloudy or yellow. If RPMI is not available, use normal saline.</p> <p>Touch preparations: Four slides prepared from the unfixed core biopsy (before placed into formalin).</p> <p>Bone marrow aspirate smears: Prepare at least 10 at bedside from initial bone marrow aspirate pull from tube WITHOUT sodium heparin. Do not expose smears to formalin fumes. Allow all smears to completely dry before packaging to prevent artifact.</p> <p>Bone marrow aspirate: 2–3 ml in green-top (sodium heparin) tube AND 1–2 ml in purple-top (EDTA) tube.</p> <p>Bone marrow clot: Place in 10% neutral buffered formalin.</p> <p>Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube and a current CBC (a CBC will be performed if not submitted).</p> <p>Peripheral blood smear: Two freshly prepared smears are preferred but same-day instrument smear is acceptable. Smears can be prepared by fingerstick method if needed. Allow all smears to completely dry before packaging to prevent artifact.</p>
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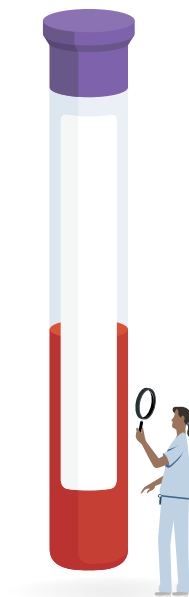
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes. Miraca will contact your office if additional testing is recommended by hematopathologist.
Turnaround time	Morphology report; 2 days

Peripheral Blood Morphology Evaluation

Specimen(s) required	Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube and current CBC report. A CBC will be performed if a recent report is not submitted. Peripheral blood smear: Two freshly prepared smears are preferred. Two (2) ml of blood in a purple-top (EDTA) tube is required if smear is not provided.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes.
Turnaround time	Morphology report; 2 days

Tissue Morphology Evaluation (lymph nodes and other tissue)/Consultation (slides prepared elsewhere)

Specimen(s) required	Fixed tissue and/or paraffin blocks: Place fresh tissue biopsy in 10% neutral buffered formalin. Indicate time placed into formalin on specimen jar, label, or requisition. If tissue has been processed already, send all associated paraffin blocks or at least 10 unstained slides for immunohistochemistry (charged slides). If available, include pathology report and results of ancillary testing (such as flow cytometry, FISH, molecular).
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled specimens.
Special notes	Include current CBC and doctor's notes and pathology report if available. Testing will be determined by hematopathologist based on clinical data and morphologic findings, and may include immunohistochemistry, special histology stains, FISH analysis, and/or molecular testing.
Turnaround time	Morphology report; 2 days



Test-Specific Information by Technology

Flow Cytometry (Multiparameter)

Bone Marrow Aspirate

Specimen(s) required	Bone marrow aspirate: 2–3 ml aspirate in purple-top (EDTA) tube is preferred, but green-top (sodium heparin) is acceptable.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes. Samples received at >48 hours past collection are considered suboptimal, however, every attempt is made to provide results.
Antibodies	Testing may include, but is not limited to, markers for CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD56, CD64, CD117, HLA-DR, kappa light chain, and lambda light chain.
Turnaround time	Flow cytometry report, 1–2 days.

Peripheral Blood

Specimen(s) required	Peripheral blood: 2–3 ml whole blood in purple-top (EDTA) tube is preferred, but green-top (sodium heparin) is acceptable.
Shipping requirements	Store at room temperature in a designated shipper and a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Special notes	Include current CBC and doctor's notes. Samples received at >48 hours past collection are considered suboptimal, however, every attempt is made to provide results.
Antibodies	Testing may include CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD56, CD64, CD117, HLA-DR, kappa, lambda.
Turnaround time	Flow cytometry report, 1–2 days.

Body Fluid, including CSF

Specimen(s) required	2 ml of representative fluid
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled or unlabeled specimens.
Special notes	Include current CBC and doctor's notes. Samples received at >48 hours past collection are considered suboptimal, however, every attempt is made to provide results.
Antibodies	Testing may include, but is not limited to, markers for CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD56, CD64, CD117, HLA-DR, kappa light chain, and lambda light chain.
Turnaround time	Flow cytometry report; 1–2 days

Fine Needle Aspirate (FNA) and Tissue (lymph node or other tissues)

Specimen(s) required	Fresh (unfixed) tissue in RPMI media: Large pieces of tissue such as excisional biopsies should be cut into small pieces about the size of a rice grain if sample is being submitted for flow cytometry only. This allows for better preservation of the antigens. RPMI should be pinkish orange in color; do not use RPMI if cloudy or yellow. If RPMI is not available, use saline.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled or unlabeled specimens. Fixed or necrotic tissues.
Special notes	Include current CBC and doctor's notes. Samples received at >48 hours past collection are considered suboptimal, however, every attempt is made to provide results.
Antibodies	Testing may include, but is not limited to, markers for CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD33, CD34, CD38, CD45, CD56, CD64, CD117, HLA-DR, kappa light chain, and lambda light chain.
Turnaround time	Flow cytometry report; 1–2 days

ZAP-70 for CLL

Specimen(s) required	Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Bone marrow aspirate or clotted blood sample. Improperly labeled or unlabeled specimens.
Special notes	Send-out test. Patient should have a document B-cell CLL clone in the blood. Include current CBC results and doctor's notes.
Turnaround time	1–2 days

Paroxysmal Nocturnal Hemoglobinuria (PNH)

Specimen(s) required	Peripheral blood: 2–3 ml whole blood in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Bone marrow aspirate, clotted blood sample, or improperly labeled specimen.
Special notes	Include current CBC and doctor's notes. Samples received at >48 hours past collection are considered suboptimal, however, every attempt is made to provide results.
Antibodies	CD235a (Glycophorin A), CD59, CD14, CD15, CD16, CD24, CD33, CD45, FLAER.
Turnaround time	1–2 days

Immunohistochemistry Paraffin Blocks

Specimen(s) required	Representative paraffin block with H&E slide
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled specimens.

Special notes	Include doctor's notes and specific markers requested. For comprehensive and morphology cases, hematopathologist will determine markers needed for diagnosis and prognosis.
Turnaround time	2 days

Cytogenetic Analysis

Karyotype—Bone Marrow Aspirate

Specimen(s) required	Bone marrow aspirate: 3 ml in green-top (sodium heparin) tube
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted, improperly labeled specimens, and/or those submitted in EDTA.
Special notes	None
Turnaround time	5–7 days

Karyotype—Peripheral Blood

Specimen(s) required	Peripheral blood: 3 ml in green-top (sodium heparin) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens or those submitted in EDTA.
Special notes	Cytogenetic analysis of the peripheral blood will only yield results for myeloid disorders if there are circulating blasts. Peripheral blood is an acceptable sample for CLL.
Turnaround time	5–7 days

Fluorescence in situ hybridization (FISH)

All of the FISH probes comprising the various panels can be ordered individually.

B-cell ALL Panel

Specimen(s) required	Bone marrow aspirate or peripheral blood: 3 ml in green-top (sodium heparin) tube is preferred.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.
Probes	CEP 4, p16(9q21)/CEP9, CEP 10, BCR/ABL t(9;22), MLL (11q23), TEL/AML t(12;21)
Turnaround time	3–5 days

AML Panel

Specimen(s) required	Bone marrow or peripheral blood: 3 ml in green-top (sodium heparin) tube is preferred.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens.

Probes ETO(RUNX1T1)/AML1(RUNX1) t(8;21), MLL (11q23), PML/RARA t(15;17), CBFB inv(16)/t(16;16), BCR/ABL t(9;22), RPN1/MECOM inv(3), EGR1 (5q31)/D5S23, D7S522 (7q31)/D7Z1

Turnaround time 3–5 days

B-cell CLL Panel

Specimen(s) required **Bone marrow aspirate or peripheral blood:** 3 ml in green-top (sodium heparin) tube is preferred.

Shipping requirements Store at room temperature in a designated shipper with a FROZEN cold pack for transport.

Criteria for rejection Clotted or improperly labeled specimens.

Probes ATM (11q22.3), CEP 12, CCND1/IgH t(11;14), D13S319 (13q14.3)/LAMP1, TP53 (17p13.1), MYB (6q23.3)/CEP6

Turnaround time 3–5 days

CML Panel

Specimen(s) required **Bone marrow aspirate or peripheral blood:** 3 ml in green-top (sodium heparin) tube is preferred.

Shipping requirements Store at room temperature in a designated shipper with a FROZEN cold pack for transport.

Criteria for rejection Clotted or improperly labeled specimens.

Probes BCR/ABL t(9;22)

Turnaround time 3–5 days

Eosinophilia Panel

Specimen(s) required **Bone marrow aspirate or peripheral blood:** 3 ml in green-top (sodium heparin) tube is preferred.

Shipping requirements Store at room temperature in a designated shipper with a FROZEN cold pack for transport.

Criteria for rejection Clotted or improperly labeled specimens.

Probes PDGFRA/FIP1L1/CHIC2 (4q12), PDGFRB (5q32-q33), FGFR1 (8p12)/CEP8, BCR/ABL t(9;22)

Turnaround time 3–5 days

MDS Panel

Specimen(s) required **Bone marrow aspirate:** 3 ml in green-top (sodium heparin) tube is preferred.

Shipping requirements Store at room temperature in a designated shipper with a FROZEN cold pack for transport.

Criteria for rejection Clotted or improperly labeled specimens.

Probes EGR1 (5q31)/D5S23, D7S522 (7q31)/D7Z1, CEP8, MLL (11q23), RB1 (13q14.2)/LAMP1, D20S108 (20q12), RPN1/MECOM inv(3)

Turnaround time 3–5 days

Plasma Cell Neoplasm Panel (Myeloma Panel)

Specimen(s) required	Bone marrow aspirate: 3 ml in green-top (sodium heparin) tube is preferred.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Peripheral blood, clotted specimen, improperly labeled specimens.
Probes	CEP7, CEP9, CCND1/IgH t(11;14), FGFR3/IgH t(4;14), IgH/MAF t(14;16), RB1(13q14.2)/LAMP1, p53 (17p13.1), CKS1B/CDKN2C (1q21/1p32.3)
Turnaround time	3–5 days

B-cell Non Hodgkin Lymphoma Panel

Specimen(s) required	Bone marrow aspirate: 3 ml in green-top (sodium heparin) tube is preferred. Formalin-fixed paraffin-embedded (FFPE) tissue (non-decalcified) also is acceptable.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens. FISH cannot be performed on decalcified tissues.
Probes	BCL6 (3q27), c-MYC (8q24), CCND1/IgH t(11;14), IgH/BCL2 t(14;18), MALT1 (18q21)
Turnaround time	3–5 days

Burkitt Lymphoma

Specimen(s) required	Bone marrow: 3 ml in green-top (sodium heparin) tube is preferred. Formalin-fixed paraffin-embedded (FFPE) tissue (non-decalcified) also is acceptable.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens. FISH cannot be performed on decalcified tissues.
Probe	c-MYC (8q24)
Turnaround time	3–5 days

Follicular Lymphoma

Specimen(s) required	Bone marrow: 3 ml in green-top (sodium heparin) tube is preferred. Formalin-fixed paraffin-embedded (FFPE) tissue (non-decalcified) also is acceptable.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens. FISH cannot be performed on decalcified tissues.
Probe	IgH/BCL2 t(14;18)
Turnaround time	3–5 days

Mantle Cell Lymphoma

Specimen(s) required	Bone marrow: 3 ml in green-top (sodium heparin) tube is preferred. Formalin-fixed paraffin-embedded (FFPE) tissue (non-decalcified) also is acceptable.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Clotted or improperly labeled specimens. FISH cannot be performed on decalcified tissues.
Probe	CCND1/IgH t(11;14)
Turnaround time	3–5 days

Solid Tumor Probes

HER2/ALK/ROS1

Specimen(s) required	Representative paraffin block with H&E
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled specimen; decalcified specimen.
Special notes	None
Turnaround time	3–5 days

UroVysion

Specimen(s) required	Urine (≥ 33 ml) preserved in Carbowax or PreservCyt
Shipping requirements	Refrigerate; ship in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled specimens.
Probes	CEP3, CEP7, LS19p21, CEP17
Special notes	None
Turnaround time	5–7 days

Malignant Melanoma

Specimen(s) required	Representative paraffin block with H&E
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Improperly labeled specimens.
Special notes	None
Turnaround time	3–5 days

Molecular Testing

AML Prognostic Panel (FLT-3, NPM1, CEBPA)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Specimen is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory. Individual tests can be performed.
Turnaround time	Send-out test; minimum of 14 days

PML/RARA (quantitative)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube. Extracted RNA of at least 1 ug.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted RNA should be shipped frozen.
Criteria for rejection	Serum or plasma. Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <48 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 5–7 days

BCR-ABL Major p210/Minor p190 (quantitative)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube or green-top (sodium heparin) tube. Extracted RNA of at least 50ul @>62.5ng/ul with a 260/280 of ~2.0.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted RNA should be shipped frozen.
Criteria for rejection	Serum or plasma. Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <48 hours old from the time of collection to receipt in the laboratory.
Turnaround time	5–7 days

BCR/ABL Kinase Domain Mutation (T315I)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube. Extracted RNA of at least 1 ug.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted RNA should be shipped frozen.
Criteria for rejection	Serum or plasma. Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <48 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 10–12 days

JAK2 V617F (qualitative)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube or green-top (sodium heparin) tube. Extracted DNA of at least 30uL @>5ng/ul with a 260/280 of ~1.8.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample, broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory. May reflex to CALR, MPL W515L/K (cMPL), JAK2 Exon 12.
Turnaround time	5–7 days

JAK2 Exon 12 (qualitative)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube or green-top (sodium heparin) tube. Extracted DNA of at least 30 uL @>5ng/ul with a 260/280 of ~1.8.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubs; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	7–10 days

MPL W515K/L (cMPL)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube or green-top (sodium heparin) tube. Extracted DNA of at least 30uL @>5ng/ul with a 260/280 of ~1.8.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	5–7 days

Calreticulin (CALR)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml aspirate in purple-top (EDTA) tube or green-top (sodium heparin) tube. Extracted DNA of at least 30uL @>5ng/ul with a 260/280 of ~1.8.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.

Turnaround time 7–9 days

KIT (D816V) Mutation for Mastocytosis

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube. Formalin-fixed paraffin-embedded (FFPE) tissue block.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Fresh tissue should be sent frozen or on dry ice. Formalin-fixed paraffin-embedded (FFPE) tissue should be sent at room temperature or refrigerated.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation; specimens fixed/processed in alternative fixatives or heavy metal fixatives or tissue sections on slides; decalcified specimens.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 5–7 days

B- and T-Cell Clonality/Gene Rearrangement Testing

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube or green-top (sodium heparin) tube. Formalin-fixed paraffin-embedded (FFPE) block or at least 10 sections. Extracted DNA of at least 200uL @ >20ng/ul with a 260/280 of ~1.8.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. FFPE should be shipped room temperature or refrigerated. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	7–12 days

IgVH Mutation Analysis for CLL/SLL

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml aspirate in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper and a FROZEN cold pack for transport. Extracted RNA should be shipped frozen.
Criteria for rejection	Serum or plasma. Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <48 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 12–14 days

BCL-1

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube. Formalin-fixed paraffin-embedded (FFPE) block or at least 10 sections.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. FFPE should be shipped at room temperature or refrigerated.

Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 5–7 days
MYD88 (L265P)	
Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport. Extracted DNA should be shipped frozen.
Criteria for rejection	Specimen container is unlabeled/mislabeled; hemolyzed or degraded sample, broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory.
Turnaround time	Send-out test; 7–10 days

Hematologic Malignancy Gene Mutation Panel (by Baylor Genetics)

Specimen(s) required	Bone marrow aspirate or peripheral blood: 2–3 ml in a purple-top (EDTA) tube.
Shipping requirements	Store at room temperature in a designated shipper with a FROZEN cold pack for transport.
Criteria for rejection	Specimen is unlabeled/mislabeled; hemolyzed or degraded sample; broken or leaking tubes; improper transportation.
Special notes	Peripheral blood or bone marrow should be <96 hours old from the time of collection to receipt in the laboratory. Individual tests can be performed.
Turnaround time	Send-out test; minimum of 14 days

Contact Miraca Client Services (see page one) for questions about new or discontinued tests.

Revisions

Revision Number	Effective Date	Reason for Change
0	9/16	Initial implementation. Common document for multiple sites.