labcorp | Oncology

Client Services
Shelton, CT: (800) 447-5816
Fax: (212) 698-9532

HEMATOPATHOLOGY

oncology.labcorp.com

Highlighted fields are REQUIRED

CLIENT INFORMATION

ORDERING PHYSICIAN	NPI #
TREATING PHYSICIAN	NPI #
PHYSICIAN/AUTHORIZED SIGNATURE	

Client#

Client Name

Address

Phone Number Fax Number

PATIENT INFORMATION

Name (LAST, FIRST, MI):

Date of Birth: Sex: ☐ Male ☐ Female

Address:

City, State, Zip:

Phone Number:

Med. Rec. # / Patient #:

BILLING INFORMATION (attach face sheet and copy of insurance card – both sides)

Bill: ☐ My Account ☐ Insurance ☐ Medicare ☐ Medicaid ☐ Patient ☐ Workers Comp
Patient Hospital Status: ☐ In-Patient ☐ Out-Patient ☐ Non-Patient
Insurance Information: ☐ See attached Authorization # _____

PRIMARY BILLING PARTY	SECONDARY BILLING PARTY
INSURANCE CARRIER	INSURANCE CARRIER
ID #	ID #
GROUP #	GROUP #
INSURANCE ADDRESS	INSURANCE ADDRESS
NAME OF INSURED PERSON	NAME OF INSURED PERSON
RELATIONSHIP TO PATIENT	RELATIONSHIP TO PATIENT
EMPLOYER NAME	EMPLOYER NAME

*IF MEDICAID STATE | PHYSICIAN'S PROVIDER # | WORKERS COMP ☐ Yes ☐ No

SPECIMEN INFORMATION

Collection Date: Time: ☐ AM ☐ PM

Specimen ID #(s):

Body Site/ Descriptor:

Fixative: ☐ 10% Neutral Buffered Formalin ☐ Other: Hours Fixed:

Specimen Type:		Smears:
☐ BM Aspirate	☐ Fluid:	☐ Peripheral Blood #
☐ BM Clot	☐ FNA:	☐ BM Touch Preps #
☐ BM Core	☐ CSF	☐ BM Aspirate #
☐ Dry Tap	☐ Lymph Node:	☐ Effusion #/Source
☐ Peripheral Blood	☐ Slides #	☐ Fresh Tissue #/Site

If Slide Procurement required, indicate below:

Facility Name:

Address:

Phone Number: Fax Number:

CLINICAL INDICATION FOR STUDY (attach clinical history and pathology reports)

Narrative Diagnosis/Clinical Data (please include Pathology report with diagnosis, indication for study, and previous test results):

For pediatric patients ONLY: ☐ COG Study ☐ COG Post Treatment

All diagnoses should be provided by the ordering physician or an authorized designee.
Diagnosis/Signs/Symptoms in ICD-CM format in effect at Date of Service (Highest Specificity Required)

ICD-CM	ICD-CM	ICD-CM
☐ Acute Lymphoblastic Leukemia ☐ B-cell ☐ T-cell ☐ Lineage Uncertain	☐ Hodgkin Lymphoma	☐ Myelodysplastic Syndrome
☐ Acute Myeloid Leukemia	☐ Leukemia, Unspecified	☐ Myeloproliferative Neoplasm
☐ Anemia	☐ Leukocytosis, Unspecified	☐ Non-Hodgkin Lymphoma
☐ Chronic Lymphocytic Leukemia	☐ Leukopenia	☐ Polycythemia
☐ Chronic Myelogenous Leukemia	☐ Lymphadenopathy	☐ Suspected malignant neoplasm
	☐ Monoclonal Gammopathy	☐ Thrombocytopenia
	☐ Myeloma, Plasma Cell	☐ Thrombocytosis

When ordering tests for which Medicare or Medicaid reimbursements will be sought, physicians should order only those tests that are medically necessary for the diagnosis or treatment of the patient.

MORPHOLOGIC EVALUATION

☐ Bone Marrow Morphology (with IHC/special stains)
☐ Hematopathology Consultation (with IHC/special stains)
☐ Hematopathology Consultation as above with Diagnostic tests per IO reflex criteria (see reverse)
☐ Second Opinion Consultation (stained slides without FFPE)
☐ Peripheral Blood Morphology
☐ Other: _____
☐ IHC/Special Stains with Interpretation (specify):
_____
_____

FLOW CYTOMETRY (see reverse for antibody list)

☐ Hematolymphoid/Neoplasia Assessment (HNA)
☐ Add diagnostic tests per IO Reflex Criteria (see reverse)
☐ Add prognostic tests per IO Reflex Criteria (see reverse)
☐ DNA Ploidy/S-Phase Assessment
☐ Leukocyte Adhesion Deficiency Assessment♦[1]
☐ BAL CD4:CD8 Assessment[1]
☐ ZAP70/CD38 Assessment
☐ PNH♦
☐ Stem Cell Enumeration[1]
☐ CLL MRD
☐ ALL MRD (meets COG requirements)
[1] Send to TN

VIRTUAL FLOW CYTOMETRY (Technical Component; reflex criteria on reverse)

☐ Hematolymphoid/Plasma Cell Neoplasia (Blood, Bone Marrow, or tissue samples)

CYTOGENETICS©

☐ Cancer Cytogenetics ☐ Constitutional Cytogenetics‡

FISH (select disease state profile OR individual probes)

Disease State Profiles (see reverse for panel components)

☐ ALL (Adult) ☐ ALL (Pediatric) ☐ AML ☐ CLL
☐ Multiple Myeloma ☐ MPN/CML ☐ MPN w/ Eosinophilia ☐ MDS
☐ Aggressive B-Cell Lymphoma

Pediatric (COG) ☐ ALL (Std Risk) ☐ ALL (High Risk) ☐ AML
COG Single Probes ☐ ABL1 ☐ ABL2 ☐ PDGFRb

Individual Probes (for a complete list of probes visit oncology.labcorp.com)

☐ ALK ☐ BCL6 ☐ BCR/ABL1
☐ BCR/ABL1, if neg reflex to JAK2 V617F Qual, if JAK2 neg reflex to CALR and MPL
☐ CBFB (inv16) ☐ CCND1/IGH, t(11;14) ☐ IGH/BCL2, t(14;18) ☐ IGH/MYC, t(8;14)
☐ MALT1 ☐ PML/RARA ☐ KMT2A (MLL) ☐ RUNX1/RUNX1T1, t(8;21)
☐ TCRA/D ☐ TP53 (17p-)
Other FISH, specify: _____

MOLECULAR©

IntelliGEN® NGS Assay (see reverse for gene list; bone marrow or peripheral blood)

☐ IntelliGEN® Myeloid for AML, MDS, MPN
Indication: _____

Reveal® SNP Microarray* *If suspect balanced translocations, run cytogenetics and/or FISH*

☐ SNP Microarray for ALL, AML, CLL, MDS and other Hematologic Malignancies
Indication: _____
☐ FISH + SNP Microarray for Multiple Myeloma ☐ SNP Microarray for Multiple Myeloma
If MM(FISH+SNP) is ordered, probes t(4; 14), t(11; 14), t(14; 16) are performed

Acute Leukemia
☐ FLT3 Mutation
☐ IDH 1/2 Mutation
☐ CEBPA Mutation
☐ NPM1 Mutation
☐ PML/RARA (Quantitative)
☐ cKIT Mutation
☐ LeukoStrat® CDx FLT3 Mutation

Lymphoid Neoplasms
☐ B-cell Rearrangement IgH
☐ T-cell Rearrangement TRG
☐ B-cell Rearrangement IgK
☐ T-cell Rearrangement TRB
☐ BCL1 Rearrangement
☐ BCL2 Rearrangement
☐ IgVH Mutation
☐ p53 (CLL/B-cell ONLY)
☐ BRAF Mutation
☐ MYD88 Mutation

MPN/CML/Mastocytosis
☐ BCR/ABL1 Quantitative
☐ ABL Kinase Domain Mutation (BCR/ABL will be run)
☐ JAK2 V617F Mutation, Qual if negative reflex to:
☐ CALR
☐ JAK2 Exon 12-15
☐ MPL 515
☐ JAK2 Exon 12-15 Mutation
☐ MPL 515 Mutation
☐ CALR Mutation
☐ KIT D816V Mutation Digital PCR

☐ Other Molecular, specify: _____

SPECIAL CHEMISTRY (Serum ONLY)

Multiple Myeloma Diagnostic: *Meets IMWG Guidelines
☐ 120256 Immunofixation (sIFE), Protein Electrophoresis (SPE), Quant Free κ/λ Light Chains (sFLC)*
☐ 123200 Mutiple Myeloma Cascade, SPE Reflex to sIFE and sFLC

Multiple Myeloma Monitoring:
☐ 001495 sIFE, SPE ☐ 001487 SPE ☐ 001685 sIFE
☐ 123218 sIFE DARZALEX® (daratumumab patients ONLY)
☐ 121137 sFLC, Quantitative Free Light κ/λ Chains plus Ratio
☐ 123062 sIFE SARCLISA® (isatuximab patients ONLY)

♦Peripheral blood only
*If sending DNA, the lab only accepts isolated or extracted nucleic acids for which extraction or isolation is performed in an appropriately qualified CLIA and/or CAP/CMS equivalent laboratory.

Prognostic Test Reflex Criteria

Disease Category	Timing	Findings (Morphology, Flow cytometry, FISH and/or karyotyping)	Tests to Perform
ALL	Initial Diagnosis	ALL	Pediatric FISH Profile (<22 years) or Adult FISH Profile (>22 years); Reveal® SNP Array
AML	Initial Diagnosis	AML or borderline AML	FISH probes for RUNX1T1/RUNX1 t(8;21), CBFB inv(16), or PML/RARA t(15;17) or MLL respectively, as indicated; NGS myeloid panel + FLT3 testing for patients <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
AML	Relapse	Findings indicative of relapse	NGS myeloid panel <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
CLL (peripheral blood/bone marrow)	Initial Diagnosis	CD5+ neoplasm with classic or variant CLL features; >5K/uL circulating monoclonal B-cells or 10% or more marrow based monoclonal B-cells	CLL FISH profile or CLL SNP array with FISH probe for CCND1/IGH t(11;14), ZAP70/CD38 assay, and IgVH mutation analysis
CLL (peripheral blood/bone marrow)	Follow-up*	Features of refractory disease or disease progression/transformation	FISH probe for TP53 (17p-) deletion, TP53 mutation analysis, and SNP array
CML	Initial Diagnosis	Compatible or diagnostic findings for CML	Quantitative BCR/ABL1 assay and cytogenetics
CML	Follow-up*	Prior diagnosis of CML	Quantitative BCR/ABL1 assay; if features of progression, discuss addition of NGS myeloid panel with client or place comment in report
MPN	Initial Diagnosis	Morphologic features of MPN, but negative for JAK2 V617F, CALR, and MPL mutations	NGS myeloid panel for patients <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
MPN	Follow-up*	History of MPN, currently with features of progression (increased blasts or dysplastic features)	Discuss additon of NGS myeloid panel with client or place comment in report
MDS	Initial Diagnosis	Morphologic diagnosis of MDS with normal cytogenetic karyotype	NGS myeloid panel for patients <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
Plasma cell neoplasia	Initial Diagnosis	5% or more neoplastic plasma cells by morphology or 1% or more by flow cytometry	Myeloma FISH profile
Plasma cell neoplasia	Follow-up*	Features of disease progression	FISH probes for TP53 (17p-), CKS1B (1q21), Monosomy 13/13q-
SLL	Initial Diagnosis	SLL identified in tissue sample by flow cytometry with 10% or more neoplastic cells	CLL FISH profile or CLL SNP array with FISH probe for CCND1/IGH t(11;14), IgVH mutation analysis

*recommendation for follow-up evaluation requires that prior material was evaluated in an IO facility

Diagnostic Test Reflex Criteria Based on Flow Cytometry or Surgical Pathology Consultation Findings

Disease Category	Timing	Findings	Tests to Perform
AML	Initial Diagnosis	Diagnostic or suspicious for AML with RUNX1T1/RUNX1 t(8;21), CBFB inv(16), or PML/RARA t(15;17), acute myelomonocytic, or acute monocytic/ monoblastic leukemia	FISH probes for RUNX1T1/RUNX1 t(8;21), CBFB inv(16), or PML/RARA t(15;17) or MLL respectively, as indicated; NGS myeloid panel + FLT3 testing for patients <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
B-cell lymphoma	Initial Diagnosis	Findings suspicious or diagnostic for B-cell lymphoma, but with equivocal findings with regard to subclassification (for tissue cases 5% or more abnormal B-cells by flow cytometry; for peripheral blood/bone marrow cases, 10% or more abnormal B-cells)	FISH probes from NHL FISH panel and molecular assays as indicated
Large B-cell lymphoma or Burkitt lymphoma	Initial Diagnosis	Abnormal B-cells diagnostic or suspicious for large B-cell lymphoma or Burkitt lymphoma	FISH probes for MYC, BCL6, and BCL2 translocations and cytogenetic karyotyping, as indicated; reflex to 11q FISH probe (BCL1 and ATM) for MYC, BCL6, BCL2 negative cases suspicious for Burkitt lymphoma, as indicated
Eosinophilia	Initial Diagnosis	Peripheral blood with 1.0K/uL or more eosinophils	FISH probes for PDGFRA, PDGFRB, and FGFR-1
Hairy Cell Leukemia (HCL)	Initial Diagnosis	CD103+ monoclonal B-cells (5% or more) inconclusive for HCL	BRAF mutation
Lymphoplasmacytic Lymphoma (LPL)	Initial Diagnosis	Monoclonal B-cells (10% or more) with features indicating LPL in differential diagnosis	MYD88 mutation
Mantle cell lymphoma (MCL)	Initial Diagnosis	Monotypic B-cells (5% or more) diagnostic or suspicious of MCL	FISH probe for CCND1/IGH t(11;14)
Mastocytosis	Initial Diagnosis	Atypical mast cells by flow cytometry	High-sensitivity KIT D816V mutation analysis for mast cell disease
CML	Initial Diagnosis	Flow cytometric findings suspicious for CML	FISH for BCR/ABL1
MDS/MPN	Initial Diagnosis	Findings suspicious for MDS/MPN (CMML, aCML, etc.)	NGS myeloid panel for patients <60 years; discuss necessity of testing with client or place comment in report for patients >= 60 years
T-cell lymphoma/leukemia	Initial Diagnosis	Atypical T-cells diagnostic or suspicious for T-cell lymphoma/leukemia	TCR gene rearrangement; ALK FISH probe for CD30+ cases, as indicated; cytogenetic karyotyping if material adequate

+LeukoStrat® CDx FLT3 Mutation performed by The Laboratory for Personalized Molecular Medicine (LabPMM®) ‡Informed consent is required for non-oncology genetics testing for New York state patients.

Flow Cytometry*

Peripheral blood/bone marrow panel (HNA) 24 *▯ antibodies	Tissue/fluids panel (HNA) 19 *▯ antibodies	PNH Evaluation
CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b, CD13, CD14, CD16, CD19, CD20, CD23, CD57, CD33, CD34, CD38, CD45, CD56, CD64, HLA-DR, kappa light chain, lambda light chain	CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11c, CD13 or CD33, CD19, CD20, CD22, CD23, CD38, CD45, CD56, CD71, kappa light chain, lambda light chain	CD14, CD15, CD24, CD45, CD64, FLAER. CD59 and CD235a may be added at discretion of reviewing pathologist

*Additional antibodies may be added if determined to be medically necessary to render a diagnosis in the opinion of the reviewing pathologist. ▯Markers performed determined by testing facility.

Technical Component Flow Cytometry Reflex Criteria

Labcorp Oncology uses a 24 antibody panel for peripheral blood/bone marrow and a 21 antibody panel for tissue/fluids. If necessary, additional antibodies will be added based on the following reflex criteria. Additional CPT codes and associated charges will apply if reflex testing is performed.

- If submitted history of monoclonal gammopathy or if ≥0.5% plasma cells are detected cytoplasmic kappa and lambda light chains, and possibly CD138, will be added.
- If monoclonal/suspicious B-cells are present in blood or bone marrow samples, CD23, FMC-7, CD22, CD103, and CD11c will be added; if the atypical cells express CD103, CD25 will be added; if surface immunoglobulin light chains are absent, cKappa and cLambda may be added.
- If atypical lymphoblasts detected, CD1a, cCD3, CD22, CD25, cCD79a, cMPO, and/or cTdT may be added.
- If ≥10% blasts are present, CD15, CD11c, CD25, cMPO, cTdT, cCD79a, cCD3, CD61, CD41, CD235a, and CD71 may be added.
- If atypical B-lymphoblasts are detected, cTdT, cCD22, cCD79a, MPO, and cCD3 may be added.
- If atypical T-cells possibly representing T-cell lymphoma are detected, CD1a, CD11c, CD25, TCRAB, TRCGD, cTdT, CD30, CD52, cCD3, and CD103 may be added.
- If insufficient sample for a full study is received or atypical findings outside the above protocols are detected, you will be contacted by an analyst in order to define a strategy for the case.

FISH (disease state profile OR individual probes)

ALL (Adult)
- BCR/ABL1, t(9;22)
- KMT2A (MLL)
- MYC
- 6
- 21q

ALL (Pediatric/Std Risk)
- BCR/ABL1, t(9;22)
- 4
- 10
- 17
- KMT2A (MLL)
- CDKN2A (p16)
- TCF3 (E2A)
- ETV6/RUNX1, t(12;21)

ALL (High Risk) includes the above probes PLUS:
- ABL1
- ABL2
- PDGFRB

AML
- PML/RARA, t(15;17)
- CBFB, inv(16)
- RUNX1T1/RUNX1, t(8;21)
- 5q
- 7q
- KMT2A (MLL)

Aggressive B-cell Lymphoma
- BCL2
- BCL6
- MYC

CLL
- TP53 (17p-)
- ATM (11q-)
- CCND1/IGH, t(11;14)
- 13q14 (DLEU)
- 12

MDS
- 5q
- 7q
- 20q
- 8

MPN/CML
- 20q
- 8
- 9
- 13q14 (DLEU)
- BCR/ABL1, t(9;22)

MPN with Eosinophilia
- FGFR1
- PDGFRA
- PDGFRB

Multiple Myeloma
- Monosomy 13/13q-
- TP53 (17p-)
- 7
- 9
- 15
- CCND1/IGH, t(11;14)
- CKS1B (1q21)
- FGFR3/IGH, t(4;14)
- IGH/MAF, t(14;16)

NHL
- ALK
- BCL6
- CCND1/IGH, t(11;14)
- IGH/BCL2, t(14;18)
- IGH/MYC, t(8;14)
- MALT1
- TCRA/D

SERUM - Multiple Myeloma Cascade, Protein Electrophoresis (SPE) reflex to Immunofixation (sIFE) and Free Light Chain (sFLC)

for interpretation, refer to www.Labcorp.com

IntelliGEN® (for genes evaluated, refer to oncology.labcorp.com)

Lab Locations

Accupath Diagnostic Laboratories, Inc.		Esoterix Genetic Laboratories, LLC
201 Summit View Drive, Suite 100 Brentwood, TN 37027	5005 South 40th Street Phoenix, AZ 85040	3 Forest Parkway Shelton, CT 06484

Patient, client, and billing information is requested for timely processing of this case. Medicare and other third party payors require that services be medically necessary for coverage, and generally do not cover routine screening tests.

When ordering tests that are subject to ABN guidelines, refer to the policies published by your Medicare Administrative Contractor (MAC), CMS, or www.LabCorp.com/MedicareMedicalNecessity.
Symbols Legend
@ = Subject to Medicare medical necessity guidelines
^ = Medicare deems investigational. Medicare does not pay for services it deems investigational.

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