MAYO CLINIC LABORATORIES

FILE DEFINITION TEST CHANGE

Notification Date: November 10, 2026
Effective Date: December 15, 2026

Hematologic Disorders, Leukemia/Lymphoma; Flow Hold, Varies

Test ID: HLLFH

Explanation: The Testing Algorithm and Reflex Test Table will be updated on the effective date.

Current Algorithm	New Algorithm
This test is designed to delay the start of leukemia/lymphoma immunophenotyping until the preliminary assessment is completed. Spinal fluid specimens are held in the laboratory until noon (12 p.m. Central time) 1 day after the collection date. All other specimen types are held in the laboratory until noon (12 p.m. Central time) 2 days after the collection date. For testing to be canceled, the client must call 800-533-1710. The testing process will be initiated and fully charged if no notification is received within this time period. To expedite the beginning of testing, call 800-533-1710.	This test is designed to delay the start of leukemia/lymphoma immunophenotyping until the preliminary assessment is completed. Spinal fluid specimens are held in the laboratory until noon (12 p.m. Central time) 1 day after the collection date. All other specimen types are held in the laboratory until noon (12 p.m. Central time) 2 days after the collection date. For testing to be canceled, the client must call 800-533-1710. The testing process will be initiated and fully charged if no notification is received within this time period. To expedite the beginning of testing, call 800-533-1710.
The testing process begins with a screening panel. The panel will be charged based on the number of markers tested (FIRST for first marker, ADD1 for each additional marker). The interpretation will be based on markers tested in increments of 2 to 8, 9 to 15, or 16 and greater. In addition, reflex testing may occur to fully characterize a disease state or clarify any abnormalities from the screening test. Reflex tests will be performed at an additional charge for each marker tested (FIRST if applicable, ADD1 if applicable).	The testing process begins with a screening panel. The panel will be charged based on the number of markers tested (FIRST for first marker, ADD1 for each additional marker). The interpretation will be based on markers tested in increments of 2 to 8, 9 to 15, or 16 and greater. In addition, reflex testing may occur to fully characterize a disease state or clarify any abnormalities from the screening test. Reflex tests will be performed at an additional charge for each marker tested (FIRST if applicable, ADD1 if applicable).
In addition to reflexing flow cytometric panels, AMLMF / Acute Myeloid Leukemia (AML), Specified FISH, Varies testing for *PML::RARA* translocation t(15;17) may be added by the Mayo Clinic pathologist to exclude acute promyelocytic leukemia if there is morphologic suspicion and/or blasts and promyelocytes are CD34 and *HLA-DR*-negative.	In addition to reflexing flow cytometric panels, APLDF / Acute Promyelocytic Leukemia-PML::RARA Fusion, Expedited Diagnostic FISH, Varies testing for PML::RARA translocation t(15;17) may be added by the Mayo Clinic pathologist to exclude acute promyelocytic leukemia if there is morphologic suspicion and/or blasts and promyelocytes are CD34 and HLA-DR-negative.
The triage panel is initially performed on peripheral blood, bone marrow, and fluid samples to evaluate for monotypic B cells by kappa and lambda immunoglobulin light chain expression, increased numbers of blasts by CD34 and CD45 expression along with side scatter gating, and increased plasma cells by CD45 expression and side	The triage panel is initially performed on peripheral blood, bone marrow, and fluid samples to evaluate for monotypic B cells by kappa and lambda immunoglobulin light chain expression, increased numbers of blasts by CD34 and CD45 expression along with side scatter gating, and increased plasma cells by CD45 expression and side

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scatter gating. The triage panel also includes antibodies to assess the number of CD3-positive T cells and CD16-positive/CD3-negative natural killer (NK) cells present. This triage panel also determines if there is an increase in the number of T cells that aberrantly coexpress CD16, an immunophenotypic feature of T-cell granular lymphocytic leukemia.

The tissue triage panel is initially performed on tissue specimens to evaluate for monotypic B cells by kappa and lambda immunoglobulin light chain expression, CD5, CD10, CD19, CD20, and CD23. Increased numbers of blasts and plasma cells are identified by CD45 expression along with side scatter gating. The panel can also evaluate T cells with CD3, CD5, and CD7. Additionally, viability is assessed on all tissue specimens using 7-AAD (7-amino actinomycin d) exclusion.

This testing, together with the provided clinical history and morphologic review is used to determine what, if any, additional testing is needed for disease diagnosis or classification. If additional testing is required, it will be added per algorithm to fully characterize a disease state with a charge per unique antibody tested.

If no abnormalities are detected by the initial triage panel, no further flow cytometric assessment will be performed unless otherwise indicated by specific features of the clinical presentation or prior laboratory results.

In addition to reflexing flow cytometric panels, fluorescence in situ hybridization (FISH), molecular testing or cytochemical stains may be recommended by the Mayo Clinic pathologist to facilitate diagnosis. They will contact the referring provider or pathologist to confirm the addition of these tests.

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The tissue triage panel is initially performed on tissue specimens to evaluate for monotypic B cells by kappa and lambda immunoglobulin light chain expression, CD5, CD10, CD19, CD20, and CD23. Increased numbers of blasts and plasma cells are identified by CD45 expression along with side scatter gating. The panel can also evaluate T cells with CD3, CD5, and CD7. Additionally, viability is assessed on all tissue specimens using 7-AAD (7-amino actinomycin d) exclusion.

This testing, together with the provided clinical history and morphologic review is used to determine what, if any, additional testing is needed for disease diagnosis or classification. If additional testing is required, it will be added per algorithm to fully characterize a disease state with a charge per unique antibody tested.

If no abnormalities are detected by the initial triage panel, no further flow cytometric assessment will be performed unless otherwise indicated by specific features of the clinical presentation or prior laboratory results.

In addition to reflexing flow cytometric panels, fluorescence in situ hybridization (FISH), molecular testing or cytochemical stains may be recommended by the Mayo Clinic pathologist to facilitate diagnosis. They will contact the referring provider or pathologist to confirm the addition of these tests.

Current Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
FCINT	Flow Cytometry Interp, 2-8 Markers	No (Bill Only)	No
FCIMS	Flow Cytometry Interp, 9-15 Markers	No (Bill Only)	No
FCINS	Flow Cytometry Interp,16 or greater	No (Bill Only)	No
AMLMF	AML, Specified FISH	Yes	No

New Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
FCINT	Flow Cytometry Interp, 2-8 Markers	No (Bill Only)	No
FCIMS	Flow Cytometry Interp, 9-15 Markers	No (Bill Only)	No
FCINS	Flow Cytometry Interp,16 or greater	No (Bill Only)	No
APLDF	APL – PML::RARA fusion, FISH, BL/BM	Yes	No

Questions

Contact Melissa Lonzo, Laboratory Resource Coordinator, at 800-533-1710.

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