

TEST CHANGE

B-Lymphoblastic Leukemia (B-ALL) Minimum Residual Disease Detection by Flow Cytometry

3000724, B-ALL MRD

Specimen Requirements:

Patient Preparation:

Collect: Bone marrow. Whole blood: Green (sodium heparin) or lavender (EDTA).

Specimen Preparation: Transport 2 mL heparinized bone marrow (Min: 1.0 mL) ~~±~~ OR 3 mL whole blood (Min: 1.0 mL) ~~±~~ 1 mL

Transport Temperature: Room temperature. Also acceptable: Refrigerated. Specimen should be received within 24 hours of collection for optimal cell viability.

Unacceptable Conditions: Clotted or hemolyzed specimens.

Remarks: Provide specimen source, CBC, Wright stained smear (if available), clinical history, differential diagnosis. Follow up: If previous leukemia/lymphoma phenotyping was performed at another lab, the outside flow cytometry report and histograms (if possible) should accompany the specimen.

Stability: Ambient: 48 hours; Refrigerated: 48 hours; Frozen: Unacceptable

Methodology: Flow Cytometry

Performed: Sun-Sat

Reported: 1-~~3~~ days

Note: This assay is a minimal residual disease assessment of B-ALL by flow cytometry. Available markers*: CD3, CD9, CD10, CD13, CD19, CD20, CD33, CD34, CD38, CD45, CD58, CD71, Syto 16, CD66b, CD24, CD22 *Not all markers will be reported in all cases. If COG panel is not specified, a 10-marker panel will be run: CD10, CD19, CD20, CD22, CD24, CD34, CD38, CD45, CD58, CD66b If COG panel is specified, indicate time point and specimen type: DAY 8 Peripheral blood sample will have CD10, CD19, CD20, CD34, CD45, and Syto 16 run and reported- (6 markers total). Day 29 Bone marrow sample will have CD3, CD9, CD10, CD13, CD19, CD20, CD33, CD34, CD38, CD45, CD58, CD71, Syto 16 run and reported- (13 markers total). The report

will include a pathologist interpretation and a marker interpretation range corresponding to CPT codes of 2-8 markers or 9-15 markers interpreted. Charges apply per marker.

CPT Codes: 88184; 88185 each additional marker; 88187 or 88188.

New York DOH Approval Status: Specimens from New York clients will be sent out to a New York DOH approved laboratory, if possible.

Interpretive Data:

Refer to report.

Reference Interval:

By Report

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.