AML MRD Assay
Multiparametric Flow Cytometry

CAP/CLIA Validated

Clinical Information

The 12-color AML MRD Assay provides a comprehensive approach to evaluate bone marrow samples for the presence or absence of measurable (minimal) residual disease (MRD) in patients treated for acute myeloid leukemia (AML).

12-color Multiparametric Flow Cytometry (MFC) is a state of the art method for MRD assessment that it is highly sensitive and specific. Using a comprehensive selection of antibodies and a standardized panel across all testing points, MRD populations can be characterized and tracked down to 0.01%. Use of up to 12 biomarkers per tube, allows identification of more leukemia associated immunophenotypes (LAIPS) with less sample than previously available. A panel of 21 antibody markers is used to characterize potential AML blast cells using a LAIP based different from normal (DfN) approach for MRD identification. If available, information from diagnosis is used, although the assay can identify aberrant cells that have diverged from normal maturation without previous patient history.

In addition to MRD monitoring, this panel's extensive biomarker selection may be used to enroll and monitor subjects in clinical trials, thereby accelerating drug approvals.

Indications for Testing

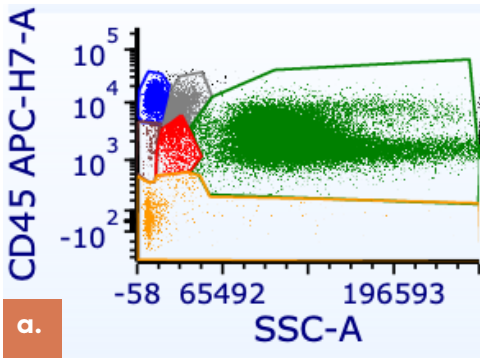
- Monitor response to therapy
- Monitor and evaluate for disease relapse and recurrence
- Enroll and monitor subjects in clinical trials
- Identify tumor-specific markers for post-treatment monitoring

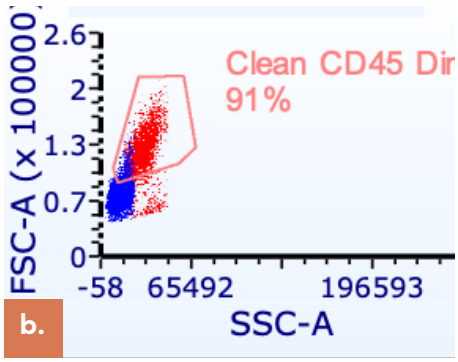
Biomarkers in the Screening Panel		
CD2	CD4	CD5
CD7	CD11b	CD13
CD14	CD15	CD16
CD19	CD33	CD34
CD36	CD38	CD45
CD56	CD64	CD117
CD123	HLA-DR	7AAD

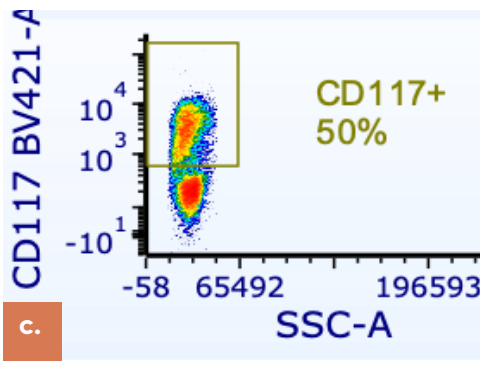
Key Points

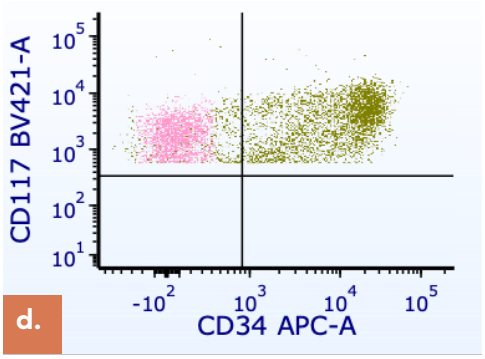
- 12-Color Panel of 21 Biomarkers
- Provides up to 0.01% Sensitivity and unparalleled Specificity with less sample
- LAIP based DfN approach for MRD identification
- Globally standardized Testing through LabPMM Network
- Multiparametric Flow Cytometry and NGS Testing Available
- Accurate results comparisons using a primary sample
- 2018 ELN MRD Working Party Consensus[2], 2006 Bethesda Consensus[5] and 2017 WHO Classification Guidance[6]

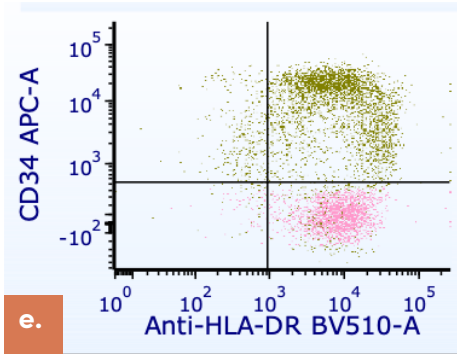
Interpretation	Turnaround Time	Specimen Requirements	Shipping Conditions	Storage Conditions
An interpretive report will indicate the presence/absence of AML cell populations, level of detection in relation to the clinical cutoff, percent and number of aberrant myeloblasts and their associated immunophenotypic profile.	24 - 48 hours	2-4 mL of bone marrow in EDTA or Sodium Heparin	Ambient or Cool; Do not freeze	Specimens should be stored at 2-8 °C and must be received by lab within 48 hours after draw

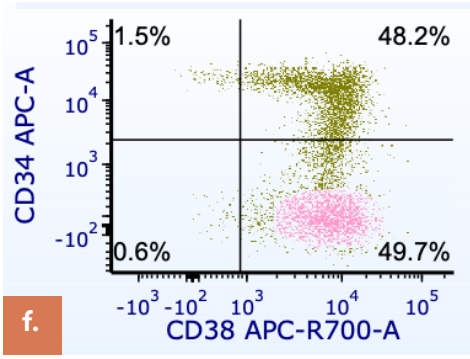












a. After initial quality assessment of stable flow of acquisition , exclusion of doublets, non-viable cells, RBCs, and debris, live cells are gated based on CD45 vs. side scatter (SSC). CD45 is a pan leukocyte marker that helps presumptive separation of WBC population in relation to SSC with likely populations (blue-lymphocytes, gray –monocytes, green- granulocytes, red-blasts/progenitors, and other rare events, yellow-erythroid, megakaryocytic and other CD45 neg events including debris). Dot plots are created using the Boolean gate strategy (off the CD45 pos events). b. A clean CD45 dim gate is used to remove lymphocytes and other cell contamination from CD45 dim (blasts/progenitor) gate. Blasts often have a higher FSC/SSC than lymphocytes (blue). c. Back gating to identify CD117 positive cells on CD45/SSC plot. Blast % is assessed based on clean dim CD45 gate. Similar strategy is also used for CD34 pos cells. d. Aberrant myeloblast population identified based on DfN open gates, CD117 pos/CD34 negative. AML MRD population (LAIP) is gated by choosing combinations that make aberrant populations prominent and trackable across the tube (pink). e. Aberrant myeloblasts are CD34 neg/HLA-DR pos (pink) f. Aberrant myeloblasts are CD34 neg/CD38 pos (pink).

References

1. BL Wood. Curr Protoc in Cytom. 93(1), e73 (2020). 2. GL Schuurhuis et al. Blood 131(12):1275-1291 (2018). 3. J Cloos. et al. J of Vis. Exp: JoVE. (133) (2018). 4. N Feller et al. Blood Cancer J. 3(8): e129-e129 (2013). 5. BL Wood et al. Cytometry B: Clin Cytom. 72(S1), S14-S22 (2007). 6. SH Swerdlow et al., WHO Classification of Tumours, (Revised 4th Edition) IARC: Lyon, 421 (2017). 7. M Stetler-Stevenson. Clinical and Laboratory Standards Institute (2007).

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