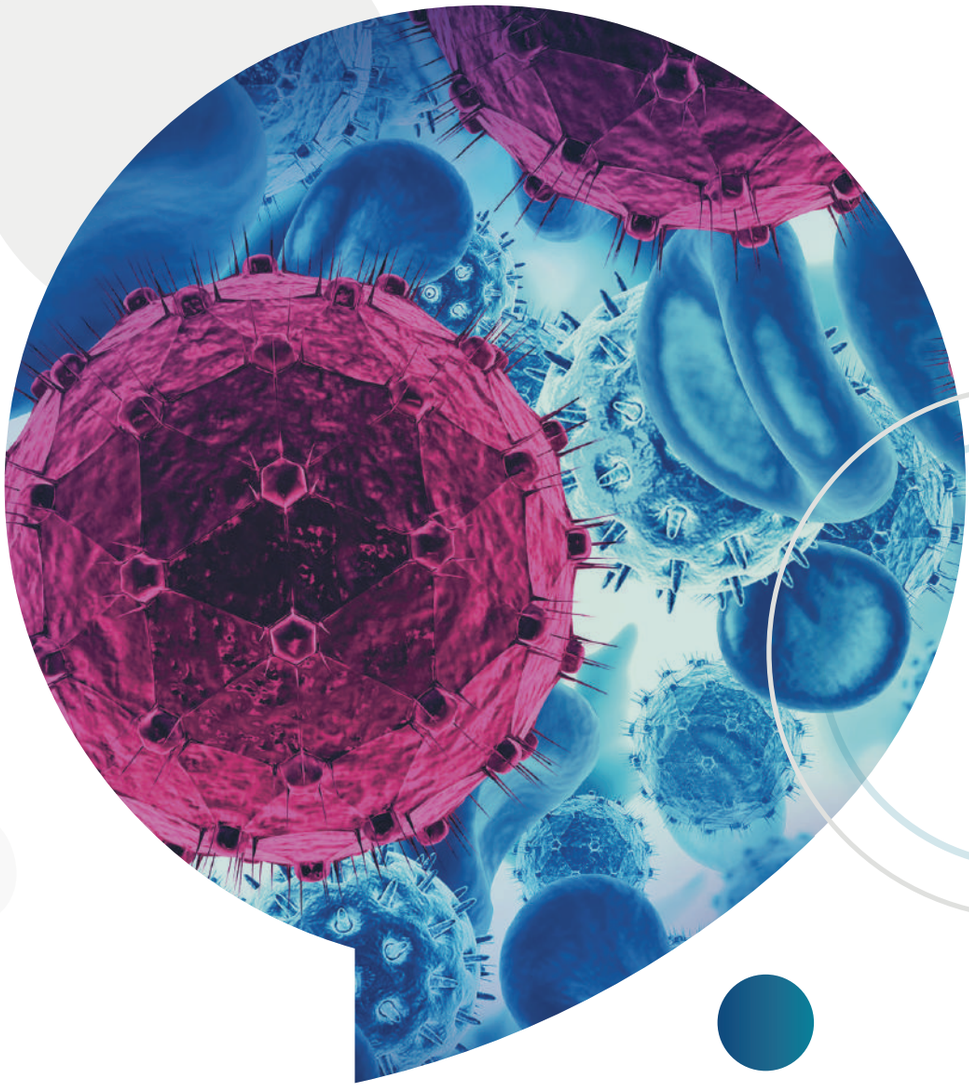
mfine
/diagnostics



Precise & Accurate diagnosis of

HEMATOLOGICAL MALIGNANCIES

by wide range of Flowcytometry Panels

ACUTE LEUKEMIA

— Broader Classification —

Acute Myeloid Leukemia

- MPO (by flow cytometry, immunohistochemistry, or cytochemistry)
- Monocytic differentiation (≥2 of the following: non-specific esterase, CD11c, CD14, CD64, lysozyme)

Acute Lymphoid Leukemia

- B-cell lineage: strong CD19 with ≥1 of the following strongly expressed: CD79a, cytoplasmic CD22, CD10 or weak CD19 with ≥2 of the above
- T-cell lineage: Cytoplasmic CD3 (by flow or immuno*) or surface CD3

Acute Leukemia's of ambiguous lineage

- Acute undifferentiated
- Mixed phenotype

Initial Diagnostic Workup of Acute Leukemia

Guidelines from the College of America Pathologists and the American Society of Hematology

Strong Recommendation for Testing for FLT3-ITD; Recommendation for Testing for Other Mutational Analysis. For pediatric and adult patients with suspected or confirmed AML of any type, the pathologist or treating clinician should ensure that testing for FLT3-ITD is performed. The pathologist or treating clinician may order mutational analysis that includes, but is not limited to, IDH1, IDH2, TET2, WT1, DNMT3A, and/or TP53 for prognostic and/or thherapeutic purposes.

REFERENCES:

1. Bennett JM, Catovsky D, Daniel MT, et al. Proposals for the classification of the acute leukaemias: French-American-British (FAB) co-operative group. Br J Haematol. 1976;33(4):451–458.
2. Bennett JM, Catovsky D, Daniel MT, et al. Proposal for the recognition of minimally differentiated acute myeloid leukaemia (AML-MO). Br J Haematol. 1991;78(3):325–329.
3. Bennett JM, Catovsky D, Daniel MT, et al. Criteria for the diagnosis of acute leukemia of megakaryocyte lineage (M7): a report of the French-American-British Cooperative Group. Ann Intern Med. 1985;103(3):460–462

Clinical Utility

Flow panels help in Identifying tumor lineage, phenotype for diagnosis & prognosis of Leukemia & Lymphoma as per WHO classification after review of the clinical history and morphology.

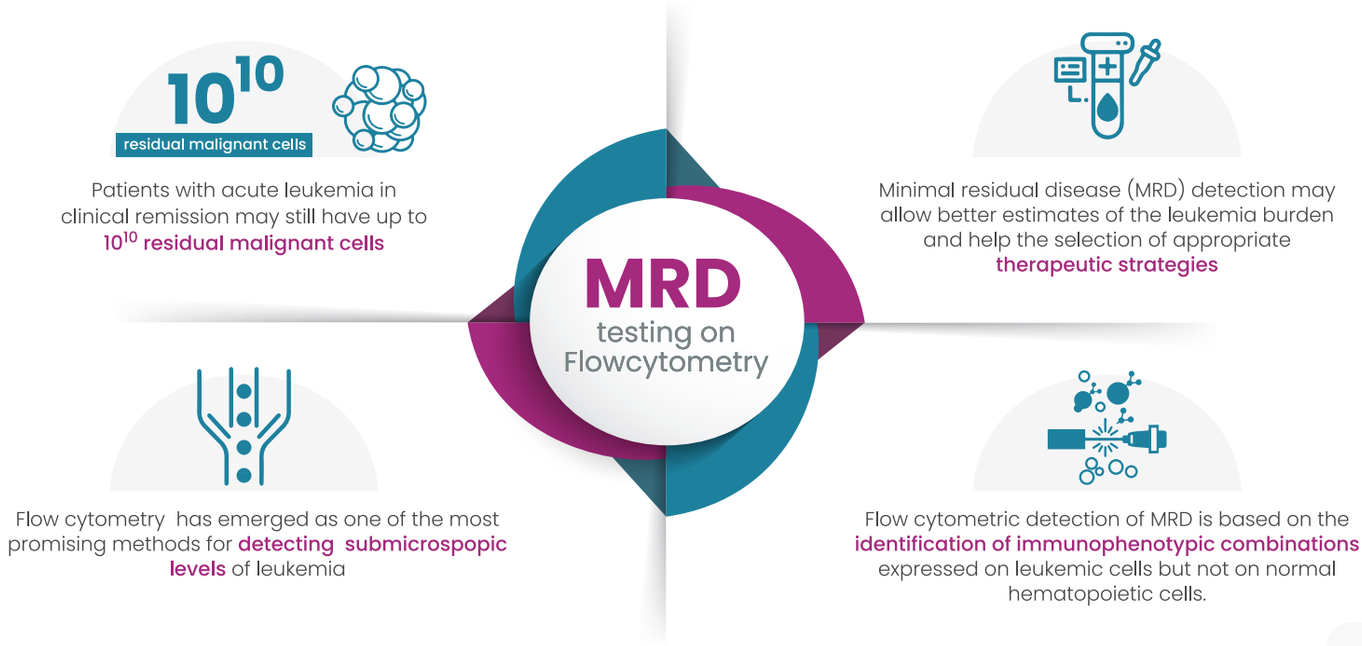
Using highly sensitive BD FACS Canto II with 3 laser 8 colored and extendable to 10 and 12 colored configurations.

Cytogenetic/molecular testing is available for further risk stratification of acute leukemias.

What specimens and sample types should be evaluated on all cases?

Peripheral blood, bone marrow (BM) aspirate and/or touch imprints. BM core biopsy and/or marrow clot.

If sufficient BM aspirate is not available for flow, a second core biopsy can be used for flow and genetic studies.



Clinical Utility

- Detection of minimal residual disease in acute lymphoblastic leukemia predicts outcome.
- Can identify patients at higher/lower risk of relapse.
- Detection of minimal residual disease is important for risk assessment and stratification of therapy.

Identify patients at Higher Risk of Relapse	Identify patients at Lower Risk of Relapse
+ Treatment intensification	+ Non-intensified treatment protocol + Treatment reduction ??

MRD assessment is important in both pediatric and adult T cell ALL patients

Assessment time points are:
- D29/D33 end of induction
- D78 end of consolidation

STANDARD RISK	INTERMEDIATE RISK	HIGH RISK
MRD<0.01% at D33 & D78: **Excellent Prognosis**	MRD at either D33/D78 with <0.1% **Close monitoring of the patient for relapse**	>0.1% at Day78: **Alternate Treatment Options to be suggested to patient**

The clearance of MRD at D78 formed a better prognostic indicator than D33 MRD. Relevant in both high risk/standard risk/all cytogenetic risk groups

Mandatory requirements:

(i) Sample time point (day of chemo: post induction, Post consolidation, prior to maintenance therapy, relapse-----)
(ii) Previous immunophenotype report (flow cytometry report).
(iii) Clinical History and original TRF.
(iv) Date and time when sample was drawn to be mentioned on the TRF.

NOTE: All the above information to be given at the time of registration/before sample is processed.

— Test Ordering information —

Test Code	Test Name	Components	Specimen Type	Methodology	TAT
ONCO0089	OncoLife - Acute Leukemia Panel, flow	T, B Myeloid	3-5ml whole blood /bone Marrow in EDTA & Sodium Heparin tubes with date & time of collection. Clinical history is required.	Flowcytometry	2 Days
ONCO0124	Oncolife Leukemia Lymphoma comprehensive panel, flow	T, B Myeloid/ CLPD.Markers to decided by Pathologist depending upon case		Flowcytometry	2 Days
ONCO0135	OncoLife -Acute Leukemia Advance Panel	T-cell Markers : CD3, CD5, CD7, CD4, CD8, CD56, CD1A, Cy CD3. B-cell Markers : CD19, CD20, Myeloid & Monocytic Markers : CD13, CD33, MPO, CD64, CD14, CD36. Others: CD10, CD34, CD38, CD117, HLADR, CD45,		Flowcytometry	2 Days
ONCO0129	Oncolife Basic B CLL Screening panel, flow	T cell markers: CD5, B cell markers CD19, CD20, CD23, CD79b, CD200, FMC7, Kappa, Lambda, others: CD 45		Flowcytometry	2 Days
ONCO0084	OncoLife - Chronic Lymphoproliferative Disorder (CLPD) Panel, flow	T cell markers: CD3,CD5, CD7,CD4, CD8, B cell markers CD19, CD20, CD23, CD79b, CD200, FMC7,CD79b, S.IgM, Kappa, Lambda, Hairy Cell- CD25, CD103, CD11c, others: CD 45.(if non CLPD than use TCR A/B,TCR G/D ,CD56 .)		Flowcytometry	2 Days
ONCO0130	Oncolife Hairy Cell Leukemia, flow	B- cell Markers: CD19, CD20, Kappa, Lambda, CD25, CD103, CD11c, HLADR, CD45		Flowcytometry	2 Days
ONCO0127	Oncolife MDS evaluation Panel, flow	Multiple antibodies		Flowcytometry	2 Days
P0071	PNH confirmation test, Blood	Flaer, CD14, CD15, CD24, CD45,CD59, CD64, GIY-A		Flowcytometry	2 Days
ONCO0085	OncoLife - Myeloma Panel, flow	CD38, CD56, CD19, CD138, CD117, CY.KAPPA, Cy.LAMBDA, CD45, CD27, CD81		Flowcytometry	2 Days
ONCO0125	Oncolife Customized (Any 5 markers) Panel, flow	Any 5 markers		Flowcytometry	2 Days
ONCO0126	Oncolife Customized (Any 7 markers), Flow	Any 7 markers		Flowcytometry	2 Days
ONCO0119	Oncolife comprehensive Acute leukemia panel	Leukemia diagnostic panel, Acute Leukemia - T, B or Myeloid *Chromosome analysis for hematological malignancy *Leukemia Genetic Profile - any 6 markers, PCR	4 mL (3 mL min.) Bone Marrow Aspirate / Whole blood in 1 Green Top (Sodium Heparin) tube AND 3 mL (2 mL min.) Whole blood / Bone Marrow Aspirate in 1 Lavender Top (EDTA) tube.	Flow Cytometry, Culture, Microscopy, Karyotype, Real Time PCR	8 Days

MRD Analysis

ONCO0088	Oncolife Acute Leukemia MRD Panel	AML/ALL MRD	3ml Bone Marrow	Flowcytometry	2 Days
ONCO0086	OncoLife - B-ALL MRD Panel, flow	B-ALL MRD	3ml Bone Marrow	Flowcytometry	2 Days
ONCO0087	OncoLife - T-ALL MRD Panel, flow	T-ALL MRD	3ml Bone Marrow	Flowcytometry	2 Days
ONCO0132	Oncolife CLL MRD Panel, flow	Multiple markers	3-5ml whole blood /bone Marrow in EDTA & Sodium Heparin tubes with date & time of collection. Clinical history is required.	Flowcytometry	2 Days
ONCO0121	Oncolife multiple myeloma MRD panel	*CD45 *CD19 *CD20 *CD27 *CD38 *CD138 *CD56 *CD117 *CD200 *CD81 *Kappa *Lambda	mL (1 mL min.) Bone Marrow (first pull aspirate) in 1 Green Top (Sodium Heparin) tube. Mix thoroughly & Ship immediately at 18-22ºC or at 2-8ºC. DO NOT FREEZE. Following information is mandatory: Sample time point (Chemotherapy time points); Previous diagnostic immunophenotype report; Clinical History specially mention if patient is on anti-CD38 therapy; original TRF; Date and time when sample was drawn; 1 or 2 unstained BMA smears to be made at source	Flowcytometry	3 Days