Accelerate Drug Development

State-of-the-art multiparametric flow cytometry (MFC) assays are highly sensitive, fast and cost-effective. Our internationally harmonized MFC assays are designed based on 2018 ELN MRD Working Party Consensus,[8] 2006 Bethesda Consensus[9] and 2017 WHO Classification Guidance.[10]

Our MFC services provide powerful analytic tools to:

- **Stratify patients** for enrollment based on immunophenotypic profiles
- **Predict therapy efficacy** for program prioritization by monitoring response
- **Expedite clinical trials** by serving as surrogate endpoints

Global Reach

Fast-track clinical trial enrollment using the LabPMM network to provide internationally standardized testing with CLIA, CAP and ISO 15189 certifications.

Regulatory Expertise

Our experienced team has over 50 product registrations and companion diagnostic approvals in the US, EU, and Japan.

Custom Product Development

Leverage nearly 30 years of assay development experience to accelerate drug approvals. Custom assays are designed and manufactured under an ISO certified quality management system.

Talk to our scientists to learn more:

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LabPMM® Global Network

The Laboratory for Personalized Molecular Medicine® (LabPMM®) offers standardized testing of novel and proprietary biomarkers across an international network of clinical labs.

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GLOBALLY STANDARDIZED MULTIPARAMETRIC FLOW CYTOMETRY ASSAYS

Identify, Stratify and Monitor Hematologic Malignancies

LabPMM®
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A CLIA-certified/CAP Accredited International Laboratory Network

Diagnosis and Stratification

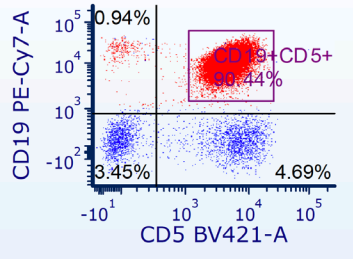
Hematologic malignancies (HMs) account for approximately 6.5% of all cancers, and are the fourth most frequently diagnosed cancer in economically developed countries.[1,2] Over the past decade, the number of clinical trials targeting HMs has increased at a rapid rate,[3] perpetually changing the diagnostic and therapeutic paradigm.

Hematolymphoid Screening Panel

A comprehensive approach to evaluate bone marrow and peripheral blood for hematolymphoid malignancies.

- **Provides** a wide array of applications due to its comprehensive biomarker selection
- **Evaluate** Acute Leukemia, plasma cell dyscrasias, NK, B- and T-cell disorders

Biomarkers in the Hematolymphoid Screening Panel		
CD2	CD3	CD4
CD5	CD7	CD8
CD10	CD11b	CD13
CD14	CD15	CD16
CD19	CD20	CD23
CD33	CD34	CD38
CD45	CD56	CD57
CD64	CD71	CD117
CD123	HLA-DR	Kappa
Lambda	TCR Gamma/Delta	



Abnormal B-cells co-expressing T-cell antigen CD5 with CD19.

MRD as a Surrogate Endpoint

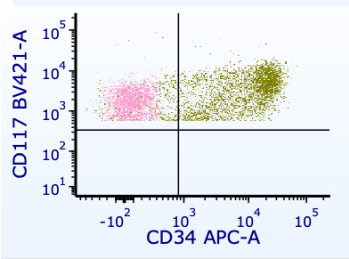
While the overall incidence of leukemia has declined, rates of Acute Myeloid Leukemia (AML) and Chronic Lymphocytic Leukemia (CLL) are increasing, accounting for nearly 40% of total leukemia cases worldwide.[4] Fortunately, a plethora of agents have recently entered the market, some targeting specific mutations or cell survival signal pathways[5] and other strategies using CAR-T cells[6] and immune checkpoint inhibitors[7]—all of which require confirmation of treatment response.

AML MRD Assay

Use of a LAIP-based DfN approach and an extensive selection of antibodies, including a standardized 12-color panel, enables immunophenotypic profiling with unparalleled specificity.

- **Characterize and monitor** MRD populations to 0.01%
- **Predict** treatment outcomes and use as a potential primary end point in clinical trials

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



AML MRD population (LAIP) is gated by choosing combinations that make aberrant populations identifiable and trackable based on DfN.

Prognostication and Tracking

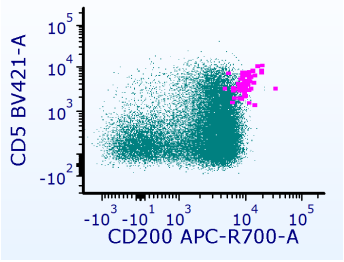
Globally, CLL has increased by approximately 7% over the past 30 years, with a higher incidence among men and adults over 65.[4,11] Furthermore, CLL is the most prevalent type of leukemia, comprising of 25% - 30% of all leukemias in Western populations.[1]

CLL MRD Assay

An extensive 11-color panel targeting 12 specific biomarkers, depicts clear separation of CLL cells from other B-lineage cells.[12-14] Designed to work with peripheral blood and bone marrow specimens.

- **Characterize** aberrant cell population by MFC
- **Detect and track** residual disease to 0.005%
- **Assess** therapeutic response and use as a surrogate endpoint to accelerate approvals

Biomarkers in the CLL MRD Assay		
CD3	CD5	CD19
CD20	CD22	CD40
CD43	CD79b	CD81
CD200	7AAD	CD38



Identification of a CLL MRD population in a scatter plot indicating CD5 and CD200 antigen expression.

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