

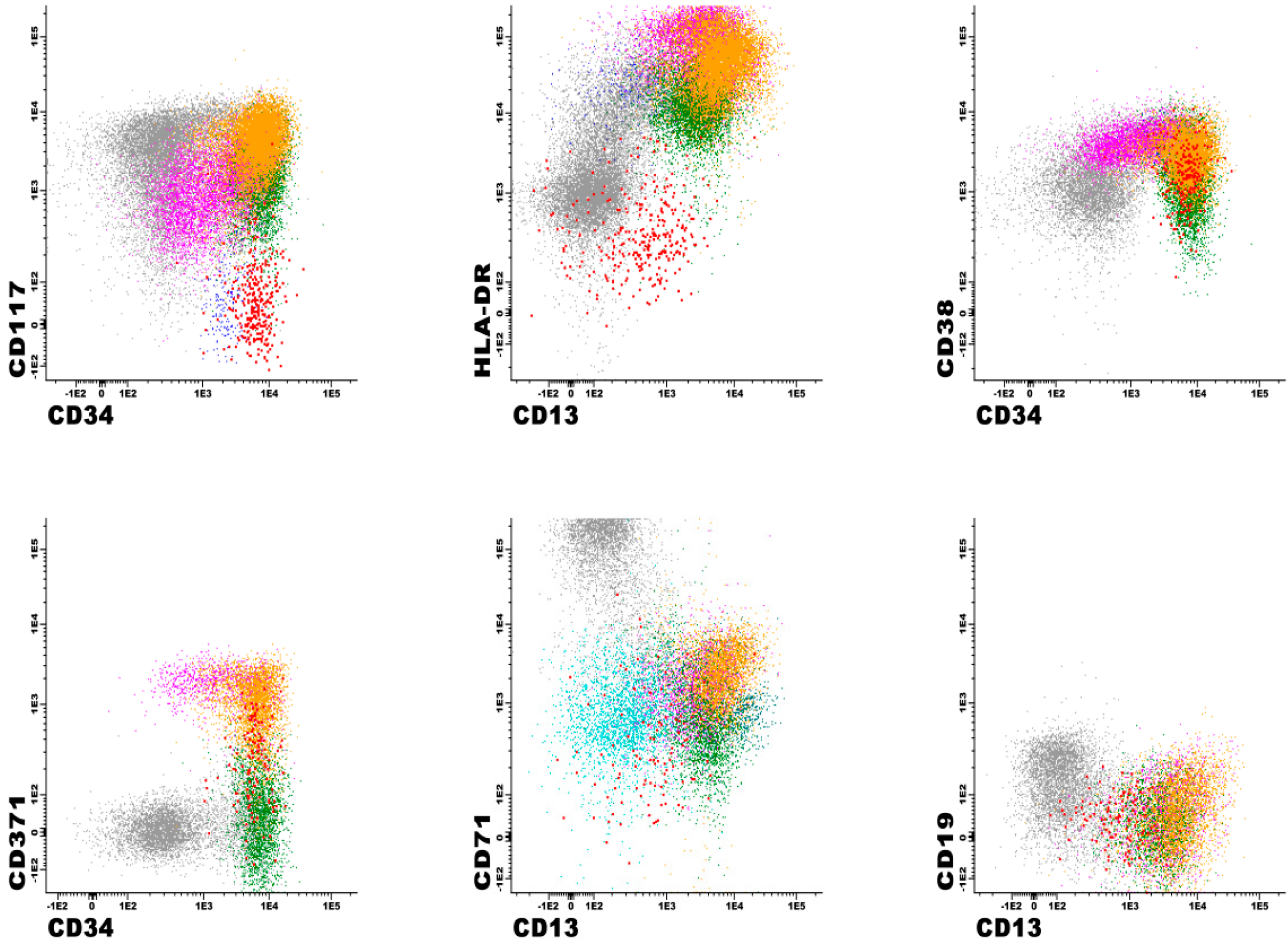
MEASURABLE RESIDUAL DISEASE

Cell identity, assay limits & low-event clinical reporting

CFCM / CLINICAL POSTER SERIES / SPECIALIST CLINICAL FLOW CYTOMETRY

Cross-disease interpretation framework with a published AML example. No simulated counts, gates, patient plots or treatment recommendations.

1 Clinical question & context	2 Disease-specific strategy	3 Panel design & validation
What can this specimen establish? Define disease, compartment, time point, treatment and the clinical question before choosing a panel. Three separable questions Are the events disease-related? Is detection analytically supported? Is the result quantitatively reliable? A convincing answer to one does not answer the others. Specimen-dependent sensitivity Use the informative denominator after exclusions. Assess viability, recovery and haemodilution; report compromised samples explicitly [1,3].	AML Combine diagnostic LAIP with different-from-normal analysis. Include regeneration controls and avoid a CD34-only search [1]. CLL Use a validated CLL assay; ERIC low-event performance examples belong to their methods and denominator [2]. Plasma-cell disorders Account for sample quality, phenotype heterogeneity and therapeutic interference [3,4]. A common event cutoff does not make these assays interchangeable.	Higher colour, when useful A 10–14-colour design may preserve identity, aberrancy and normal comparators together. Extra colours do not establish better sensitivity by themselves. Allocate by biological question Protect weak discriminating markers from spreading. Verify clones, titration, compensation / unmixing, stability and the full preparation. Validate the complete process Challenge blank background, low-level samples, precision, recovery, carryover and robustness. Changing reagents, preparation or instrument requires an assessed verification plan [5].

4 Published dot plots & visual interpretation	5 From cluster to report
Published AML example: cell identity precedes counting  Figure 3a reproduced from Jum'ah et al. [6], © 2025 authors, CC BY 4.0. Original patient plots, gates and colours unchanged; layout resized. The authors identify an abnormal red compartment using several simultaneous deviations [6]. A reproduced image does not provide raw-event access, independent gate validation or a new CFCM MRD percentage.	1 Coherent identity Corroborate the population across informative marker combinations and back-gating; exclude technical artifacts. 2 Detection supported Use the locally validated detection criteria and background. A few isolated events are not automatically disease. 3 Quantification supported Apply the validated quantification boundary and precision requirement using the actual denominator. 4 Below / at the boundary When identity and detection are supported but counts are at or below that boundary: detected but not quantifiable. 5 Not detected is bounded State achieved sensitivity and specimen limitations. Do not convert a compromised or insufficient sample into a confident negative.

6 Rare-event pitfalls	7 LoB, LoD & LoQ	8 Report what is supported	9 Concise evidence
Regeneration Hematogones and regenerating myeloid compartments can resemble abnormal islands in limited dimensions [1]. Artifacts Dead cells, nonspecific binding, spreading and acquisition instability can create false rare populations. Carryover / contamination Use the assay's preventive and investigative procedures; more events will not distinguish contamination from disease by itself.	Keep the terms distinct LoB addresses blank background, LoD supports detection and LoQ supports acceptable quantitative performance [5]. Counts and denominator The same target count can imply different frequencies in different informative totals. Do not report a detection limit based only on the nominal acquisition target. Published examples ERIC CLL uses 20 / 50-event examples [2]; they are not universal thresholds for AML or myeloma.	Quantifiable positive Only when the population meets identity, detection and quantitative performance requirements above the adopted boundary. Detected but not quantifiable Explicitly separate credible detection from a reliable percentage; do not round a marginal count into a quantifiable positive. Not detected / limited Provide achieved limits, denominator and adequacy. Explain if the sample or analysis cannot support the requested sensitivity.	[1] Heuser M et al. Blood 2021;138:2753–2767. doi:10.1182/blood.2021013626. [2] Rawstron AC et al. Leukemia 2016;30:929–936. doi:10.1038/leu.2015.313. [3] Stetler-Stevenson M et al. Cytometry B 2016;90:26–30. doi:10.1002/cyto.b.21249. [4] Arrozo M et al. Cytometry B 2016;90:31–39. doi:10.1002/cyto.b.21228. [5] Wood B et al. Cytometry B 2013;84:315–323. doi:10.1002/cyto.b.21108. [6] Jum'ah HA et al. Cancers 2025;17:1155. doi:10.3390/cancers17071155. Technical support: Shapiro HM. Practical Flow Cytometry. 4th ed. Wiley-Liss;2003. doi:10.1002/0471722731. No book figures reproduced.

Do not collapse biological identity, detection and quantification into one binary MRD label.