

ΔN :™ (difference from normal) Flow Cytometry Measures the Intensity of Surface Marker Expression to Monitor Clonal Evolution in Acute Leukemia

Traditional measurable residual disease (MRD) testing by flow cytometry is dependent on the diagnostic phenotype, and focuses on identifying this phenotype post treatment, which can lead to the possibility of false negative results since the phenotype of the acute leukemia can change, over time or a new clone can arise. ΔN :™ is not dependent on the diagnostic sample but instead identifies populations as being abnormal based on fluorescent intensity differences from normal populations allowing for the detection of phenotypic evolution as well as new occurring clones. This case study clearly shows an example of this. Sample 1 (no diagnostic sample available) shows MRD with a single clone. Sample 2 shows the presence of two distinct clones, and sample 3 shows the absence of the original clone while the 2nd clone is still present.

Case Study – MRD Evaluation by ΔN :™ Flow Cytometry

1. **29-day** post induction therapy patient with clinical history of acute leukemia with two blast populations: T-cell ALL & undifferentiated leukemia/AML.

Analysis/Conclusions: Findings reveal an aberrant myeloid progenitor population present at 2.5% of total non-erythroid cells consistent with residual AML.

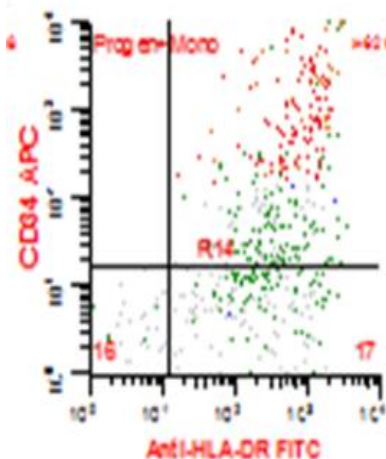
2. **39-day** follow up sample.

Analysis/Conclusions: Findings reveal an aberrant myeloid progenitor population present at 0.02% (consistent with the populations seen in the previous specimen) and a 0.03% population of abnormal progenitor cells with myeloid and T cell differentiation, consistent with residual acute leukemia.

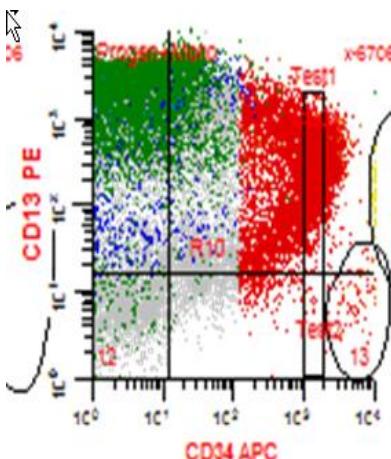
3. **18 month** follow up sample.

Analysis/Conclusions: Findings reveal an abnormal progenitor population present at 35% of total non-erythroid cells, consistent with residual leukemia with an immunophenotype consistent with that of the 2nd clone identified in the previous specimen with no indication of the original clone.

1. Day 29



2. Day 39



3. 18 Months

