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CBFA2T3-GLIS2 Fusion Transcript by RQ-PCR

The CBFA2T3 -GLIS2 fusion transcript is a common feature in pediatric AML (M7) patients that have normal cytogenetic results. This transcript has been shown to be useful in monitoring pediatric patients that show the RAM phenotype.

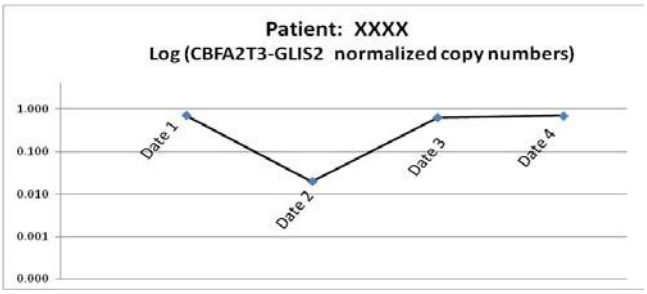
ΔN:™ "Difference from Normal" flow cytometry provides a definitive diagnostic phenotype for RAM and is highly predictive of poor outcome. It occurs in 10% of infants (<1-year-old) who lack known risk factors. Early diagnosis allows for the most effective treatment.

Eidenschink Brodersen L. et al. "A Recurrent Immunophenotype at Diagnosis Independently Identifies High Risk Pediatric Acute Myeloid Leukemia: A report from Children's Oncology Group." Leukemia. 2016. 30(10):2077-2080.

MOLECULAR ANALYSIS REPORT

CBFA2T3-GLIS2 RT-PCR Results: POSITIVE

Date	HLID#	Specimen	CBFA2T3-GLIS2 NCN	% Reduction	Log Reduction
Date 1	HLID1	BMA	0.724	Baseline	Baseline
Date 2	HLID2	BMA	0.020	97.2	1.6
Date 3	HLID3	BMA	0.643	11.2	0.1
Date 4	HLID4	BMA	0.702	3.0	0.0



NCN (normalized copy numbers): 0.702

Quantitative assay units: CBFA2T3-GLIS2 transcript levels are reported as a ratio of fusion gene transcript to ABL reference gene transcript.

Analysis/Conclusions:

The specimen tested *positive* for CBFA2T3-GLIS2 fusion transcripts, which are the molecular result of the cryptic chromosome 16 inversion [inv(16)(p13.3q24.3)], associated with a poor prognosis in AML.

- **The quantitative CBFA2T3-GLIS2 NCN value of 0.702 is reduced by 3.0% (log reduction 0.0) in comparisonto the patient's baseline specimens.**
- **Clinical and histological correlation is required for definitive diagnosis.**

This PCR test can detect the CBFA2T3-GLIS2 transcript with sensitivity up to 1 in 10e5 transcripts (0.001%). Note: Control gene amplification indicated good RNA quality.