MAYO CLINIC

1-800-533-1710

RUNX1/RUNX1T1, t(8;21), Quant, V

T821Q

PATIENT NAME				ORDER NUMBER
TESTINGRNV, REPORT M				**L328000092**
PATIENT ID SA00149964	DATE OF BIRTH 09/09/1999	AGE 22 Y	SEX Male	REQUESTED BY CLIENT CLIENT
COLLECTED 12/27/2021, 7:00 AM	RECEIVED 12/28/2021, 8:20 AM	REPORTED 12/28/2021, 8:31 AM		
The collected, received, and reported dates and times on the report are in the time zone of the performing location. 7028846 MCL RochesterCampus Rochester MN 55901				CLIENT ORDER NUMBER SA00149964 CLIENT MRN SA00149964

Signing Pathologist	**BENJAMIN BAILEY**
Specimen Type	**Bone marrow**

INTERPRETATION

Bone marrow, *RUNX1-RUNX1T1* mRNA quantitative analysis,

Positive. *RUNX1-RUNX1T1* mRNA transcripts were detected at 4315/10,000 *ABL1* copies (43%). See comment.

Comment:
In acute myeloid leukemia with t(8;21)(q22;q22.1);*RUNX1-RUNX1T1* , trends in the level of *RUNX1-RUNX1T1* transcript should be followed carefully. A >3 log reduction in BM between diagnosis and after consolidation or two cycles of chemotherapy was associated with lower risk of relapse in most studies. Persistent PCR positivity especially at higher levels and a rising trend of the leukemic transcript after initial molecular response are highly associated with disease relapse. A log increase (10 fold) in measurable/minimal residual disease (MRD) levels between 2 positive samples is consistent with molecular relapse/molecular progression. Significant MRD level changes including ≥ 1 log increase or conversion from MRD-negative to MRD-positive should be confirmed in subsequent bone marrow and peripheral blood samples, as clinically indicated. Of note: very low, stable levels of *RUNX1-RUNX1T1* transcripts (e.g. <10/10,000 ABL1 copies) may persist in the bone marrow in a subset of patients without evidence of relapse (Schuurhuis GJ, et al., 29330221; Rücker FG, et al., 31554635; Höllein A, et al., 29568097; Willekens C, et al., 26635039; Yin JA, et al., 22875911; Jourdan E, et al., 23321257). The reproducibility of this assay is such that results within 0.5 log change (3.16 fold) should be considered equivalent. Clinical and laboratory correlation is recommended.

METHOD

Method Summary: *RUNX1-RUNX1T1* mRNA transcript level was evaluated using real-time quantitative reverse transcription PCR (RT-PCR), and normalized to the transcript level of the housekeeping gene ABL1. The analytical sensitivity of this assay has been determined at 1/10,000 *RUNX1-RUNX1T1/ABL1* transcript copies (0.01%). This test can be used at diagnosis to confirm the presence of the *RUNX1-RUNX1T1* fusion in acute myeloid leukemia with t(8;21)(q22;q22.1), and also for minimal/measurable residual disease monitoring after treatment. The reproducibility of this assay is such that results within 0.5 log (3.16 fold) should be considered equivalent. Significant changes in result status during monitoring including change from negativity to positivity should be verified with a subsequent specimen.

DISCLAIMER

This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.

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