MAYO CLINIC

1-800-533-1710

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

T821Q

PATIENT NAME				ORDER NUMBER
TESTINGRNV, REPORT M				**L328000091**
PATIENT ID SA00149963	DATE OF BIRTH 09/09/1999	AGE 22 Y	SEX Male	REQUESTED BY CLIENT CLIENT
COLLECTED 12/27/2021, 7:15 AM	RECEIVED 12/28/2021, 8:21 AM	REPORTED 12/28/2021, 8:29 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 SA00149963 CLIENT MRN SA00149963

Signing Pathologist	**BENJAMIN BAILEY**
Specimen Type	**Peripheral blood**

INTERPRETATION

Peripheral blood, *RUNX1-RUNX1T1* mRNA quantitative analysis,

Negative. No *RUNX1-RUNX1T1* mRNA transcripts detected. Minimal/measurable residual disease negative (MRD-negative). 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 (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). A negative MRD status does not exclude the presence of a myeloid neoplasm or other neoplastic disorders. The analytic sensitivity of this assay for the *RUNX1-RUNX1T1* fusion is 1/10,000 (*RUNX1-RUNX1T1 /ABL1* transcript copies, 0.01%). Samples with *RUNX1-RUNX1T1* fusion levels below the analytic sensitivity may therefore not be detected by this test. Suggest correlation with historical *RUNX1-RUNX1T1* test results, and clinical and other laboratory findings.

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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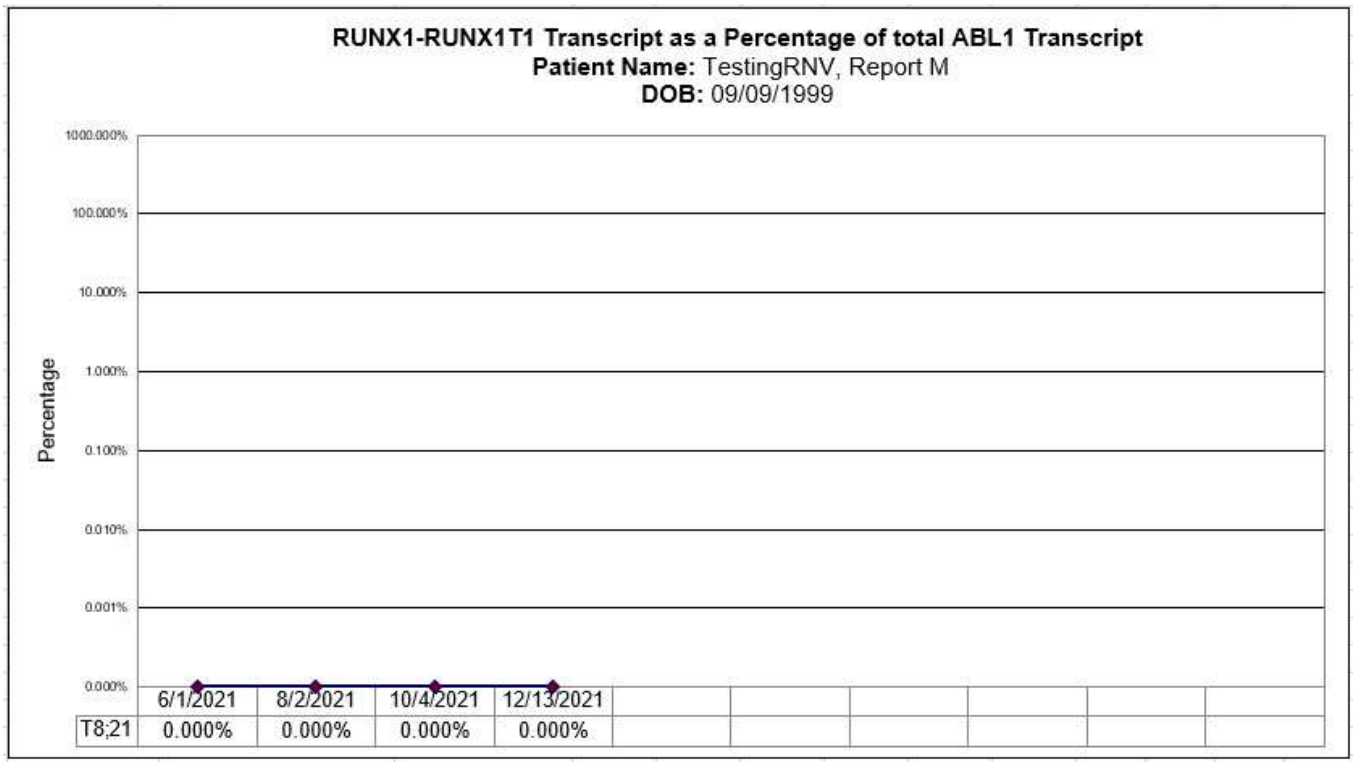

Code : MCR Laboratory : Mayo Clinic Laboratories - Rochester Main Campus Address : 200 FIRST STREET SW
Lab Director : WILLIAM G MORICE, II MD, PhD CLIA Certificate : 24D0404292 ROCHESTER MN 55905