MAYO CLINIC

1-800-533-1710

Inv(16); CBFB-MYH11, Quant, V

IN16Q

PATIENT NAME				ORDER NUMBER
TESTINGRNV, REPORT				**K829000309**
PATIENT ID SA00145667	DATE OF BIRTH 09/09/1999	AGE 21 Y	SEX Male	REQUESTED BY CLIENT CLIENT
COLLECTED 7/28/2021, 8:00 AM	RECEIVED 7/29/2021, 3:59 PM	REPORTED 7/29/2021, 4:01 PM		
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 SA00145667 CLIENT MRN SA00145667

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

INTERPRETATION

Positive. CBFB-MYH11 mRNA transcripts were detected at 2500/10,000 ABL1 copies (25%). See comment.

Comment:
In acute myeloid leukemia with inv(16)(p13q22)/t(16;16)(p13.1;q22);CBFB-MYH11, trends in the level of CBFB-MYH11 transcript should be followed carefully. Persistent PCR positivity especially at higher levels and a rising level of the leukemic transcript after initial molecular response are highly associated with disease relapse. A log increase (10 fold) in MRD between 2 positive samples is consistent with molecular relapse/molecular progression. Significant MRD level changes including equal or greater than a log10 increase or conversion from MRD-negative to MRD-positive should be confirmed in a subsequent bone marrow and peripheral blood sample, if clinically indicated (Schuurhuis GJ, et al., 29330221; Yin JA, et al., 22875911; Jourdan E, et al., 23321257; Corbacioglu A, et al., 20625124; Dohner H, et al., 27895058; https://www.nccn.org). The reproducibility of this assay is such that results within 0.5 log change (3.16 fold) should be considered equivalent. Suggest correlation with historical CBFB-MYH11 test results, as well as clinical and other laboratory findings.

METHOD

Method Summary: CBFB-MYH11 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 CBFB-MYH11/ABL1 transcript copies (0.01%). This test can be used at diagnosis to confirm the presence of the CBFB-MYH11 fusion in acute myeloid leukemia with inv(16)(p13.1q22) or t(16;16)(p13.1;q22), and also for minimal residual disease monitoring after treatment. This assay detects the three major fusion forms of CBFB-MYH11 (types A, D, and E), which account for at least 95% of CBFB-MYH11 fusions. 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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