MAYO CLINIC

1-800-533-1710

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

IN16Q

PATIENT NAME				ORDER NUMBER
TESTINGRNV, VALIDATION				**L016000455**
PATIENT ID SA00147744	DATE OF BIRTH 09/09/1999	AGE 22 Y	SEX Male	REQUESTED BY CLIENT CLIENT
COLLECTED 9/15/2021, 7:00 AM	RECEIVED 9/16/2021, 3:27 PM	REPORTED 9/16/2021, 3:29 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 SA00147744 CLIENT MRN SA00147744

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

INTERPRETATION

Negative. No CBFB-MYH11 mRNA transcripts detected. Minimal residual disease negative (MRD-negative). See comments.

Comments:
In acute myeloid leukemia with inv(16)(p13.1q22)/t(16;16)(p13.1;q22);CBFB-MYH11, trends in the level of CBFB-MYH11 transcript should be followed carefully. Persistent PCR positivity at higher levels and a rising level of leukemic transcript after initial molecular response are highly associated with disease relapse. Significant MRD changes including 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). 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 three most common CBFB-MYH11 fusion types (A, D and E) is 1/10,000 (CBFB-MYH11/ABL1 transcript copies, 0.01%). Samples with CBFB-MYH11 fusion levels below the analytic sensitivity or harboring other rare CBFB-MYH11 fusion types (<5%) may therefore not be detected by this test. Suggest correlation with historical CBFB-MYH11test results, and 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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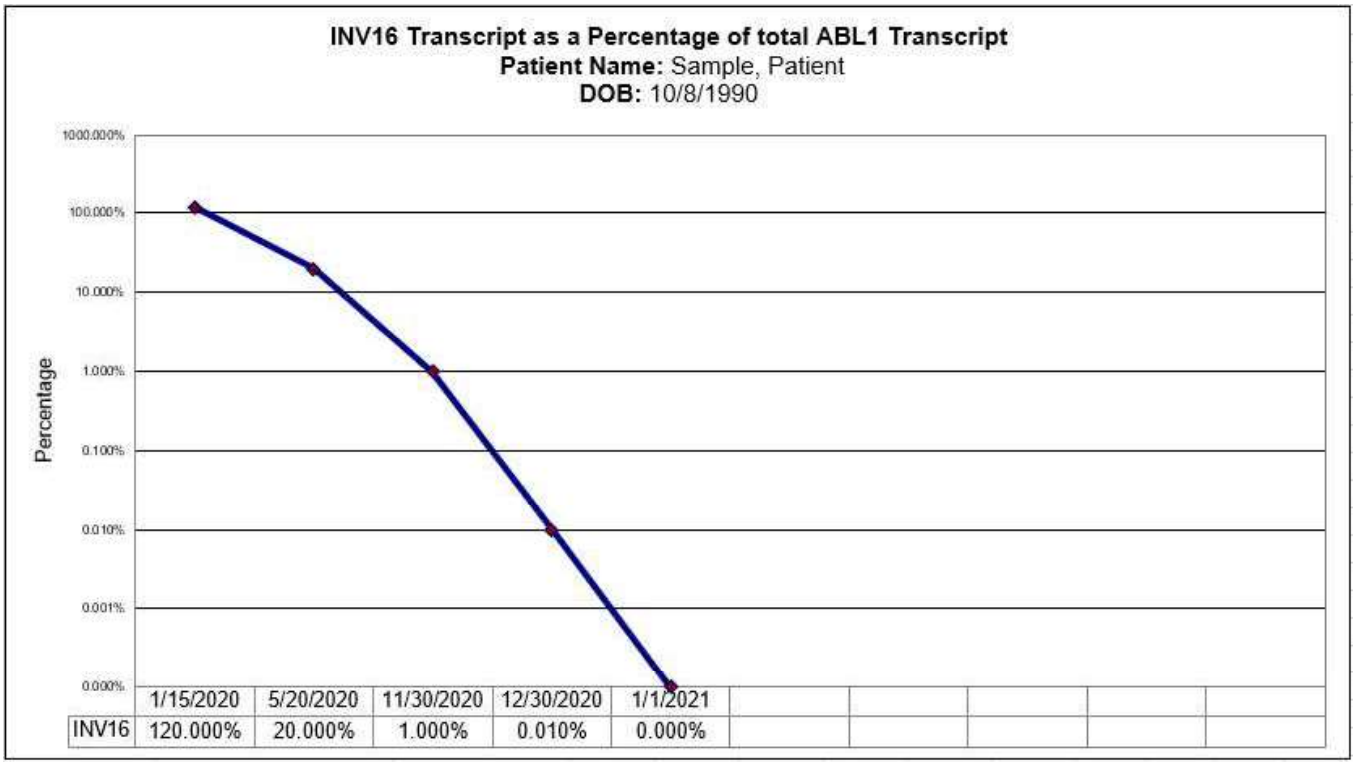

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