



1-800-533-1710

NPM1Q**NPM1 Mutation Analysis, V**

PATIENT NAME TESTINGRNA, VALIDATION			ORDER NUMBER J413000251
PATIENT ID SA00129081	DATE OF BIRTH 09/09/1999	SEX Male	REQUESTED BY CLIENT CLIENT
COLLECTED 5/13/2020, 11:31 AM	RECEIVED 5/13/2020, 11:33 AM	REPORTED 5/13/2020, 12:02 PM	
7028846 DLMP Rochester Rochester MN 55901			CLIENT ORDER NUMBER SA00129081
			CLIENT MRN SA00129081
Specimen Type		Bone marrow	
Signing Pathologist		BENJAMIN BAILEY	

INTERPRETATION

Bone marrow, NPM1 gene Mutation analysis:

Negative for NPM1 mutation. Minimal/measurable residual disease negative (MRD-negative). See comments.

Comments: In NPM1-mutated acute myeloid leukemia patients, absence of NPM1-mutated transcript after at least two cycles of cytotoxic chemotherapy is associated with lower risk of relapse and higher rate of survival in comparison to those showing persistence of NPM1-mutated transcript (Kronke et al, 2011, 21555683; Shayegi et al, 2013, 23656730; Hills et al, 2016, 26789727; Schuurhuis et al, 2018, 29330221). A negative mutation 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 NPM1 mutation types A/B/D is approximately 1/10,000 (mutated NPM1/ABL1 transcript copies), but is approximately 5% (mutated/wild-type NPM1 DNA) for other rare non-type A/B/D NPM1 mutations. Samples with mutations below the analytic sensitivity limits may therefore not be detected by this reflex test. Suggest correlation with historical NPM1 test results, and clinical and other laboratory findings.

METHOD

The assay starts with a sensitive quantitative reverse transcription real-time polymerase chain reaction (RT-PCR) which detects and quantifies the most common mutant NPM1 transcripts (A, B, D forms, account for approximately 90% of NPM1 mutations in acute myeloid leukemia (AML)). If a mutant NPM1 transcript is not detected, the test reflexes to a qualitative NPM1 exon 12 mutation screen that detects essentially all mutant forms reported in AML, including the rare non-A, B, D forms (with lower sensitivity). For the quantitative test, extracted RNA is reverse transcribed into cDNA and quantitative PCR is then performed. The quantitative value of NPM1 transcript copy number is determined relative to ABL1 as the reference transcript. The analytic sensitivity of this quantitative assay is approximately 1/10,000 (mutated NPM1/ABL1 transcript copies, 0.01%). The quantitative test will not detect other rarer NPM1 mutation types. The qualitative PCR assay is performed on extracted DNA using primers that amplify a fragment of NPM1 DNA containing the region susceptible to insertion mutation and detects essentially all types of NPM1 mutations (insertion/deletion) described in acute myeloid leukemia. The amplified fragments are size separated by capillary electrophoresis. The analytical sensitivity of the qualitative test is approximately 5% (mutated/wild-type NPM1 DNA).

DISCLAIMER

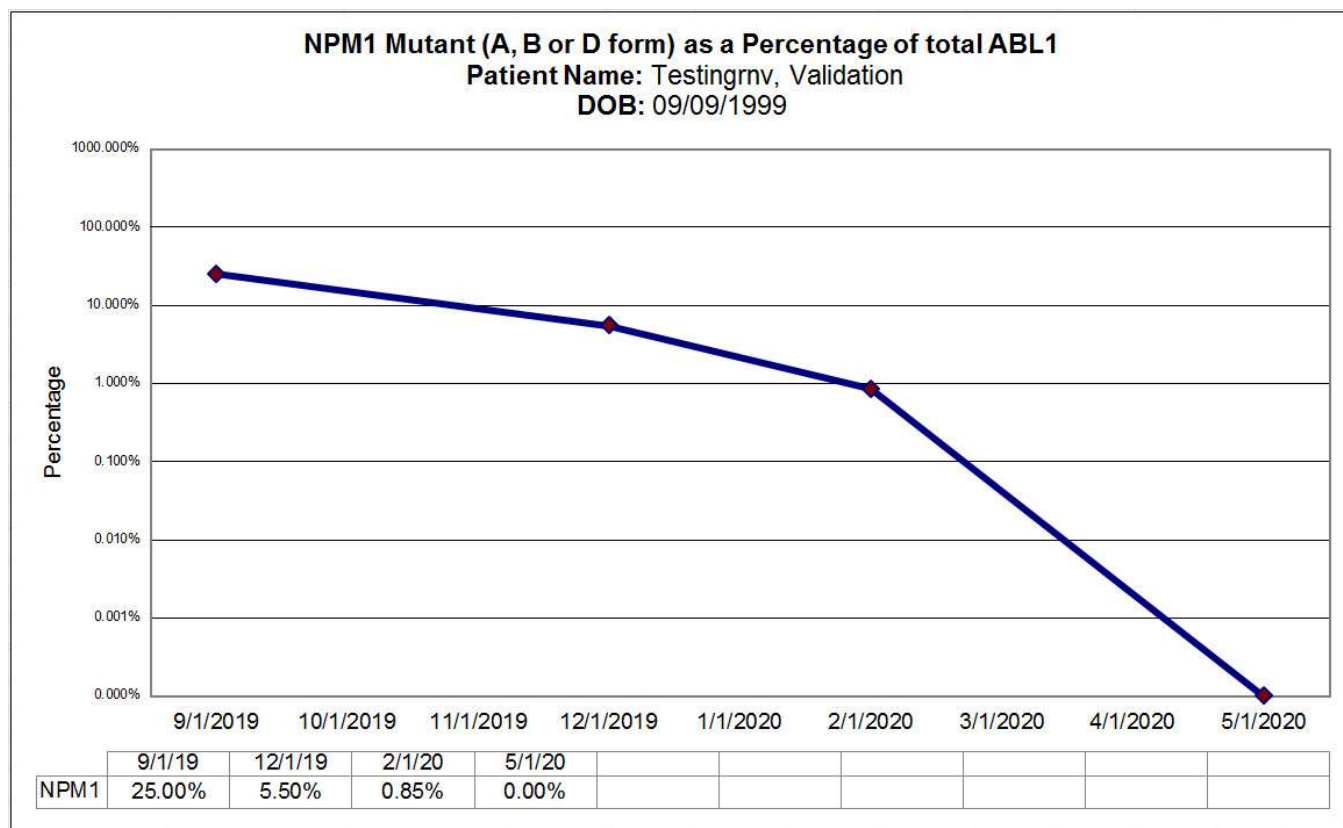
This test was developed and its performance characteristics determined by Mayo Clinic in a manner consistent with CLIA requirements. This test has not been cleared or approved by the U.S. Food and Drug Administration.



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Code : MCR Laboratory : Mayo Clinic Laboratories - Rochester Main Campus
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The collected, received, and reported dates and times on the report are in the time zone of the performing location.

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