MAYO CLINIC LABORATORIES

1-800-533-1710

BRAFB

Cell-Free DNA BRAF V600, Blood

Patient ID	Patient Name		Birth Date	Sex	Age
SA00182120	BRAFBABNORMAL, ATLAS		2005-06-06	M	21
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00182120	SA00182120	CLIENT,CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		05 Nov 2026 00:00			

cfDNA BRAF V600 Test, Blood

Result Summary

MCR

POSITIVE

Result

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BRAF status: Mutant (V600E)
Mutant copies per mL (plasma): 12914
Variant allele fraction: 33%

Interpretation

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Approximately 40–60% of patients with melanoma have a somatic mutation in the BRAF gene (1). BRAF mutations result in constitutive activation of the RAS/MAPK signaling pathway (2, 3). The most prevalent mutations in melanoma are BRAF V600E (70–90%) and V600K (5–30%); other mutations are rare.

Clinically approved targeted therapy is available for patients with unresectable or metastatic melanoma with BRAF V600 mutations (4).

REFERENCES

1. cancer.sanger.ac.uk/cancergenome/projects/cosmic/
2. Nature. 2002 Jun 27;417(6892);949–54 (PMID 12068308)
3. J Transl Med. 2010 Jul 14;8:67 (PMID 20630094)
4. https://www.fda.gov/drugs

Specimen

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Whole Blood

Method

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Cell-free DNA was isolated from the plasma and evaluated for the presence of BRAF V600E/K mutations using digital droplet PCR analysis.

Disclaimer

[1] MCR

This assay is designed to detect BRAF V600E (c.1799T>A) and V600K (c.1798_1799delGTinsAA) mutations. Other variants at or adjacent to codon 600 may yield indeterminate results due to probe cross-hybridization. Additionally, rare polymorphisms in the target region for this assay could lead to false-negative or false-positive results.

Patients with a negative test result may still harbor a V600E or K mutation, and tissue-based testing for BRAF mutations is recommended.

This assay detects BRAF V600E and V600K mutations at or above approximately 0.1% variant allele fraction in plasma, depending on the fraction of circulating tumor DNA present. This is a biological variable that cannot be controlled.

The validated Limit of Detection (LOD) and Limit of Quantitation (LOQ) thresholds for plasma are as follows:

Threshold	V600E	V600K
LOD	11 copies/mL	9 copies/mL
LOQ	21 copies/mL	20 copies/mL

The LOD for this assay is defined as the concentration of mutant copies per mL plasma corresponding to 95% detection capability. Positive results between the LOD and LOQ are associated with a coefficient of variation (CV) >35%.

Released By

MCR

Katherine B. Geiersbach, M.D.

Received: 05 Nov 2026 08:12 **Reported:** 05 Nov 2026 10:03

Laboratory Notes

[1] This test was developed and its performance characteristics were 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.

Performing Site Legend

Code	Laboratory	Address	Lab Director	CLIA Certificate
MCR	Mayo Clinic Laboratories - Rochester Main Campus	200 First Street SW, Rochester, MN 55905	Nikola Baumann Ph.D.	24D0404292

Test Environment FTBM Template