MAYO CLINIC LABORATORIES

1-800-533-1710

BRAFB

Cell-Free DNA BRAF V600 Test, Blood

Patient ID	Patient Name		Birth Date	Gender	Age
SA00107837	TESTING, REPORTS		1982-01-01	F	36
Order Number	**Client Order Number**	**Ordering Physician**	**Report Notes**		
SA00107837	SA00107837	CLIENT, CLIENT			
Account Information		**Collected**			
C7028846 DLMP Rochester		21 Jun 2018 00:00			

cfDNA BRAF V600 Test, Blood

Result Summary

MCR

POSITIVE

Result

MCR

BRAF status: Mutant (V600E)

Interpretation

[1] MCR

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.

Current data suggest that the efficacy of BRAF-targeted therapy and anti-MEK therapy in melanoma is limited to patients whose tumors harbor a V600E/K mutation. Thus, detection of the V600E mutation in this tumor specimen suggests that this patient may respond to such therapy (3–8).

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. Lancet. 2012 May 19;379(9829):1893–901 (PMID 22608338)
5. N Engl J Med. 2012 Feb 23;366(8):707–14 (PMID 22356324)
6. N Engl J Med. 2015 Jan 1;372(1):30–9 (PMID 25399551)
7. N Engl J Med. 2014 Nov 13;371(20):1877–88 (PMID 25265492)
8. Lancet Oncol. 2014 Mar;15(3):323–32 (PMID 24508103)

ADDITIONAL INFORMATION

Cell-free DNA was isolated from the plasma and evaluated for the presence BRAF V600E/K mutations using digital droplet PCR analysis. The limit of detection of this assay (approximately 0.1–0.5%) for the detection of BRAF V600E and V600K mutations is influenced by the amount of cfDNA in the blood. This is a biological variable that cannot be controlled.

This assay was designed to detect V600E and K mutations.

The limit of detection of this assay for the detection of the BRAF mutations is influenced by the amount of cfDNA in the blood. The limit of detection for this assay is 16 BRAF mutant copies per mL plasma.

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

This test has not been clinically validated for use as a tool to monitor response to therapy or for early detection of tumors.

Specimen

MCR

WB Whole Blood

Released By

MCR

Benjamin R. Kipp, Ph.D.

Received: 21 Jun 2018 13:35 **Reported:** 22 Jun 2018 10:37

Laboratory Notes

[1] 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.

Performing Site Legend

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