

Client: Example Client ABC123
123 Test Drive
Salt Lake City, UT 84108
UNITED STATES

Physician: Doctor, Example

Patient: Patient, Example

DOB: ██████████
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

BRAF V600E Mutation Detection in Circulating Cell-Free DNA by Digital Droplet PCR

ARUP test code 2013921

BRAF V600E cfDNA Result

Detected *

A BRAF V600E mutation was detected in the BRAF gene.

This result has been reviewed and approved by ██████████

BACKGROUND INFORMATION: BRAF V600E Mutation Detection in circulating cell-free DNA by Digital Droplet PCR

Determining BRAF mutation status is useful in identifying patient eligibility for therapy with kinase inhibitors. The oncogenic BRAF c.1799T>A, p.Val600Glu (V600E) mutation is associated with clinical response to the BRAF inhibitors dabrafenib (Tafinlar) and vemurafenib (Zelboraf) and the MEK inhibitors trametinib (Mekinist) and cobimetinib (Cotellic) in some tumor types.

METHODOLOGY: Circulating cfDNA is extracted from plasma. Mutation status and quantitation for BRAF V600E is determined by digital droplet PCR. The BRAF V600E mutant allele frequency (mutant alleles/(mutant + wild type alleles)*100 percent) and BRAF V600E mutant copies per mL plasma are calculated.

LIMITATIONS: Other variants at the BRAF V600 codon (V600K, V600R) will not be detected. Mutations in other locations within the BRAF gene or in other genes will not be detected. **LIMIT OF DETECTION:** Limit of detection is dependent on amplifiable cell-free DNA extracted from plasma. Limit of detection ranges from 0.5 percent to below 0.01 percent mutant allele frequency.

CLINICAL DISCLAIMER: Results of this test must always be interpreted within the clinical context and other relevant data and should not be used alone for the diagnosis of malignancy.

This test was developed and its performance characteristics determined by ARUP Laboratories. It has not been cleared or approved by the US Food and Drug Administration. This test was performed in a CLIA certified laboratory and is intended for clinical purposes.

BRAF V600E cfDNA Mutant Allele Frequency 1.45

BRAF V600E cfDNA Mutant copies/mL 24.00

H=High, L=Low, *=Abnormal, C=Critical

VERIFIED/REPORTED DATES

Procedure	Accession	Collected	Received	Verified/Reported
BRAF V600E cfDNA Result	23-103-401806	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
BRAF V600E cfDNA Mutant Allele Frequency	23-103-401806	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
BRAF V600E cfDNA Mutant copies/mL	23-103-401806	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00

END OF CHART

H=High, L=Low, *=Abnormal, C=Critical

Unless otherwise indicated, testing performed at:

ARUP LABORATORIES | 800-522-2787 | aruplab.com
500 Chipeta Way, Salt Lake City, UT 84108-1221
Jonathan R. Genzen, MD, PhD, Laboratory Director

Patient: Patient, Example
ARUP Accession: 23-103-401806
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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