

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

Physician: Doctor, Example

Patient: Patient, Example

DOB 4/12/1970
Gender: Male
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
Collection Date: 00/00/0000 00:00

KIT Mutations Melanoma

ARUP test code 3004283

KIT Mutation, Melanoma Interpretation

Not Detected

No KIT or PDGFRA mutation was detected. This result does not rule out the possibility of a mutation below the detectable limit of the assay.

This result has been reviewed and approved by [REDACTED]

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

Test information: KIT Mutations, Melanoma

CHARACTERISTICS: This assay is designed to detect mutations in the KIT gene exons 9, 11, 13, 14, 17 or 18 and in PDGFRA gene exons 12, 14 or 18. Mutations in the KIT gene may indicate responsiveness to certain targeted therapies. For specific treatment recommendations please refer to NCCN Clinical Practice Guidelines in Oncology for Melanoma (www.nccn.org).

GENES TESTED: KIT gene (NM_000222.2) exons 9, 11, 13, 14, 17, and 18 and PDGFRA gene (NM_006206.4) exons 12, 14, and 18

METHODOLOGY: Genomic DNA is isolated from microscopically-guided dissection of tumor tissue and then enriched for the targeted regions of the tested genes. The mutation status of the targeted genes is determined by massively parallel sequencing (next generation sequencing). The hg19 (GRCh37) reference sequence is used as a reference for identifying genetic mutations.

LIMITATIONS: This test will not detect mutations in other locations within the KIT or PDGFRA genes, in other genes, or below the limit of detection. This test evaluates for variants in tumor tissue only and cannot distinguish between somatic and germline variants. It is possible that some large insertion/deletion mutations (especially those greater than 60bp) may not be detected. Tissue samples yielding at least 10ng are acceptable but may yield suboptimal results if yield is less than 50ng.

LIMIT OF DETECTION: 5 percent mutant allele frequency for single nucleotide variants (SNV) and small to medium sized multi-nucleotide variants (MNV) (insertions/deletions less than 60bp).

ANALYTICAL SENSITIVITY (PPA): Analytical sensitivity for all variant classes is available through this link:
<http://ltd.aruplab.com/Tests/Pdf/294>.

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 a diagnosis of malignancy. This test is not intended to detect minimal residual disease.

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.

Block ID

F22-3495

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

VERIFIED/REPORTED DATES				
Procedure	Accession	Collected	Received	Verified/Reported
KIT Mutation, Melanoma Interpretation	22-365-400376	00/00/0000 00:00	00/00/0000 00:00	00/00/0000 00:00
Block ID	22-365-400376	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: 22-365-400376
Patient Identifiers: 01234567890ABCD, 012345
Visit Number (FIN): 01234567890ABCD
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