Warde Medical Laboratory

LABORATORY REPORT

Example Client, XYZ123
1234 Warde Road
Ann Arbor MI 48108

EXAMPLE, REPORT W
WX0000003827 M 07/08/1978 45 Y

Referral Testing

Collected: 04/16/2024 13:53 Received: 04/16/2024 13:53

Test Name	Result	Flag	Ref-Ranges	Units	Site

IDH1 and IDH2 Mutation Detection

IDH1-IDH2 Int	Detected				ARRL

IDH1 and IDH2 Mutation Detection

A mutation in IDH1 was detected: c.395G>A, p.Arg132His (NM_005896.3).

This result has been reviewed and approved by Rakhi Jattani, Sequencing Analyst.
BACKGROUND INFORMATION: IDH1 and IDH2 Mutation Detection

CHARACTERISTICS: This assay is an amplicon enrichment-based massively parallel sequencing assay targeting hotspot variants in genes critical for the diagnostic, prognostic, and therapeutic assessment of various solid tumors. The amplicon primer pool is designed to interrogate variants within a limited set of highly clinically relevant gene loci for the identification of actionable somatic variants in FFPE tissue from solid tumors.

GENES TESTED: IDH1 (NM_005896) exon 4 and IDH2 (NM_002168) exon 4 are evaluated to detect hotspot variants. Targeted regions include chr2:209113083-209113124, chr15:90631809-90631869, and chr15:90631901-90631989.

METHODOLOGY: Genomic DNA was isolated from a microscopically-guided dissection of FFPE tumor tissue and then enriched for the targeted regions of the tested genes. The variant status of the targeted genes was determined by massively parallel sequencing. The hg19 (GRCh37) reference sequence was used as a reference for identifying genetic variants. Clinically significant single nucleotide variants and variants of uncertain significance within the preferred transcripts are reported. Other types of variants may be reported with a disclaimer, if detected.

LIMITATIONS: This test will not detect variants in areas outside the targeted genomic regions or below the limit of detection. More information about the targeted regions of this test is included in the Additional Technical Information available in the Laboratory Test Directory. Copy number alterations (losses or amplifications), translocations, microsatellite instability, tumor mutational burden, deep intronic variants, and insertions/deletions will not be detected. Since this is a

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DNA-based assay, RNA variants will not be detected. This test evaluates for variants in tumor tissue only and cannot distinguish between somatic and germline variants. Therefore, if a hereditary/familial cancer is of clinical concern, additional clinical evaluation and genetic counseling should be considered prior to additional testing. In some cases, variants may not be identified due to technical limitations related to the presence of known pseudogenes, GC-rich regions, repetitive or homologous regions, low mappability regions, and/or variants located in regions overlapping amplicon primers. Tissue samples yielding between 1ng and 5ng total DNA input may yield suboptimal results and will be accepted for testing with a client-approved disclaimer. Benign or likely benign variants in the preferred transcript are not reported. Variant allele frequency (VAF) is not reported. Additional evaluation should be considered for complete genetic analysis, including detection of variants outside of the hotspot regions of IDH1 or IDH2, variants within other genes, gene methylation, translocations, or gene rearrangements, if clinically indicated.

LIMIT OF DETECTION (LOD): The LOD for this assay is 10 percent VAF. For variants near the assay LOD, positive percent agreement (PPA) was found to be greater than 90 percent.

ANALYTICAL ACCURACY/SENSITIVITY (PPA): The PPA estimate for the relevant variant class (with 95 percent credibility region) is listed below. Genes included on this test are a subset of a larger methods-based validation from which the PPA values are derived.
Single nucleotide variants (SNVs): 98.4 percent (95.1-99.7 percent)

CLINICAL DISCLAIMER: Results of this test must always be interpreted within the context of clinical findings and other relevant data and should not be used alone for a diagnosis of malignancy, determination of prognosis, or recommendation of therapy. 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 U.S. Food and Drug Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

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Block ID	TEST12345				ARRL

Performed By: ARUP Laboratories
500 Chipeta Way
Salt Lake City, UT 84108
Laboratory Director: Jonathan R. Genzen, MD, PhD
CLIA Number: 46D0523979

Reported Date: 04/16/2024 13:54 IDHMD

Performing Site:
ARRL: ARUP REFERENCE LAB 500 Chipeta Way Salt Lake City UT 841081221

LAB: L - LOW, H - HIGH, AB - ABNORMAL, C - CRITICAL, . - NOT TESTED

G016000010
WX0000003827
Printed D&T: 04/16/24 13:54

Ordered By: KAJAL SITWALA, MD, PHD
WX00000000002354

Kajal V. Sitwala, MD, PhD - Medical Director
Form: MM RL1