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PATIENT REPORT

Patient Age/Sex: Unknown

Specimen Collected: 12-Mar-24 15:29

Colorectal Cancer Mutation Panel	**Received: 12-Mar-24 15:29**		**Report/Verified: 18-Mar-24 17:44**
Procedure	**Result**	**Units**	**Reference Interval**
CRC Mut Int	Detected [f1 i1]		

Colorectal Cancer Mutation Panel	**Received: 12-Mar-24 15:29**		**Report/Verified: 19-Mar-24 06:39**
Procedure	**Result**	**Units**	**Reference Interval**
Block ID	1		

Result Footnote

f1: CRC Mut Int

Colorectal Cancer Mutation Panel

A mutation in KRAS was detected: c.34G>A, p.Gly12Ser

This result has been reviewed and approved by Rakhi Jattani, Sequencing Analyst.

Test Information

i1: CRC Mut Int

BACKGROUND INFORMATION: Colorectal Cancer Mutation Panel

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 different DNA variant classes including single nucleotide variants (SNVs), multiple nucleotide variants (MNVs), and small insertions and deletions (1-25 base pairs [bp]) 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: The following regions are evaluated to detect hotspot SNVs, MNVs, small insertions, and small deletions, unless otherwise indicated: BRAF (NM_004333) exon 15; KRAS (NM_004985) exons 2, 3, 4; NRAS* (NM_002524) exons 2, 3, 4. All exons are partially covered for hotspots only and not reported in full. More information about the targeted regions of this test is included in the Additional Technical Information available in the Laboratory Test Directory.
*Only SNVs are validated for NRAS; other variants may be reported with a disclaimer, if detected.

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 variants and variants of uncertain significance within the preferred transcripts are reported.

Test Information

i1: CRC Mut Int

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 larger than 25bp will not be detected. Since this is a 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 covered by this test, translocations, or gene rearrangements, if clinically indicated.

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

ANALYTICAL ACCURACY/SENSITIVITY (PPA): The PPA estimates for the respective variant classes (with 95 percent credibility region) are 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)
Deletions (1-25bp): 96.6 percent (89.6-99.3 percent)
Insertions/duplications (1-25bp): 96.8 percent (90.2-99.3 percent)
Multiple nucleotide variants (MNVs): 98.2 percent (91.8-99.8 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

Test Information

i1: CRC Mut Int
Administration. This test was performed in a CLIA-certified laboratory and is intended for clinical purposes.

*=Abnormal, #=Corrected, C=Critical, f=Result Footnote, H-High, i-Test Information, L-Low, t-Interpretive Text, @=Performing lab