Patient Name	Centre
Age/Gender	OP/IP No/UHID
MaxID/Lab ID	Collection Date/Time
Ref By	Reporting Date/Time

SIN No:DF1117538

TEST REQUESTED

Max Focus Fusion Panel

METHOD USED

Next Generation Sequencing (NGS)

CLINICAL INFORMATION/SAMPLE INFORMATION

As per histopathology impression, features are suggestive of poorly differentiated Squamous cell carcinoma in core biopsy from left posterior pharyngeal wall.
FFPE Block: (Block No.: S-379/24, Tumor Content: ~30-40%)

TARGETED GENES

HOTSPOT GENES COVERED

AKT1	*ALK*	*AR*	*BRAF*	*CDK4*	*CTNNB1*	*DDR2*	*EGFR*	*ERBB2*	*ERBB3*
ERBB4	*ESR1*	*FGFR2*	*FGFR3*	*GNA11*	*GNAQ*	*HRAS*	*IDH1*	*IDH2*	*JAK1*
JAK2	*JAK3*	*KIT*	*KRAS*	*MAP2K1*	*MAP2K2*	*MET*	*MTOR*	*NRAS*	*PDGFRA*
PIK3CA	*RAF1*	*RET*	*ROS1*	*SMO*					

GENES WITH COPY NUMBER VARIANTS (CNV)

ALK	*AR*	*BRAF*	*CCND1*	*CDK4*	*CDK6*	*EGFR*	*ERBB2*	*FGFR1*	*FGFR2*
FGFR3	*FGFR4*	*KIT*	*KRAS*	*MET*	*MYC*	*MYCN*	*PDGFRA*	*PIK3CA*	

GENES WITH FUSIONS

ABL1	*AKT3*	*AXL*	*ALK*	*BRAF*	*EGFR*	*ERBB2*	*ERG*	*ETV1*	*ETV4*
ETV5	*FGFR1*	*FGFR2*	*FGFR3*	*MET*	*NTRK1*	*NTRK2*	*NTRK3*	*PPARG*	*RAF1*
RET	*ROS1*								

PRIMARY FINDINGS

No Pathogenic variant found in Hotspot genes
No Fusions found
No CNV found

SUMMARY

- This test did not identify any variant in Hotspot genes covered in the panel.
- This test did not identify any gene with fusions from the genes covered in the panel.
- This test did not identify any genes with CNVs from the genes covered in the panel.
- No other variant that warrants to be reported was detected. Variations with high minor allele frequencies which are benign will be given upon request.

SAMPLE STATISTICS

Coverage	100%
Depth	12,128X

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MOLECULAR AND BIO-MARKER DIRECTED THERAPY (AS PER NCCN GUIDELINES)

Therapy	Tested Markers	Predicted Response
Erlotinib, Gefitinib	EGFR, ERBB2, KRAS, BRAF	
Afatinib	EGFR, ERBB2, KRAS, BRAF	
Dacomitinib	EGFR	
Osimertinib	EGFR	
Erlotinib + ramucirumab	EGFR	
Erlotinib + bevacizumab	EGFR	
Osimertinib	EGFR	
Amivantamab-vmjw	EGFR	
Mobocertinib	EGFR, ERBB2	
Sotorasib	KRAS G12C	
Capmatinib	MET Exon 14 Skipping mutation, MET Amplification	
Fam-trastuzumub	ERBB2	
Ado-trastuzumub	ERBB2	
Crizotinib	ALK, ROS1, MET Amplification, MET Exon 14 Skipping mutation	
Tepotinib	MET Amplification, MET Exon 14 Skipping mutation	
Entrectinib	ROS,	
Ceritinib	ALK, ROS1	
Alectinib	ALK	
Brigatinib	ALK	
Lorlatinib	ALK, ROS1	
Dabrafinib/trametinib	BRAF	
Dabrafenib	BRAF	
Vemurafenib	BRAF	

PREDICTED RESPONSE OF THERAPY

Green	Good response
Red	Contraindicated response
Orange	Limited response
Blue	Therapeutic Guidelines not availaible

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TEST METHODOLOGY

Background

Multi gene analysis through next generation sequencing allows the identification of variants to understand their prognostic and therapeutic implications in different cancer types, if any. Targeted application of next-generation sequencing (NGS) technology allows detection of specific mutations that can provide treatment opportunities to the patients. This panel with improved primer design and as little as 10 ng of DNA enable researchers to sequence challenging samples such as Formalin fixed, paraffin embedded (FFPE) tissue which exhibit variable quality.

Method - NGS

This panel targets 52 genes along with fusions and uses methodologies of Next generation sequencing using Oncomine focus assay. These genes have been selected on the basis of their known impact as actionable targets of existing and emerging anti-cancer therapies, and the prognostic features in specific tumor types.

The sensitivity of the assays depends on the quality of the block, and tumor content. In validation studies the minimum analytic detection limit is 5%. Genomic positions are given in reference to the GRCh37 (hg19) assembly of the human genome.

Limitations

The accuracy and completeness may vary due to variable information available in different databases. The classification of variants of unknown significance can change over time. Synonymous mutations were not considered while preparing this report. The mutations have not been confirmed using Sanger sequencing and/or alternate technologies. To rule out germ line mutations i.e. variant with variant allele frequency at nearly 50% or 100%, whole blood sample is recommended to process along with tissue sample. No other variant that warrants to be pathogenic was detected. Variations with high minor allele frequencies which are benign/likely benign will be given upon request.

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DISCLAIMER

A Negative result implying non-detection of mutation/deletion indicates a Benign/likely Benign polymorphism. A negative test result may also be due to the inherent technical limitations of the assay. Results obtained should be interpreted with consideration of the overall picture obtained from clinical, laboratory, and pathological findings. Rare polymorphisms may lead to false negative or positive results. False negative results may be due to sampling error/errors in sample handling as well as clonal density below the limit of detection. Misinterpretation of results may occur if the information provided is inaccurate or incomplete. Identification of a mutation in one or more of these genes does not guarantee activity of the drug in a given indication due to the presence of contraindicated mutation in the gene not covered by the panel.

The accuracy and completeness may vary due to variable information available in different databases. Classification of the variant may change overtime. An updated variant classification may be obtained on request. Insertions and deletions greater than 20bp in size may not be detected by this assay. The scope of this assay limits to SNVs, MNVs and short deletions/duplications. Due to poor quality of FFPE DNA, indeterminate result due to low gene coverage or low variant depth cannot be ruled out. The sensitivity of the assays depends on the quality of the block, and tumor content.

The information provided should only be utilized as a guide or aid and the decision to select any therapy option based on the information reported here resides solely with the discretion of the treating physician. Patient care and treatment decisions should only be made by the physician after taking into account all relevant information available including but not limited to the patient's condition, family history, findings upon examination, results of other diagnostic tests, and the current standards of care. This report should only be used as an aid and the physician should employ sound clinical judgment in arriving at any decision for patient care or treatment. Since only a portion of the tumor was tested, it is possible that this result may not represent the entire tumor population.

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