Laboratory Investigation Report

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

SIN No:DF1029066

TEST REQUESTED

MAX NGS LUNG CANCER PANEL

CLINICAL/SAMPLE INFORMATION

As per Histopathology impression, there is Adenocarcinoma in biopsy from right lung lesion.

FFPE Block (Block No.: S-6611/23-B, Tumor Content: ~30%)

TARGETED GENES

HOTSPOT GENES COVERED (Next Generation Sequencing)

AKT1	*ALK*	*AR*	*BRAF*	*CDK4*	*CTNNB1*	*DDR2*	*EGFR (1)*	*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 FUSIONS (Next Generation Sequencing)

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

GENES WITH CNV (Next Generation Sequencing)

BL1	*AKT3*	*AXL*	*BRAF*	*EGFR*	*ERBB2*	*ERG*	*ETV1*	*ETV4*	*ETV5*
FGFR1	*FGFR2*	*FGFR3*	*MET*	*NTRK1*	*NTRK2*	*NTRK3*	*PPARG*	*RAF1*	*RET*
ROS1									

MET Exon14 Skipping (Fragment Analysis)

Met 9(13)-MET (15)	*Not Detected*

PRIMARY FINDINGS

Gene	CDS Variant	Amino Acid Change	Exon	Allele Frequency	Coverage	dbSNP ID	Pathogenicity (Clinvar)
EGFR	NM_005228.5:c.2573T>G	p.Leu858Arg	21	15.74%	1950	rs121434568	Drug Response

INTERPRETATION SUMMARY

- This test identified a variant in EGFR gene in exon 21 [NM_005228.5(EGFR):c.2573T>G (p.Leu858Arg); VAF-15.74%]. As per ClinVar database, this variant has been classified as Drug Response.
- This test did not identify any clinically significant fusions in the genes mentioned in the panel.
- This test did not identify any clinically significant CNVs in the genes mentioned in the panel.
- This test did not identify MET Exon14 Skipping by fragment analysis.

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Sample Cancer Type: Lung Cancer

Relevant Lung Cancer Findings

Gene	Finding	Gene	Finding
ALK	None detected	NTRK1	None detected
BRAF	None detected	NTRK2	None detected
EGFR	***EGFR L858R***	NTRK3	None detected
ERBB2	None detected	RET	None detected
KRAS	None detected	ROS1	None detected
MET	None detected		

Relevant Biomarkers

Genomic Alteration	Relevant Therapies (In this cancer type)	Relevant Therapies (In other cancer type)	Clinical Trials
EGFR L858R Allele Frequency: 15.74%	**afatinib** [1, 2] **bevacizumab* + erlotinib** [2] **dacomitinib** [1, 2] **erlotinib** [1, 2] **erlotinib + ramucirumab** [1, 2] **gefitinib*** [1, 2] **osimertinib** [1, 2] atezolizumab + bevacizumab + chemotherapy gefitinib + chemotherapy	None	234

Public data sources included in relevant therapies: FDA[1], NCCN, **EMA**[2], ESMO
*** Includes biosimilars/generics**

Alerts informed by public data sources: Contraindicated, Resistance, Breakthrough, Fast Track

EGFR L858R	**patritumab deruxtecan** [1] **osimertinib + quaratusugene ozeplasmid** [1]

Public data sources included in alerts: FDA[1], NCCN, **EMA**[2], ESMO

Test Performed at :910 - Max Hospital - Saket M S S H, Press Enclave Road, Mandir Marg, Saket, New Delhi, Delhi 110017
Booking Centre :1103 - Max Hospital Saket(East Block), 1, 2, Press Enclave Marg, Saket Institutional Area, Saket, New Delhi, 7982100200
The authenticity of the report can be verified by scanning the Q R Code on top of the page

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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 using control material and a variety of cell lines, the minimum analytic detection limit for each of the assays is 5%.

Genomic positions are given in reference to the GRCh37 (hg19) assembly of the human genome.

Method – Fragment Analysis

This panel covers Met exon 14 skipping by fragment analysis.

References

- NCCN Guidelines Version 1.2023, Non-Small Cell Lung Cancer
- Li MM, Datto M, Duncavage EJ, Kulkarni S, Lindeman NI, Roy S, Tsimberidou AM, Vnencak-Jones CL, Wolff DJ, Younes A, Nikiforova MN. Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists. J Mol Diagn. 2017 Jan;19(1):4-23. PMID: 27993330

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. 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.

This is a laboratory developed test (LDT). 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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