LABORATORY REPORT

Reg. No	:	**30100200186**	Reg. Date	:	31-Jan-2023 10:20
Name	:	**LUGGYA BENON**	Collected on	:	31-Jan-2023 10:20
Sex/Age	:	**Male / 69 Years**	Approved Date	:	20-Feb-2023 17:49
Ref. By	:		Tele. No	:	
Location	:	LILAC INSIGHTS PVT. LTD. @ MUMBAI	Dispatch At	:	

Please find detailed report of NGS Oncomine Precision Assay in the following pages.

---------- End Of Report ----------

Neeraj Arora

Dr. Neeraj Arora
M.D (Path), PDF (Mol Haemat),
PDF (Haematopath)
22396

Patient Details

Patient Name	**LUGGYA BENON**	**Sample Id/LabID**	**30100200186**
Gender	Male	**DOB/AGE**	69 yrs
Ref.By	LILAC INSIGHTS PVT. LTD.	**Date of Sample Collection**	31/01/2023
Sample Type	FFPE BLOCK:984A/23	**Date of Receipt**	31/01/2023
Tumor Cellularity	50%	**Date of Report**	20/02/2023

NGS Oncomine Precision GX Assay (DNA mutations, CNVs, RNA Fusions)

Clinical Details:

Case of Carcinoma Prostate. Right upper lobe lung lesion
?? Mets/ ?? Primary

RESULT

NEGATIVE:

No clinically Relevant Pathogenic Mutation/ Fusion identified.

Comments:

These findings should be correlated with other clinical and laboratory tests like for a definite conclusive interpretation.

Relevant Biomarkers

No biomarkers associated with relevant evidence found in this sample

Methodology

Nucleic acid (DNA/RNA) was extracted from FFPE sample, using standard Qiagen nucleic acid isolation kits. Automated library preparation and sequencing run was perfomed using Oncomine Precision assay GX on Genexus platform as per user manual. Generated data was analyzed using on board analysis software with default filter chain. Default filter chain is optimized for reporting detected variants with the Oncomine™ Precision Assay GX.This filter chain provides results for INDELs and SNV variant types, and minor allele frequencies between 0.0 and 1.0E-6 based on 5000Exomes and ExAC annotation source databases that have homopolymer lengths less than or equal to 7 and allele frequencies between 0.05 and 1.0.

Run QC statistics
Sample is sequenced at Average base coverage depth of 5,432. The Target base coverage at 500X is 99.46%.

Variant Classification

- **Pathogenic**: The pathogenic variant are the one which is believed to account for the symptoms. It increases an individual's susceptibility or predisposition to a certain disease or disorder. This mutation is always included in results section of report.
- **Likely Pathogenic**: The likely pathogenic variant are the one which most likely have harmful effect but, there is insufficient evidence that a variant is the definite cause for symptoms. This mutation is always included in results section of report
- **Variant of Uncertain Significance**: The Variant of Uncertain Significance (VUS) are the one which have limited and/or conflicting evidence regarding pathogenicity. Its exact effect on gene function is not known. With more information available over time, a VUS may be reclassified as likely pathogenic or likely benign. This mutation is always included in results section of report.
- **Likely benign**: The likely benign variants are the one which are most likely not associated with disease risk. However, additional evidence is needed to confirm this assertion. This mutation is not included in report
- **Benign**: The benign variants are the one which are represented by alteration in gene compare to wild-type allele but it is not associated with disease risk. This mutation is not included in report.

Evidence-based variant Categorization

Tier I	Variants with strong clinical significance	Level A evidence	FDA-approved therapy included in professional guidelines
		Level B evidence	Well-powered studies with consensus from leaders in the field
Tier II	Variants with potential clinical significance	Level C evidence	FDA-approved therapies for different tumor types or investigational therapies. Multiple small published studies with some consensus
		Level D evidence	Preclinical trials or few case reports without consensus.
Tier III	Variants of unknown clinical significance		Not observed at significant allele frequency in the general or specific subpopulation databases, or pan-cancer or tumor-specific variant databases. No convincing published evidence of cancer association

Genes Assayed

Genes Assayed for the Detection of DNA Sequence Variants

AKT1, AKT2, AKT3, ALK, AR, ARAF, BRAF, CDK4, CDKN2A, CHEK2, CTNNB1, EGFR, ERBB2, ERBB3, ERBB4, ESR1, FGFR1, FGFR2, FGFR3, FGFR4, FLT3, GNA11, GNAQ, GNAS, HRAS, IDH1, IDH2, KIT, KRAS, MAP2K1, MAP2K2, MET, MTOR, NRAS, NTRK1, NTRK2, NTRK3, PDGFRA, PIK3CA, PTEN, RAF1, RET, ROS1, SMO, TP53

Genes Assayed for the Detection of Copy Number Variations

ALK, AR, CD274, CDKN2A, EGFR, ERBB2, ERBB3, FGFR1, FGFR2, FGFR3, KRAS, MET, PIK3CA, PTEN

Genes Assayed for the Detection of Fusions

ALK, AR, BRAF, EGFR, ESR1, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK2, NTRK3, NUTM1, RET, ROS1, RSPO2, RSPO3

Limitations and Disclaimer

1. This test was developed and its performance characteristics determined by Unipath Specialty Laboratory Ltd, Ahmedabad. It has not been cleared or approved by the US Food and Drug Administration and NABL.
2. This NGS test used does not allow definitive differentiation between germline and somatic variants. However, variants with variant allele frequency at nearly 50% or 100% should be considered Germline mutation. To rule out germ line mutations, repeat analysis using peripheral blood/saliva sample is recommended.
3. Certain genes may not be covered completely, and few mutations may not be detected in the presence of pseudogenes or in repetitive or homologous regions.
4. False negative results may be due to sampling issues, errors in sample handling, mislabeling, transportation issues, technical limitations of the assay and mutations frequency below the limit of detection of the assay, i.e., 5% for SNVs and 10% for short indels. It is also possible some complex insertion/deletion variants may not be identified.
5. Sanger confirmation of reported mutations is available on request with additional charges.
6. This test is not intended to detect minimal residual disease.
7. Results of this test need be interpreted within the context of clinical findings and other relevant clinical and laboratory data and should not be used alone.

Report Signed by:

DR. SPANDAN CHAUDHARY, Ph.D
(Sr. Scientist, NGS Division)

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