ONCOLOGY genpath an OPKO Health Company

Final Report

PHYSICIAN

SAMPLE, PHYSICIAN
ONCOLOGY HOSPITAL
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PATIENT

SAMPLE, PATIENT
DOB: 1/1/1967 **Age:** 54 Y **Sex:** M
Surgical #:
Patient ID:
Address:

SAMPLE

Specimen ID: **XXXXXXXXX**
Date of Report: 05/07/2021 4:16 PM
Date Collected: 04/02/2021 Time Unknown
Date Received: 04/30/2021 1:33 PM
North America Central Time Zone
Source: LUNG BIOPSY

ONKOSIGHT NEXT GENERATION SEQUENCING GENE FUSION PANEL

INTERPRETATION

POSITIVE: Pathogenic AGTPBP1 → NTRK2 gene fusion DETECTED.

NTRK2 Fusion is a predictive biomarker for use of entrectinib and larotrectinib in patients.
Of the therapies with NTRK2 Fusion as a predictive biomarker, 2 are FDA-approved in at least one clinical setting.

No pathogenic gene fusions detected involving ALK, AXL, BRAF, CCND1, EGFR, FGFR1, FGFR2, FGFR3, MET, NRG1, NTRK1, NTRK3, PPARG, RAF1, RET, ROS1, THADA.

RESULTS

Tumor Cellularity: 20-50%

Tumor Type: Squamous Cell Carcinoma

Surgical Block ID:

5'GENE FUSION TRANSCRIPT
AGTPBP1;exon:1;NM_015239.2

3'GENE FUSION TRANSCRIPT
NTRK2;exon:17;NM_006180.3

METHOD

Tissue sections are reviewed by a pathologist; specimens with minimal tumor cells may be rejected. RNA is isolated from the selected area of the sample. Anchored multiplex PCR for targeted next-generation sequencing is performed. The sequenced sample is a reverse transcription PCR-amplified fragment library in which each sample is uniquely identified by ligation of a short oligonucleotide barcode. The panel targets mutltiple rearrangements and the resultant sequence identifies the exons of the fusion transcript arising from that target and the partner gene. Each sample is monitored for quality to ensure reliable fusion detection. Variants are identified by an automated process that takes into account statistical confidence of base calling and alignment and mapping quality [Archer Analysis vs 3.3]. The software requires a single read spanning two separate genes of at least 23 bp each to be considered a valid fusion candidate and each read that spans the same breakpoint is grouped together. A final consensus sequence is constructed and used to annotate the two (or more) fusion partners by comparing to the human genome with BLAST and annotations from the RefSeq database cross-referenced with the manufacturers database of known fusions published in the literature [Archer Quiver Database]. The assay can detect RNA fusions in samples containing 5% or more cells with the chromosomal translocation.

These tests were developed and their performance characteristics were determined by BioReference Laboratories. They may not be cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary. These results may be used for clinical, investigational or for research purposes, and should be interpreted with other relevant clinicopathologic data.

Wojciech Swat, PhD, FACMG
Pathologist
This report was electronically signed.

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James Weisberger, M.D.
Laboratory Director

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