

THE UNIVERSITY OF TEXAS  
**MD Anderson**  
~~Cancer Center~~

**The University of Texas MD Anderson Cancer Center**  
 1515 Holcombe Blvd., Houston, TX 77030

Making Cancer History®

Print Date: 12/8/2020 10:25 CST

**NAME: XXXXX**

Location: MN Molecular Diag

**MRN: XXXXX**

Ordering: GONZALEZ PA,CIPRIANO C

DOB/Age/Sex: X/XX/XXXX 60 years Female

*Molecular Diagnostics*

MD- XXXXXXX

**Solid Tumor Genomic Assay-Fusions Report**

**Accession:** MD-20-XXXXXX

**Collection Date:** 05/05/2020

**Received In-lab Date:** 11/25/2020 2:13 PM

**Specimen Type:** FFPE Slides

Pathology Accession for Source Material: XX-XXXX 5 Outside Accession: XXX-XXXX

Histologic Diagnosis for Source Material (refer to source accession for details): Salivary carcinoma with myoepithelial differentiation

NAME XXXXX

MRN XXXXX

MDL XXXXX

**Solid Tumor Genomic Assay 2018 - RNA (Fusions)**

Clinical test requisition for fusion studies on the following genes was received: *NTRK1*, *NTRK2*, *NTRK3*

A next generation sequencing (NGS)-based analysis for the detection of targeted inter- and intragenic fusions involving 51 genes was performed.

**FINDINGS:**

Gene Fusions

None identified

**NAME** XXXXX

Case Number: XXXXX

**Med Rec Number:** XXXXX

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### Molecular Diagnostics

#### **METHODOLOGY:**

**Test platform:** cDNA prepared from extracted RNA is combined with targeted amplicon based next generation sequencing (NGS) to amplify both a set of expected control RNA sequences and a set of targeted fusion sequences corresponding to clinically relevant known inter- and intragenic fusions in 51 genes (*AKT2, ALK, AR, AXL, BRAF, BRCA1, BRCA2, CDKN2A, EGFR, ERB84, ERBB2, ERG, ESR1, ETV1, ETV4, ETV5, FGFR1, FGFR2, FGFR3, FGR, FLT3, JAK2, KRAS, MDM4, MET, MYB, MYBL1, NF1, NOTCH1, NOTCH4, NRG1, NTRK1, NTRK2, NTRK3, NUTM1, PDGFRA, PDGFRB, PIK3CA, PPARG, PRKACA, PRKACB, PTEN, RAD51B, RAF1, RB1, RELA, RET, ROS1, RSPO2, RSPO3, and TERT*). Sequences are aligned against a synthetic fusion genome and fusions are identified by coverage analysis. Detailed information about the signal-processing, base calling, alignment, and fusion calling including specific fusion partners and break-points, are available upon request.

**Analytical sensitivity and additional details:** Assessing sensitivity/limit of detection for a non-cellular fusion assay is challenging because fusion messenger RNA is likely to be expressed idiosyncratically and non-uniformly with respect to cellular/genomic equivalents. Sensitivity of detection is expected to be influenced both by this expression level and the tumor purity of the sample. Detection of a particular clinical fusion event for this assay requires that both fusion partners and the specific fusion junction between them be flanked by the amplicon primers used. Adequacy of RNA sampling is ensured by requiring that a sample have a minimum of 500,000 mapped cDNA target reads with a minimum average sequence length of 60 base pairs.

#### **Details and limitations of the test:**

- False negative results can be obtained in cases with low fusion RNA expression, low tumor percentage, or fusions that do not correspond exactly to the targeted fusion junctions on the assay. We require a minimum of 20% tumor nuclei in the sample to reduce the potential for false-negative results. Correlation with traditional methods of fusion detection such as fluorescent in situ hybridization (FISH) is recommended as applicable.

**Report annotation and generation software:** A post-variant calling analysis and annotation tool, OncoSeek version 1.8.1.490, was used in the construction of this report.

#### **DISCLAIMER:**

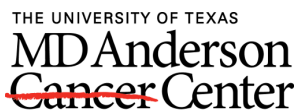
This test was developed and its performance characteristics determined by the Molecular Diagnostic Laboratory (MDL) at the M.D. Anderson Cancer Center. It has not been cleared by the U.S. Food and Drug Administration. However, such approval is not required for clinical implementation, and the test results on the ordered genes have been shown to be

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Case Number:	XXXXX
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*Molecular Diagnostics*

clinically useful. This laboratory is CAP accredited and CLIA certified to perform high complexity molecular testing for clinical purposes.

Electronically Signed By: ASIF RASHID, MD - 10160 and reported on 12/08/20 10:25 AM

Test performed by:

The University of Texas MD Anderson Cancer Center Molecular Diagnostic Lab  
6565 MD Anderson Blvd  
Houston, TX 77030

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**NAME**                    **XXXXX**

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