

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description:

Product	Material Number	Batch Number
Seraseq® FFPE Fusion RNA Reference Material v4	0710-0496	10809775
Kit Component		
Vial	0710-1275	10809690

Date of Manufacture:

06 MAY 2026

Expiration Date:

03 APR 2030

Vial Contents:

1x 10 µm FFPE curl

Concentration test Method:

AutoGen XTRACT 16+ Total RNA FFPE One-Step Kit extraction followed by Qubit RNA HS Assay Quantitation

Average RNA Yield:

1567 ng

Fusion Test Method:

Droplet Digital PCR using TaqMan™ probes tested on the BioRad QX200 system.

Measured Fusion Concentrations:

RNA Fusion	Digital PCR Average Fusion copies/ng of total RNA
CCDC6-RET	208.2
CD74-ROS1	625.0
EGFR variant III	178.8
EGFR-SEPT14	401.1
EML4-ALK	177.3
ETV6-NTRK3	378.4
FGFR3-BAIAP2L1	167.5
FGFR3-TACC3	116.6
KIF5B-RET	109.7
LMNA-NTRK1	243.1
MET Exon 14 Skipping	618.0
NCOA4-RET	219.0
PAX8-PPARG1	211.5
SLC34A2-ROS1	404.0
SLC45A3-BRAF	489.6
TFG-NTRK1	230.7
TMPRSS2-ERG	376.8
TPM3-NTRK1	148.6

NGS Result:

Positive for all 18 fusions and exon skipping events

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NGS Fusion Test Method:

Archer® FusionPlex® Solid Tumor Assay tested on the ILMN MiSeq™ instrument (v2, 2 x 150 bp PE kit) using 250 ng of input RNA

NGS Analysis Method

Data analyzed using Archer Analysis Suite Software version 6.2.7 (default settings)

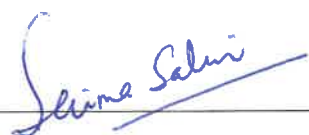
NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	111	429
CD74-ROS1	35	142
EGFR variant III	167	1051
EGFR-SEPT14	70	116
EML4-ALK	140	1610
ETV6-NTRK3	247	1250
FGFR3-BAIAP2L1	77	1400
FGFR3-TACC3	118	1610
KIF5B-RET	101	461
LMNA-NTRK1	146	1404
MET Exon 14 Skipping	24	32
NCOA4-RET	55	171
PAX8-PPARG1	115	567
SLC34A2-ROS1	19	65
SLC45A3-BRAF	75	1333
TFG-NTRK1	45	224
TMPRSS2-ERG	72	3796
TPM3-NTRK1	102	661

*Total number of reads per sample was 3.4M.

Approval:

Prepared By



Date

05/18/2020

QA Verified By



Date

18 May 2020