

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	10807635
Kit Component		
Vial	0710-1275	10807634

Date of Manufacture:

25 MAR 2026

Expiration Date:

03 MAR 2030

Vial Contents:

1x 10 µm FFPE curl

Concentration test Method:

Augencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation

Average RNA Yield:

1928.8 ng/curl

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	169.2
CD74-ROS1	465.7
EGFR variant III	376.0
EGFR-SEPT14	160.1
EML4-ALK	152.1
ETV6-NTRK3	311.9
FGFR3-BAIAP2L1	142.1
FGFR3-TACC3	176.2
KIF5B-RET	105.9
LMNA-NTRK1	322.8
MET Exon 14 Skipping	215.0
NCOA4-RET	242.5
PAX8-PPARG1	214.4
SLC34A2-ROS1	505.1
SLC45A3-BRAF	236.5
TFG-NTRK1	357.0
TMPRSS2-ERG	563.0
TPM3-NTRK1	343.3

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	173	892
CD74-ROS1	143	1902
EGFR variant III	176	1268
EGFR-SEPT14	368	902
EML4-ALK	178	1938
ETV6-NTRK3	365	2567
FGFR3-BAIAP2L1	137	2166
FGFR3-TACC3	174	3780
KIF5B-RET	209	2751
LMNA-NTRK1	188	2503
MET Exon 14 Skipping	166	536
NCOA4-RET	134	959
PAX8-PPARG1	167	1138
SLC34A2-ROS1	140	1068
SLC45A3-BRAF	76	1550
TFG-NTRK1	135	1386
TMPRSS2-ERG	131	7202
TPM3-NTRK1	225	3111

*Total number of reads per sample was 3.42 M.

Approval:


Prepared By

08 APR 2026
Date


QA Verified By

08 Apr 2026
Date