

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description: Seraseq® FFPE Fusion RNA Reference Material v4
 Material No: 0710-0496 Batch No: 10621247
 Date of Manufacture: 10-MAY-2022 Expiration Date: 02-MAY-2024

Vial Contents: 1x 10 µm FFPE curl
 Concentration test Method: Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation
 Average RNA Yield: 1485 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	114
CD74-ROS1	360
EGFR variant III	202
EGFR-SEPT14	129
EML4-ALK	139
ETV6-NTRK3	239
FGFR3-BAIAP2L1	149
FGFR3-TACC3	60
KIF5B-RET	84
LMNA-NTRK1	187
MET Exon 14 Skipping	308
NCOA4-RET	133
PAX8-PPARG1	168
SLC34A2-ROS1	411
SLC45A3-BRAF	159
TFG-NTRK1	240
TMPRSS2-ERG	300
TPM3-NTRK1	104

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NGS Result: Positive for all 18 fusions and exon skipping events
 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	163	853
CD74-ROS1	149	1631
EGFR variant III	178	1232
EGFR-SEPT14	330	763
EML4-ALK	184	2187
ETV6-NTRK3	358	2519
FGFR3-BAIAP2L1	144	3289
FGFR3-TACC3	168	2844
KIF5B-RET	191	2014
LMNA-NTRK1	249	3359
MET Exon 14 Skipping	142	456
NCOA4-RET	122	582
PAX8-PPARG1	164	1051
SLC34A2-ROS1	157	1031
SLC45A3-BRAF	76	2050
TFG-NTRK1	168	2320
TMPRSS2-ERG	169	10669
TPM3-NTRK1	230	2648

*Total number of reads per sample was 5.1M.

Approval:

Prepared By  Date 5/13/2022
 QA Verified By  Date 5/13/2022