

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description: Seraseq Fusion RNA Mix v4
 Material No: 0710-0497 Batch No: 10670288
 Date of Manufacture: 07 JUN 2023 Expiration Date: 29 MAR 2025

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 32.4 ng / μ L

Nominal Fusion Concentration: 1500 Fusion copies/ μ L
 Fusion Test Method: Droplet Digital PCR using TaqMan™ probes run on the BioRad QX200 system

Measured Fusion Concentrations:

RNA Fusion	Digital PCR Average Fusion copies/ μ L
CCDC6-RET	1080
CD74-ROS1	1953
EGFR variant III	2095
EGFR-SEPT14	1163
EML4-ALK	1139
ETV6-NTRK3	1336
FGFR3-BAIAP2L1	1069
FGFR3-TACC3	1352
KIF5B-RET	2444
LMNA-NTRK1	1757
MET Exon 14 Skipping	1408
NCOA4-RET	1484
PAX8-PPARG1	1899
SLC34A2-ROS1	1869
SLC45A3-BRAF	1617
TFG-NTRK1	1004
TMPRSS2-ERG	1597
TPM3-NTRK1	1337

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NGS Result: Positive for each of the 18 fusions and exon skipping events
 NGS Fusion Test Method: Archer® FusionPlex® Solid Tumor Assay run on the Illumina® MiSeq™ instrument (300-cycle Reagent Kit v2,) at 250 ng RNA input
 NGS Analysis Method: Data analyzed using Archer Analysis Suite Software version 6.2.7 (default parameters).

NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	160	727
CD74-ROS1	177	1609
EGFR variant III	169	603
EGFR-SEPT14	289	680
EML4-ALK	181	1460
ETV6-NTRK3	374	1541
FGFR3-BAIAP2L1	136	927
FGFR3-TACC3	153	1080
KIF5B-RET	249	2389
LMNA-NTRK1	276	3779
MET Exon 14 Skipping	106	260
NCOA4-RET	143	687
PAX8-PPARG1	153	632
SLC34A2-ROS1	169	967
SLC45A3-BRAF	86	4925
TFG-NTRK1	196	1540
TMPRSS2-ERG	84	3494
TPM3-NTRK1	336	3197

*Total number of reads per sample was 4.6M.

Approval:



Prepared By

07 JUN 2023
Date



QA Verified By

09 JUN 2023
Date