

Revised 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: 10522265
 Date of Manufacture: 12-NOV-2020 Expiration Date: 20-OCT-2022

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 32 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	1720
CD74-ROS1	1880
EGFR variant III	1396
EGFR-SEPT14	1732
EML4-ALK	1936
ETV6-NTRK3	1652
FGFR3-BAIAP2L1	1704
FGFR3-TACC3	1764
KIF5B-RET	1509
LMNA-NTRK1	1448
MET Exon 14 Skipping	1520
NCOA4-RET	1608
PAX8-PPARG1	1768
SLC34A2-ROS1	2048
SLC45A3-BRAF	1856
TFG-NTRK1	1852
TMPRSS2-ERG	2348
TPM3-NTRK1	1728

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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 5.1.7 (default parameters).

NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	162	819
CD74-ROS1	149	1379
EGFR variant III	198	1719
EGFR-SEPT14	343	853
EML4-ALK	178	1921
ETV6-NTRK3	382	2866
FGFR3-BAIAP2L1	136	2843
FGFR3-TACC3	207	5378
KIF5B-RET	224	3511
LMNA-NTRK1	238	3057
MET Exon 14 Skipping	175	727
NCOA4-RET	136	724
PAX8-PPARG1	139	892
SLC34A2-ROS1	132	736
SLC45A3-BRAF	75	1766
TFG-NTRK1	169	2654
TMPRSS2-ERG	145	9366
TPM3-NTRK1	225	2967

*Total number of reads per sample was 2.7 M.

Approval:

Prepared By  Date 24 FEB 2021
 QA Verified By _____ Date 24 FEB 2021