

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: 10543159
 Date of Manufacture: 01-MAR-2021 Expiration Date: 08-JAN-2023

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 29 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	1919
CD74-ROS1	2836
EGFR variant III	2077
EGFR-SEPT14	2271
EML4-ALK	2163
ETV6-NTRK3	3115
FGFR3-BAIAP2L1	2169
FGFR3-TACC3	4047
KIF5B-RET	1773
LMNA-NTRK1	3097
MET Exon 14 Skipping	3135
NCOA4-RET	4765
PAX8-PPARG1	2435
SLC34A2-ROS1	2604
SLC45A3-BRAF	2265
TFG-NTRK1	2583
TMPRSS2-ERG	1448
TPM3-NTRK1	2141

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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	177	1308
CD74-ROS1	153	1637
EGFR variant III	162	513
EGFR-SEPT14	399	1515
EML4-ALK	213	2583
ETV6-NTRK3	468	4508
FGFR3-BAIAP2L1	238	1939
FGFR3-TACC3	232	3886
KIF5B-RET	241	3115
LMNA-NTRK1	284	7664
MET Exon 14 Skipping	267	1963
NCOA4-RET	199	2747
PAX8-PPARG1	119	885
SLC34A2-ROS1	170	1958
SLC45A3-BRAF	97	13601
TFG-NTRK1	255	4768
TMPRSS2-ERG	114	9356
TPM3-NTRK1	367	4205

*Total number of reads per sample was 2.4M.

Approval:



29 APR 2021

Prepared By

Date



29 APR 2021

QA Verified By

Date