

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: 10468277
 Date of Manufacture: 20 FEB 2020 Expiration Date: 30 DEC 2021

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 34 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	1349
CD74-ROS1	1776
EGFR variant III	1132
EGFR-SEPT14	1000
EML4-ALK	1168
ETV6-NTRK3	1469
FGFR3-BAIAP2L1	1505
FGFR3-TACC3	3547
KIF5B-RET	1576
LMNA-NTRK1	1692
MET Exon 14 Skipping	1267
NCOA4-RET	1625
PAX8-PPARG1	1955
SLC34A2-ROS1	1597
SLC45A3-BRAF	1623
TFG-NTRK1	1797
TMPRSS2-ERG	1028
TPM3-NTRK1	1073

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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	115	450
CD74-ROS1	76	387
EGFR variant III	55	131
EGFR-SEPT14	147	352
EML4-ALK	89	418
ETV6-NTRK3	241	960
FGFR3-BAIAP2L1	112	520
FGFR3-TACC3	157	1024
KIF5B-RET	162	1073
LMNA-NTRK1	160	1714
MET Exon 14 Skipping	115	305
NCOA4-RET	74	392
PAX8-PPARG1	61	221
SLC34A2-ROS1	95	478
SLC45A3-BRAF	84	4916
TFG-NTRK1	158	1298
TMPRSS2-ERG	77	3169
TPM3-NTRK1	190	1181

*Total number of reads per sample was 1.7M.

Approval:

Prepared By

Date

QA Verified By

Date



21 FEB 2020



21 FEB 2020