

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: 10498377
 Date of Manufacture: 04 JUN 2020 Expiration Date: 11 MAY 2022

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 29.5 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	1251
CD74-ROS1	1576
EGFR variant III	1009
EGFR-SEPT14	1091
EML4-ALK	1584
ETV6-NTRK3	1396
FGFR3-BAIAP2L1	1377
FGFR3-TACC3	2847
KIF5B-RET	1535
LMNA-NTRK1	1479
MET Exon 14 Skipping	1229
NCOA4-RET	1808
PAX8-PPARG1	2103
SLC34A2-ROS1	1624
SLC45A3-BRAF	1581
TFG-NTRK1	1721
TMPRSS2-ERG	1113
TPM3-NTRK1	1051

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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	123	556
CD74-ROS1	89	444
EGFR variant III	52	73
EGFR-SEPT14	139	346
EML4-ALK	108	522
ETV6-NTRK3	221	1000
FGFR3-BAIAP2L1	108	541
FGFR3-TACC3	154	1029
KIF5B-RET	115	840
LMNA-NTRK1	202	2046
MET Exon 14 Skipping	109	210
NCOA4-RET	82	395
PAX8-PPARG1	75	279
SLC34A2-ROS1	93	396
SLC45A3-BRAF	89	2905
TFG-NTRK1	171	1083
TMPRSS2-ERG	59	1995
TPM3-NTRK1	195	1101

*Total number of reads per sample was 1.2 M.

Approval:

Prepared By

Date

QA Verified By

Date

[Signature] *04 Jun 2020*
Kimberly M Wedlock *04 JUN 2020*