

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: 10375531
 Date of Manufacture: 02-JAN-2019 Expiration Date: 06-DEC-2020

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 31 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	1395
CD74-ROS1	1801
EGFR variant III	1289
EGFR-SEPT14	1224
EML4-ALK	1868
ETV6-NTRK3	1643
FGFR3-BAIAP2L1	1813
FGFR3-TACC3	3432
KIF5B-RET	1464
LMNA-NTRK1	1524
MET Exon 14 Skipping	1465
NCOA4-RET	1839
PAX8-PPARG1	2157
SLC34A2-ROS1	1725
SLC45A3-BRAF	1896
TFG-NTRK1	1925
TMPRSS2-ERG	1023
TPM3-NTRK1	1612

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: 10375531
 Date of Manufacture: 02-JAN-2019 Expiration Date: 06-DEC-2020

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	147	639
CD74-ROS1	93	320
EGFR variant III	70	143
EGFR-SEPT14	233	574
EML4-ALK	132	667
ETV6-NTRK3	193	728
FGFR3-BAIAP2L1	131	911
FGFR3-TACC3	200	1587
KIF5B-RET	167	1001
LMNA-NTRK1	202	1661
MET Exon 14 Skipping	93	166
NCOA4-RET	99	513
PAX8-PPARG1	90	366
SLC34A2-ROS1	97	410
SLC45A3-BRAF	95	2972
TFG-NTRK1	185	1182
TMPRSS2-ERG	88	2298
TPM3-NTRK1	187	862

*Total number of reads per sample was 3.86M.

Approval:

Prepared By

Date

QA Verified By

Date



1/24/2019



2/7/19