

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: 10641778
 Date of Manufacture: 24 OCT 2022 Expiration Date: 09 FEB 2024

Nominal Concentration: 25 ng / μ L Volume: 25 μ L
 Concentration test Method: Thermo Fisher Qubit RNA BR Assay
 Measured Concentration: 28.9 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	3539
CD74-ROS1	2056
EGFR variant III	2876
EGFR-SEPT14	2007
EML4-ALK	2812
ETV6-NTRK3	2280
FGFR3-BAIAP2L1	1997
FGFR3-TACC3	2973
KIF5B-RET	2919
LMNA-NTRK1	2016
MET Exon 14 Skipping	1725
NCOA4-RET	2025
PAX8-PPARG1	1940
SLC34A2-ROS1	2121
SLC45A3-BRAF	1941
TFG-NTRK1	2219
TMPRSS2-ERG	2401
TPM3-NTRK1	1195

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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	202	1857
CD74-ROS1	170	1400
EGFR variant III	170	773
EGFR-SEPT14	441	1601
EML4-ALK	267	3891
ETV6-NTRK3	467	2990
FGFR3-BAIAP2L1	184	2036
FGFR3-TACC3	229	3003
KIF5B-RET	264	3528
LMNA-NTRK1	277	4336
MET Exon 14 Skipping	203	678
NCOA4-RET	185	1341
PAX8-PPARG1	173	1111
SLC34A2-ROS1	199	1539
SLC45A3-BRAF	93	9907
TFG-NTRK1	235	2532
TMPRSS2-ERG	113	7699
TPM3-NTRK1	321	2644

*Total number of reads per sample was 3.5M.

Approval:



24 OCT 2022

Prepared By

Date



26 OCT 2022

QA Verified By

Date