

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description:

Product	Material Number	Batch Number
Seraseq® Fusion RNA Mix v4	0710-0497	10774198
Kit Component		
Vial	0710-0922	10774197

Date of Manufacture: 28 AUG 2025 Expiration Date: 17 JUN 2029
 Nominal Concentration: 25 ng/μL Volume: 25 μL
 Concentration Test Method: Thermo Fisher Qubit RNA BR Assay
 Average Concentration (ng/μL): 29.9 ng/μL
 Nominal Fusion Concentration: 1500 Fusion copies/μL
 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/μL
CCDC6-RET	2322
CD74-ROS1	2418
EGFR variant III	2938
EGFR-SEPT14	2388
EML4-ALK	1594
ETV6-NTRK3	3631
FGFR3-BAIAP2L1	1883
FGFR3-TACC3	2599
KIF5B-RET	1005
LMNA-NTRK1	2422
MET Exon 14 Skipping	2836
NCOA4-RET	2229
PAX8-PPARG1	3200
SLC34A2-ROS1	3131
SLC45A3-BRAF	3075
TFG-NTRK1	2566
TPRSS2-ERG	2100
TPM3-NTRK1	2392

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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 6.2.2 (default parameters).
 NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	194	1828
CD74-ROS1	190	2273
EGFR variant III	158	653
EGFR-SEPT14	418	1498
EML4-ALK	191	2696
ETV6-NTRK3	549	6979
FGFR3-BAIAP2L1	188	2826
FGFR3-TACC3	216	3335
KIF5B-RET	228	2522
LMNA-NTRK1	269	5068
MET Exon 14 Skipping	271	1932
NCOA4-RET	158	1460
PAX8-PPARG1	172	1511
SLC34A2-ROS1	202	2496
SLC45A3-BRAF	96	14095
TFG-NTRK1	217	3067
TMPRSS2-ERG	100	6560
TPM3-NTRK1	394	5727

*Total number of reads per sample was 15.3M.

Approval:

Prepared By DP Date 09 SEPT 2025
 QA Verified By ES Date 10 SEP 2025