

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	10712112
Kit Component		
Vial	0710-0922	10712113

Date of Manufacture: 06-AUG-2024 Expiration Date: 12-OCT-2025
 Nominal Concentration: 25 ng/μL Volume: 25 μL
 Concentration Test Method: Thermo Fisher Qubit RNA BR Assay
 Average Concentration (ng/μL): 31.0 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	1172
CD74-ROS1	1529
EGFR variant III	2055
EGFR-SEPT14	1547
EML4-ALK	1615
ETV6-NTRK3	2068
FGFR3-BAIAP2L1	1957
FGFR3-TACC3	2375
KIF5B-RET	4240
LMNA-NTRK1	1871
MET Exon 14 Skipping	1209
NCOA4-RET	1756
PAX8-PPARG1	2791
SLC34A2-ROS1	2341
SLC45A3-BRAF	2100
TFG-NTRK1	2071
TMPRSS2-ERG	2489
TPM3-NTRK1	2099

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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 6.2.7 (default parameters).

NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	152	813
CD74-ROS1	134	804
EGFR variant III	169	581
EGFR-SEPT14	323	983
EML4-ALK	162	1342
ETV6-NTRK3	408	2653
FGFR3-BAIAP2L1	141	1128
FGFR3-TACC3	151	1339
KIF5B-RET	276	5894
LMNA-NTRK1	275	4461
MET Exon 14 Skipping	127	371
NCOA4-RET	123	631
PAX8-PPARG1	185	1298
SLC34A2-ROS1	143	1060
SLC45A3-BRAF	98	9679
TFG-NTRK1	185	2109
TMPRSS2-ERG	132	9120
TPM3-NTRK1	381	6341

*Total number of reads per sample was 12.6M.

Approval:



07 AUG 2024

Prepared By

Date



08 Aug 2024

QA Verified By

Date