

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	10743940
Kit Component		
Vial	0710-0922	10742357

Date of Manufacture: 04-APR-2025 Expiration Date: 09-JAN-2029
 Nominal Concentration: 25 ng/μL Volume: 25 μL
 Concentration Test Method: Thermo Fisher Qubit RNA BR Assay
 Average Concentration (ng/μL): 32.1 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	1108
CD74-ROS1	1449
EGFR variant III	1511
EGFR-SEPT14	1189
EML4-ALK	1001
ETV6-NTRK3	1740
FGFR3-BAIAP2L1	1025
FGFR3-TACC3	2369
KIF5B-RET	1361
LMNA-NTRK1	1433
MET Exon 14 Skipping	1224
NCOA4-RET	1231
PAX8-PPARG1	1268
SLC34A2-ROS1	1576
SLC45A3-BRAF	1491
TFG-NTRK1	1261
TPRSS2-ERG	1135
TPM3-NTRK1	1005

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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	178	828
CD74-ROS1	174	1262
EGFR variant III	175	725
EGFR-SEPT14	291	839
EML4-ALK	171	1121
ETV6-NTRK3	394	1824
FGFR3-BAIAP2L1	130	1190
FGFR3-TACC3	148	1292
KIF5B-RET	215	1362
LMNA-NTRK1	274	3985
MET Exon 14 Skipping	30	33
NCOA4-RET	139	514
PAX8-PPARG1	151	513
SLC34A2-ROS1	166	999
SLC45A3-BRAF	77	4920
TFG-NTRK1	200	1791
TPRSS2-ERG	75	1867
TPM3-NTRK1	344	3352

*Total number of reads per sample was 3.5 M.

Approval:


 Prepared By

04/08/2015
 Date


 QA Verified By

04 Apr 2015
 Date