

Revised 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	10683731
Kit Component		
Vial	0710-0922	10683730

Date of Manufacture: 29 MAR 2023 Expiration Date: 29 MAR 2027

Nominal Concentration: 25 ng/μL Volume: 25 μL

Concentration Test Method: Thermo Fisher Qubit RNA BR Assay

Average Concentration (ng/μL): 30.2 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	1080
CD74-ROS1	1953
EGFR variant III	2095
EGFR-SEPT14	1163
EML4-ALK	1139
ETV6-NTRK3	1336
FGFR3-BAIAP2L1	1069
FGFR3-TACC3	1352
KIF5B-RET	2444
LMNA-NTRK1	1757
MET Exon 14 Skipping	1408
NCOA4-RET	1484
PAX8-PPARG1	1899
SLC34A2-ROS1	1869
SLC45A3-BRAF	1617
TFG-NTRK1	1004
TMPRSS2-ERG	1597
TPM3-NTRK1	1337

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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	134	490
CD74-ROS1	154	1222
EGFR variant III	136	421
EGFR-SEPT14	280	628
EML4-ALK	177	1279
ETV6-NTRK3	346	1311
FGFR3-BAIAP2L1	129	874
FGFR3-TACC3	144	944
KIF5B-RET	238	2099
LMNA-NTRK1	257	2854
MET Exon 14 Skipping	139	345
NCOA4-RET	122	494
PAX8-PPARG1	144	616
SLC34A2-ROS1	155	883
SLC45A3-BRAF	81	4733
TFG-NTRK1	163	1296
TMPRSS2-ERG	91	2965
TPM3-NTRK1	305	2691

*Total number of reads per sample was 5M.

Approval:



15-JAN-2025

Prepared By

Date



QA Verified By

16 Jan 2025

Date