

Certificate of Analysis (Revised)

For Research Use Only, Not for use in Diagnostic Procedures

Product Description: Seraseq® FFPE Fusion RNA Reference Material v4
 Material No: 0710-0496 Batch No: 10430470
 Date of Manufacture: 03-JUL-2019 Expiration Date: 13-JUN-2021

Vial Contents: 1x 10 µm FFPE curl
 Concentration test Method: Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation
 Average RNA Yield: 805.4 ng
 Fusion Test Method: Droplet Digital PCR using TaqMan™ probes tested on the BioRad QX200 system.

Measured Fusion Concentrations:

RNA Fusion	Digital PCR Average Fusion copies/ng of total RNA
CCDC6-RET	136.0
CD74-ROS1	407.3
EGFR variant III	306.3
EGFR-SEPT14	127.0
EML4-ALK	130.0
ETV6-NTRK3	281.0
FGFR3-BAIAP2L1	114.3
FGFR3-TACC3	148.0
KIF5B-RET	104.3
LMNA-NTRK1	216.3
MET Exon 14 Skipping	289.3
NCOA4-RET	182.7
PAX8-PPARG1	186.3
SLC34A2-ROS1	363.0
SLC45A3-BRAF	210.0
TFG-NTRK1	259.0
TMPRSS2-ERG	414.0
TPM3-NTRK1	127.7

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NGS Result: Positive for all 18 fusions and exon skipping events
 NGS Fusion Test Method: Archer® FusionPlex® Solid Tumor Assay tested on the ILMN MiSeq™ instrument (v2, 2 x 150 bp PE kit) using 250 ng of input RNA
 NGS Analysis Method: Data analyzed using Archer Analysis Suite Software version (default settings)

NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	74	127
CD74-ROS1	32	61
EGFR variant III	116	226
EGFR-SEPT14	286	763
EML4-ALK	53	146
ETV6-NTRK3	109	380
FGFR3-BAIAP2L1	97	908
FGFR3-TACC3	188	2340
KIF5B-RET	86	233
LMNA-NTRK1	87	248
MET Exon 14 Skipping	99	236
NCOA4-RET	44	110
PAX8-PPARG1	82	292
SLC34A2-ROS1	25	45
SLC45A3-BRAF	77	969
TFG-NTRK1	33	61
TMPRSS2-ERG	100	1469
TPM3-NTRK1	64	122

*Total number of reads per sample was 2.81 M.

Approval:

Prepared By  Date 22 April 2020
 QA Verified By _____ Date _____