

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: 10430469
 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: 1464.0 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	133.3
CD74-ROS1	384.7
EGFR variant III	292.7
EGFR-SEPT14	125.3
EML4-ALK	123.7
ETV6-NTRK3	262.7
FGFR3-BAIAP2L1	121.3
FGFR3-TACC3	131.7
KIF5B-RET	99.0
LMNA-NTRK1	208.0
MET Exon 14 Skipping	282.0
NCOA4-RET	175.0
PAX8-PPARG1	174.7
SLC34A2-ROS1	351.0
SLC45A3-BRAF	194.3
TFG-NTRK1	251.7
TMPRSS2-ERG	322.3
TPM3-NTRK1	118.3

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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	67	112
CD74-ROS1	34	94
EGFR variant III	106	195
EGFR-SEPT14	278	675
EML4-ALK	45	110
ETV6-NTRK3	149	494
FGFR3-BAIAP2L1	95	850
FGFR3-TACC3	169	1962
KIF5B-RET	72	167
LMNA-NTRK1	75	227
MET Exon 14 Skipping	94	177
NCOA4-RET	42	102
PAX8-PPARG1	75	250
SLC34A2-ROS1	26	45
SLC45A3-BRAF	65	752
TFG-NTRK1	30	70
TMPRSS2-ERG	90	1265
TPM3-NTRK1	58	101

*Total number of reads per sample was 2.63 M.

Approval:

Prepared By:  Date: 22 April 2020
 QA Verified By:  Date: 22 APR 2020