

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: 10456409
 Date of Manufacture: 03-DEC-2019 Expiration Date: 06-NOV-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: 1475.2 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	121	417
CD74-ROS1	103	452
EGFR variant III	132	512
EGFR-SEPT14	207	401
EML4-ALK	139	1047
ETV6-NTRK3	216	1303
FGFR3-BAIAP2L1	107	1350
FGFR3-TACC3	128	2278
KIF5B-RET	196	2812
LMNA-NTRK1	194	1466
MET Exon 14 Skipping	101	300
NCOA4-RET	96	397
PAX8-PPARG1	105	505
SLC34A2-ROS1	93	287
SLC45A3-BRAF	56	469
TFG-NTRK1	132	985
TMPRSS2-ERG	88	3145
TPM3-NTRK1	175	1117

*Total number of reads per sample was 1.6 M.

Approval:

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