

Certificate of Analysis

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: 10496536
 Date of Manufacture: 21 MAY 2020 Expiration Date: 11 MAY 2022

Vial Contents: 1x 10 µm FFPE curl
 Concentration test Method: Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation
 Average RNA Yield: 833.6 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	73.1
CD74-ROS1	312.2
EGFR variant III	246.9
EGFR-SEPT14	96.2
EML4-ALK	108.5
ETV6-NTRK3	236.7
FGFR3-BAIAP2L1	87.9
FGFR3-TACC3	239.1
KIF5B-RET	71.6
LMNA-NTRK1	211.7
MET Exon 14 Skipping	196.0
NCOA4-RET	132.0
PAX8-PPARG1	153.8
SLC34A2-ROS1	268.1
SLC45A3-BRAF	166.5
TFG-NTRK1	184.5
TMPRSS2-ERG	290.7
TPM3-NTRK1	149.9

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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 Illumina 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	140	573
CD74-ROS1	95	407
EGFR variant III	185	875
EGFR-SEPT14	199	417
EML4-ALK	174	2112
ETV6-NTRK3	223	1309
FGFR3-BAIAP2L1	113	2001
FGFR3-TACC3	164	3251
KIF5B-RET	205	3787
LMNA-NTRK1	229	2066
MET Exon 14 Skipping	45	71
NCOA4-RET	102	450
PAX8-PPARG1	147	1030
SLC34A2-ROS1	89	271
SLC45A3-BRAF	68	869
TFG-NTRK1	132	904
TMPRSS2-ERG	80	3050
TPM3-NTRK1	198	1274

*Total number of reads per sample was 3.4 million.

Approval:

Prepared By  Date *26 May 2020*

QA Verified By  Date *26 MAY 2020*