

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: 10456407
 Date of Manufacture: 02-DEC-2019 Expiration Date: 05-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: 1179.2 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	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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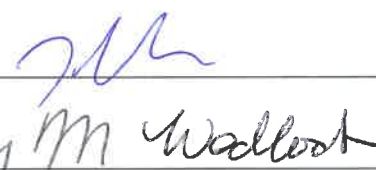
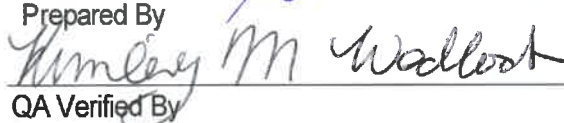
NGS Result: Positive for all 18 fusions and exon skipping events
 NGS Fusion Test Method: Archer® FusionPlex® Solid Tumor Assay tested on the ILMN MiSeq™ instrument (v2, 2 x 150 bp PE kit) using 250 ng of input RNA
 NGS Analysis Method: Data analyzed using Archer Analysis Suite Software version (default settings)

NGS Data:

RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
CCDC6-RET	115	406
CD74-ROS1	108	529
EGFR variant III	148	676
EGFR-SEPT14	233	449
EML4-ALK	138	1112
ETV6-NTRK3	234	1557
FGFR3-BAIAP2L1	106	1558
FGFR3-TACC3	158	2198
KIF5B-RET	217	3132
LMNA-NTRK1	194	1799
MET Exon 14 Skipping	116	340
NCOA4-RET	104	405
PAX8-PPARG1	114	616
SLC34A2-ROS1	96	301
SLC45A3-BRAF	63	651
TFG-NTRK1	136	1077
TMPRSS2-ERG	86	3665
TPM3-NTRK1	188	1215

*Total number of reads per sample was 1.6 M.

Approval:

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