

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product	Material Number	Batch Number
Seraseq® FFPE Fusion RNA Reference Material v4	0710-0496	10690782
Kit Component		
Vial	0710-1275	10690781

Date of Manufacture: 08-APR-2024 Expiration Date: 06-MAR-2026

Vial Contents:	1x 10 µm FFPE curl	
Concentration test Method:	Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation	
Average RNA Yield:	1267 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	109.3
	CD74-ROS1	280.0
	EGFR variant III	296.0
	EGFR-SEPT14	123.0
	EML4-ALK	133.0
	ETV6-NTRK3	230.3
	FGFR3-BAIAP2L1	102.0
	FGFR3-TACC3	78.3
	KIF5B-RET	86.0
	LMNA-NTRK1	147.3
	MET Exon 14 Skipping	246.3
	NCOA4-RET	148.7
	PAX8-PPARG1	161.7
	SLC34A2-ROS1	318.0
	SLC45A3-BRAF	163.7
	TFG-NTRK1	209.0
	TMPRSS2-ERG	313.7
	TPM3-NTRK1	128.0

NGS Result:	Positive for all 18 fusions and exon skipping events
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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 6.2.2 (default settings)		
NGS Data:	RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
	CCDC6-RET	106	457
	CD74-ROS1	44	254
	EGFR variant III	130	842
	EGFR-SEPT14	202	353
	EML4-ALK	86	665
	ETV6-NTRK3	139	855
	FGFR3-BAIAP2L1	76	1051
	FGFR3-TACC3	98	1707
	KIF5B-RET	85	539
	LMNA-NTRK1	128	1069
	MET Exon 14 Skipping	62	154
	NCOA4-RET	79	397
	PAX8-PPARG1	67	307
	SLC34A2-ROS1	22	115
	SLC45A3-BRAF	58	514
	TFG-NTRK1	70	549
TMPRSS2-ERG	124	4970	
TPM3-NTRK1	65	679	

*Total number of reads per sample was 860.

Approval:

MHA

11-APR-2024

Prepared By

Date

E. Sarker

12 APR 2024

QA Verified By

Date