

Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description:	Product	Material Number	Batch Number
	Seraseq® FFPE Fusion RNA Reference Material v4	0710-0496	10705099
	Kit Component		
	Vial	0710-1275	10705100

Date of Manufacture: 19-JUL-2024 Expiration Date: 14-JUN-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:	1189.6 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	100
	CD74-ROS1	262
	EGFR variant III	302
	EGFR-SEPT14	114
	EML4-ALK	123
	ETV6-NTRK3	222
	FGFR3-BAIAP2L1	92
	FGFR3-TACC3	69
	KIF5B-RET	80
	LMNA-NTRK1	137
	MET Exon 14 Skipping	223
	NCOA4-RET	138
	PAX8-PPARG1	154
	SLC34A2-ROS1	295
	SLC45A3-BRAF	160
	TFG-NTRK1	192
	TMPRSS2-ERG	302
	TPM3-NTRK1	130

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 6.2.7 (default settings)		
NGS Data:	RNA Fusion	NGS Average Unique Start Sites per Fusion	NGS Average Unique Reads per Fusion*
	CCDC6-RET	99	329
	CD74-ROS1	38	157
	EGFR variant III	133	840
	EGFR-SEPT14	151	265
	EML4-ALK	87	694
	ETV6-NTRK3	134	730
	FGFR3-BAIAP2L1	64	1329
	FGFR3-TACC3	98	1748
	KIF5B-RET	87	561
	LMNA-NTRK1	131	1092
	MET Exon 14 Skipping	49	111
	NCOA4-RET	63	247
	PAX8-PPARG1	77	332
	SLC34A2-ROS1	24	101
	SLC45A3-BRAF	57	375
	TFG-NTRK1	55	495
TMPRSS2-ERG	110	4868	
TPM3-NTRK1	69	585	

*Total number of reads per sample was 826.

Approval:

MAI

Prepared By

22 JUL 2024

Date

AD

QA Verified By

23 Jul 2024

Date