

# Certificate of Analysis

For Research Use Only, Not for use in Diagnostic Procedures

Product Description:	<b>Product</b>	<b>Material Number</b>	<b>Batch Number</b>
	Seraseq® FFPE Fusion RNA Reference Material v4	0710-0496	10682596
	<b>Kit Component</b>		
	Vial	0710-1275	10680594

Date of Manufacture: 21 SEP 2023      Expiration Date: 11 AUG 2025

Vial Contents:	1x 10 µm FFPE curl	
Concentration test Method:	Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation	
Average RNA Yield:	940.2 ng	
Fusion Test Method:	Droplet Digital PCR using TaqMan™ probes tested on the BioRad QX200 system.	
Measured Fusion Concentrations:	<b>RNA Fusion</b>	<b>Digital PCR Average Fusion copies/ng of total RNA</b>
	CCDC6-RET	67.2
	CD74-ROS1	207.3
	EGFR variant III	273.9
	EGFR-SEPT14	68.0
	EML4-ALK	65.5
	ETV6-NTRK3	157.4
	FGFR3-BAIAP2L1	81.9
	FGFR3-TACC3	58.9
	KIF5B-RET	67.1
	LMNA-NTRK1	185.2
	MET Exon 14 Skipping	165.7
	NCOA4-RET	121.1
	PAX8-PPARG1	112.0
	SLC34A2-ROS1	218.0
	SLC45A3-BRAF	146.0
	TFG-NTRK1	122.2
	TMPRSS2-ERG	293.5
	TPM3-NTRK1	100.3

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 (default settings)		
NGS Data:	<b>RNA Fusion</b>	<b>NGS Average Unique Start Sites per Fusion</b>	<b>NGS Average Unique Reads per Fusion*</b>
	CCDC6-RET	53	107
	CD74-ROS1	21	86
	EGFR variant III	94	410
	EGFR-SEPT14	74	118
	EML4-ALK	51	190
	ETV6-NTRK3	85	303
	FGFR3-BAIAP2L1	56	914
	FGFR3-TACC3	81	880
	KIF5B-RET	70	398
	LMNA-NTRK1	87	535
	MET Exon 14 Skipping	20	26
	NCOA4-RET	51	141
	PAX8-PPARG1	45	133
	SLC34A2-ROS1	10	29
	SLC45A3-BRAF	41	200
	TFG-NTRK1	38	258
TMPRSS2-ERG	91	2557	
TPM3-NTRK1	47	425	

\*Total number of reads per sample was 3.3M.

**Approval:**

*MH-1*

Prepared By

10 OCT 2023

Date

*[Signature]*

QA Verified By

*11 oct 2023*

Date