

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	10758152
Kit Component		
Vial	0710-1275	10758151

Date of Manufacture:

30-MAY-2025

Expiration Date:

09-MAY-2029

Vial Contents:	1x 10 µm FFPE curl																																						
Concentration test Method:	Agencourt Formapure RNA extraction followed by Qubit RNA HS Assay Quantitation																																						
Average RNA Yield:	1272.3 ng																																						
Fusion Test Method:	Droplet Digital PCR using TaqMan™ probes tested on the BioRad QX200 system.																																						
Measured Fusion Concentrations:	<table> <tr> <th>RNA Fusion</th><th>Digital PCR Average Fusion copies/ng of total RNA</th></tr> <tr><td>CCDC6-RET</td><td>151.8</td></tr> <tr><td>CD74-ROS1</td><td>589.7</td></tr> <tr><td>EGFR variant III</td><td>405.2</td></tr> <tr><td>EGFR-SEPT14</td><td>170.0</td></tr> <tr><td>EML4-ALK</td><td>154.6</td></tr> <tr><td>ETV6-NTRK3</td><td>331.5</td></tr> <tr><td>FGFR3-BAIAP2L1</td><td>202.5</td></tr> <tr><td>FGFR3-TACC3</td><td>203.4</td></tr> <tr><td>KIF5B-RET</td><td>148.2</td></tr> <tr><td>LMNA-NTRK1</td><td>351.5</td></tr> <tr><td>MET Exon 14 Skipping</td><td>306.9</td></tr> <tr><td>NCOA4-RET</td><td>247.1</td></tr> <tr><td>PAX8-PPARG1</td><td>225.3</td></tr> <tr><td>SLC34A2-ROS1</td><td>589.3</td></tr> <tr><td>SLC45A3-BRAF</td><td>305.7</td></tr> <tr><td>TFG-NTRK1</td><td>379.1</td></tr> <tr><td>TPRSS2-ERG</td><td>464.9</td></tr> <tr><td>TPM3-NTRK1</td><td>212.2</td></tr> </table>	RNA Fusion	Digital PCR Average Fusion copies/ng of total RNA	CCDC6-RET	151.8	CD74-ROS1	589.7	EGFR variant III	405.2	EGFR-SEPT14	170.0	EML4-ALK	154.6	ETV6-NTRK3	331.5	FGFR3-BAIAP2L1	202.5	FGFR3-TACC3	203.4	KIF5B-RET	148.2	LMNA-NTRK1	351.5	MET Exon 14 Skipping	306.9	NCOA4-RET	247.1	PAX8-PPARG1	225.3	SLC34A2-ROS1	589.3	SLC45A3-BRAF	305.7	TFG-NTRK1	379.1	TPRSS2-ERG	464.9	TPM3-NTRK1	212.2
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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	237	2760
	CD74-ROS1	222	5761
	EGFR variant III	247	3953
	EGFR-SEPT14	563	2248
	EML4-ALK	217	4019
	ETV6-NTRK3	487	6192
	FGFR3-BAIAP2L1	200	8812
	FGFR3-TACC3	250	12946
	KIF5B-RET	257	5928
	LMNA-NTRK1	294	7775
	MET Exon 14 Skipping	279	1773
	NCOA4-RET	204	2521
	PAX8-PPARG1	220	2573
	SLC34A2-ROS1	230	3744
	SLC45A3-BRAF	83	4707
	TFG-NTRK1	224	5176
	TMPRSS2-ERG	224	16265
	TPM3-NTRK1	357	7763

*Total number of reads per sample was 2.2M.

Approval:

 Prepared By	06/20/2025 Date
 QA Verified By	25 JUN 2025 Date