

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® ctDNA MRD 0.5% Tumor Mix		
Material Number:	0710-3671	Batch Number:	10754534
Material Description:	SeraSeq ctDNA MRD Panel 0.5% Tumor is derived from a mixture of tumor-normal cell line gDNA background combined with 22 additional DNA biosynthetic variants, fragmented and size selected, and blended at a 0.5% tumor fraction.		
Fill Volume:	20 µL per vial		
Date of Manufacture:	18 APR 2025	Expiration Date:	18 APR 2029
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 18.2 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	228 bp		
Acceptance criteria for average fragment size:	150-230 bp		
NGS Assay Test Method:	<p>Tumor and biosynthetic variants were analyzed on a custom ctDNA MRD target enrichment panel with Agilent SureSelect® XT HS2 chemistry, utilizing a 50 ng input.</p> <p>The sequencing was performed on the NextSeq® 2000 with a P2 flow cell. Variants with fewer than 3 observations were filtered.</p> <p>VCF available upon request.</p>		
Average VAF* of biosynthetic variants (%):	0.246		
Average VAF of tumor variants (%):	0.283		
Average VAF range for tumor variants (%):	0.05-0.50		

*Biosynthetic variant VAF for information only.

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Measured VAF(%)^{*} of biosynthetic variants:

Gene	COSMIC ID	Amino acid change	Seraseq ctDNA MRD 0.5% Tumor
AKT1	COSM33765	p.E17K	0.271
ALK	COSM144250	p.G1202R	0.120
ALK	COSM28055	p.F1174L	0.122
BRAF	COSM476	p.V600E	0.000
BRCA1	COSM1383519	p.K654fs*47	0.057
BRCA2	COSM1738242	p.R2645fs*3	0.190
CD74-ROS1	N/A	Translocation	0.833
EGFR	COSM12370	p.L747_P753>S	0.302
EGFR	COSM6223	p.E746_A750delELREA	0.194
EGFR	COSM6224	p.L858R	0.194
EGFR	COSM6240	p.T790M	0.290
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.361
EML4-ALK	N/A	Translocation	0.221
ERBB2	COSM20959	p.A775_G776insYVMA	0.235
KIT	COSM1314	p.D816V	0.350
KRAS	COSM516	p.G12C	0.237
KRAS	COSM521	p.G12D	0.308
KRAS	COSM554	p.Q61H	0.150
NCOA4/RET	N/A	Translocation	0.386
NRAS	COSM584	p.Q61R	0.000
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.346
PIK3CA	COSM775	p.H1047R	0.242

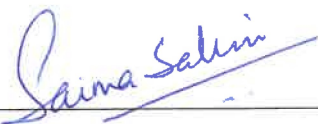
¹As of June 2019, this mutation is no longer listed in the COSMIC database.

^{*}Biosynthetic variant VAF for information only.

NA = not applicable. Variants not a part of panel used for testing.

ND = not detected.

Approval:



19-MAY-2025

Prepared By

Date