

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® ctDNA MRD 0% Tumor Mix		
Material Number:	0710-3670	Batch Number:	10754533
Material Description:	SeraSeq ctDNA MRD Panel 0% Tumor is derived a normal cell line gDNA background associated with a tumor cell line used in other SeraSeq MRD products.		
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: 14.2 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	205 bp		
Acceptance criteria for average fragment size:	150-230 bp		
NGS Assay Test Method:	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. The sequencing was performed on the NextSeq® 2000 with a P2 flow cell. Variants with fewer than 3 observations were filtered. VCF available upon request.		
Average VAF* of biosynthetic variants (%):	0.000%		
Average VAF of tumor variants (%):	0.000%		
Average VAF range for tumor variants (%):	<0.0004		

*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% Tumor
AKT1	COSM33765	p.E17K	0.000
ALK	COSM144250	p.G1202R	0.000
ALK	COSM28055	p.F1174L	0.000
BRAF	COSM476	p.V600E	0.000
BRCA1	COSM1383519	p.K654fs*47	0.000
BRCA2	COSM1738242	p.R2645fs*3	0.000
CD74-ROS1	N/A	Translocation	0.000
EGFR	COSM12370	p.L747_P753>S	0.000
EGFR	COSM6223	p.E746_A750delELREA	0.000
EGFR	COSM6224	p.L858R	0.000
EGFR	COSM6240	p.T790M	0.000
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.000
EML4-ALK	N/A	Translocation	0.000
ERBB2	COSM20959	p.A775_G776insYVMA	0.000
KIT	COSM1314	p.D816V	0.000
KRAS	COSM516	p.G12C	0.000
KRAS	COSM521	p.G12D	0.000
KRAS	COSM554	p.Q61H	0.000
NCOA4/RET	N/A	Translocation	0.000
NRAS	COSM584	p.Q61R	0.000
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.000
PIK3CA	COSM775	p.H1047R	0.000

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:

Saima Salun

19-MAY-2025

Prepared By

Date