

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA MRD Panel Mix		
Material Number:	0710-2146	Batch Number:	10780684
Material Description:	Seraseq ctDNA MRD Panel Mix 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 four tumor fractions: 0%, 0.5%, 0.05% and 0.005%.		
Fill Volume:	20 µL per vial		
Date of Manufacture:	29 SEP 2025	Expiration Date:	29 SEP 2029
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 17.8 ng/µL		
Average fragment size	0%- 172 bp		
(Agilent Bioanalyzer High	0.5% -196 bp		
Sensitivity DNA Analysis):	0.05% -195 bp		
	0.005% -195 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. Sequencing was performed on the NextSeq® 2000 with P2 flow cell. Variants with fewer than 3 observations were filtered. VCF available upon request.		

Kit component	Measured concentration (ng/µL)	Average VAF of biosynthetic* variants (%)	Average VAF of tumor variants (%)	Average VAF range for tumor variants (%)
Seraseq ctDNA MRD 0% Tumor	14.2	0.000	0.000	<0.0004
Seraseq ctDNA MRD 0.5% Tumor	17.3	0.199	0.248	0.05-0.50
Seraseq ctDNA MRD 0.05% Tumor	20.0	0.016	0.020	0.005-0.050
Seraseq ctDNA MRD 0.005% Tumor	19.6	0.002	0.001	0.0005-0.0050

*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	Seraseq ctDNA MRD 0.5% Tumor
AKT1	COSM33765	p.E17K	0.000	0.330
ALK	COSM144250	p.G1202R	0.000	0.087
ALK	COSM28055	p.F1174L	0.000	0.155
BRAF	COSM476	p.V600E	0.000	0.213
BRCA1	COSM1383519	p.K654fs*47	0.000	0.138
BRCA2	COSM1738242	p.R2645fs*3	0.000	0.215
CD74-ROS1	N/A	Translocation	0.000	0.508
EGFR	COSM12370	p.L747_P753>S	0.000	0.402
EGFR	COSM6223	p.E746_A750delELREA	0.000	0.322
EGFR	COSM6224	p.L858R	0.000	0.173
EGFR	COSM6240	p.T790M	0.000	0.331
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.000	0.161
EML4-ALK	N/A	Translocation	0.000	0.138
ERBB2	COSM20959	p.A775_G776insYVMA	0.000	0.106
KIT	COSM1314	p.D816V	0.000	0.125
KRAS	COSM516	p.G12C	0.000	0.139
KRAS	COSM521	p.G12D	0.000	0.140
KRAS	COSM554	p.Q61H	0.000	0.199
NCOA4/RET	N/A	Translocation	0.000	0.158
NRAS	COSM584	p.Q61R	0.000	0.086
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.000	0.155
PIK3CA	COSM775	p.H1047R	0.000	0.106

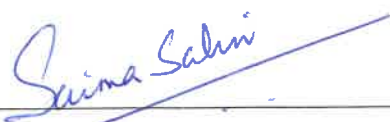
¹As of June 2019, this mutation is no longer listed in the COSMIC database.

^{*}Biosynthetic variant VAF for information only.

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

ND = not detected.

Approval:



8 October 2025

Prepared By

Date