

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:** 10694958

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: 07-FEB-2025 **Expiration Date:** 07-FEB-2029

Concentration: Nominal value: 10 ng/µL
(Qubit dsDNA BR Assay): Average measured value: 15.2 ng/µL

Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):
0%- 207 bp
0.5% -228 bp
0.05% -216 bp
0.005% -220 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 a 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	14.1	0.000	0.000	<0.0004
Seraseq ctDNA MRD 0.5% Tumor	17.9	0.246	0.283	0.05-0.50
Seraseq ctDNA MRD 0.05% Tumor	15.2	0.014	0.033	0.005-0.050
Seraseq ctDNA MRD 0.005% Tumor	13.7	0.003	0.004	0.0005-0.0050

*Biosynthetic variant VAF for information only.

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA MRD Panel Mix

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



02/17/2025

Prepared By

Date