



# 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:	10693495
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:	12 MAR 2024	Expiration Date:	15 MAR 2025
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 19.8 ng/µL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	193bp		
Acceptance criteria for average fragment size:	150-220 bp		
NGS Assay Test Method:	<p>Tumor cell line variants were analyzed using 50 ng of input in a custom SureSelect® XT HS2 panel that targets 100 somatic variants previously identified in the cell line. The ctDNA libraries for each tumor blend were sequenced on the NextSeq® 2500 with fewer than 6 observations for error correction were filtered.</p> <p>Biosynthetic variants were analyzed using 50 ng of input in the ArcherDX LiquidPlex ctDNA 28 panel. The libraries were sequenced on the NextSeq® 2500 with fewer than 4 observations for error correction. Archer Analysis v6.2.2 was used with error correction.</p> <p>VCF available upon request.</p>		

Kit component	Measured concentration (ng/µL)	Number of tumor variants with at least 1 copy observed	Total number of observed tumor variant copies	Average VAF (%) with "not observed" set to zero
SeraSeq ctDNA MRD 0% Tumor	16.9	1	1	0.0002
SeraSeq ctDNA MRD 0.5% Tumor	20.7	98	1071	0.2205
SeraSeq ctDNA MRD 0.05% Tumor	19.7	59	94	0.0188
SeraSeq ctDNA MRD 0.005% Tumor	22.0	10	11	0.0024

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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	0.00	0.35
ALK	COSM144250	p.G1202R	0.00	0.34
ALK	COSM28055	p.F1174L	0.00	0.59
BRAF	COSM476	p.V600E	0.00	0.42
BRCA1	COSM1383519	p.K654fs*47	NA	NA
BRCA2	COSM1738242	p.R2645fs*3	NA	NA
CD74-ROS1	N/A	Translocation	NA	NA
EGFR	COSM12370	p.L747_P753>S	0.00	0.51
EGFR	COSM6223	p.E746_A750delELREA	0.00	0.35
EGFR	COSM6224	p.L858R	0.00	0.24
EGFR	COSM6240	p.T790M	0.00	0.37
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.00	0.23
EML4-ALK	N/A	Translocation	NA	NA
ERBB2	COSM20959	p.A775_G776insYVMA	0.00	0.16
KIT	COSM1314	p.D816V	0.00	0.38
KRAS	COSM516	p.G12C	0.00	0.29
KRAS	COSM521	p.G12D	0.00	0.32
KRAS	COSM554	p.Q61H	0.00	0.51
NCOA4/RET	N/A	Translocation	NA	NA
NRAS	COSM584	p.Q61R	0.00	0.40
PIK3CA	COSM12464 <sup>1</sup>	p.N1068fs*4	0.00	0.58
PIK3CA	COSM775	p.H1047R	0.00	0.51

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

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

ND = not detected.

Approval:



14 MAR 2024

Prepared By

Date