

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: 10559787

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 to ~155-175 bp, and blended at four tumor fractions: 0%, 0.5%, 0.05% and 0.005%.

Fill Volume: 20 µL per vial

Date of Manufacture: 03 JUN 2021 Expiration Date: 20 MAY 2023

Concentration Test Method: Qubit ds DNA BR Assay

Nominal Concentration: 10 ng/µL per vial

NGS Assay Test Method: 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.

Biosynthetic variants were analyzed using 50 ng of input in the ArcherDX LiquidPlex ctDNA 28 panel. The libraries were sequenced on an Illumina MiSeq® with fewer than 4 observations for error correction. Archer Analysis v6.2.2 was used with error correction.

VCF available upon request.

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	11.4	1	1	0.000%
Seraseq ctDNA MRD 0.5% Tumor	14.6	83	206	0.135%
Seraseq ctDNA MRD 0.05% Tumor	13.1	20	22	0.011%
Seraseq ctDNA MRD 0.005% Tumor	13.1	4	4	0.001%

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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	0.27
ALK	COSM144250	p.G1202R	0.00	0.39
ALK	COSM28055	p.F1174L	0.00	0.62
BRAF	COSM476	p.V600E	0.00	0.54
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	0.36
EGFR	COSM6223	p.E746_A750delELREA	0.00	0.22
EGFR	COSM6224	p.L858R	0.00	0.31
EGFR	COSM6240	p.T790M	0.00	0.27
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.00	0.05
EML4-ALK	N/A	Translocation	NA	NA
ERBB2	COSM20959	p.A775_G776insYVMA	0.00	0.22
KIT	COSM1314	p.D816V	0.00	0.32
KRAS	COSM516	p.G12C	0.00	0.47
KRAS	COSM521	p.G12D	0.00	0.38
KRAS	COSM554	p.Q61H	0.00	0.40
NCOA4/RET	N/A	Translocation	NA	NA
NRAS	COSM584	p.Q61R	0.00	0.48
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.00	0.18
PIK3CA	COSM775	p.H1047R	0.00	0.39

¹As 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.

Note: Variants not included in the NGS panel were confirmed to be present by digital PCR.

Approval:



25 JUN 2021

Prepared By

Date