

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: 10611976

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 ~169-177 bp, and blended at four tumor fractions: 0%, 0.5%, 0.05% and 0.005%.

Fill Volume: 20 µL per vial

Date of Manufacture: 22 MAR 2022 Expiration Date: 15 MAR 2024

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 the NextSeq 2500 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	14.7	1	1	0.0002
Seraseq ctDNA MRD 0.5% Tumor	13.2	98	1071	0.2205
Seraseq ctDNA MRD 0.05% Tumor	13.7	59	94	0.0188
Seraseq ctDNA MRD 0.005% Tumor	12.7	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_A750delIELREA	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 ¹	p.N1068fs*4	0.00	0.58
PIK3CA	COSM775	p.H1047R	0.00	0.51

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.

Approval:



22 MAR 2022

Prepared By

Date