

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description	Seraseq® ctDNA Prostate Mix AF0.5%		
Material Number:	0710-3329	Batch Number:	10709661
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	25 µL		
Date of Manufacture:	10 SEP 2024	Expiration Date:	10 SEP 2028
Storage:	-20°C		
Concentration	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 11.4 ng/µL		
Average fragment size	195 bp		
(Agilent Bioanalyzer High			
Sensitivity DNA Analysis):			
Acceptance criteria for	150 – 220 bp		
average fragment size:			
ddPCR Test Method:	BioRad QX200™ Droplet Digital™ PCR System		
NGS Assay Test Method:	Illumina TruSight Oncology 500 ctDNA panel sequenced on a NovaSeq 6000. The total read pairs for the sample was >800M and the read depth was >35,000X.		

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Structural Variant	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
TMPRSS2-ERG	0.44	0.06
SLC45A3-ETV1	0.40	0.10

Gene	Total Copies (dPCR)	Total Copies (NGS)
CCDN1	2.60	2.77
MYC	2.98	2.88

Gene	Nucleic Acid Change	Amino Acid Change	% Allele Frequency (dPCR)	% Allele Frequency (NGS)
APC	c.4348C>T	p.R1450*	0.44	0.19
APC	c.4666dup	p.T1556fs	0.44	0.28
AR	c.2105T>A	p.L702H	0.44	0.27
AR	c.2623C>T	p.H875Y	0.44	0.30
AR	c.2632A>G	p.T878A	0.43	0.41
ATM	c.2543_2571del	p.E848fs	0.51	0.43
ATR	c.2320dup	p.I774fs	0.42	ND
BARD1	c.1600_1634delinsGCG	p.T534fs	0.45	ND
BRAF	c.1799T>A	p.V600E	0.48	0.31
BRCA1	c.3481_3491del	p.E1161fs	0.48	0.46
BRCA2	c.1813dup	p.I605fs	0.47	ND
BRCA2	c.8954-8_9136del	Deletion	0.48	ND
BRIP1	c.2392C>T	p.R798*	0.43	0.28
CDK12	c.4382del	p.G1461fs	0.41	0.18
CDKN2A	c.9_32dup	p.A4_P11dup	0.48	ND
CHEK1	c.676del	p.T226fs	0.44	N/A
CHEK2	c.1116_1117delinsGT	p.K373*	0.37	N/A
FANCA	c.2778+1G>A	Unknown	0.47	0.42
FANCL	c.1096_1099dup	p.T367fs	0.45	ND
KIT	c.2361+67_2361+72delTTTTTT	MSI BAT-25	0.44	N/A
KRAS	c.34G>T	p.G12C	0.41	0.17
MAP4K3	c.998-35_998-30delIAAAAAA	MSI MONO-27	0.39	N/A
MAP4K3	c.246-2475_246-2470delTTTTTT	MSI MONO-27	0.47	N/A
MLH1	c.1852_1854del	p.K618del	0.46	0.37
MRE11	c.1100_1131del	p.Val367fs	0.40	N/A
MSH2	c.942+3A>T	COSM26123	0.50	ND
MSH2	c.942+20_942+29delIAAAAAAAAAA	MSI BAT-26	0.45	N/A
MSH6	c.3261dup	p.F1088fs	0.38	ND
NBN	c.1396del	p.R466fs	0.44	0.58
PALB2	c.1059_1077delinsGG	p.S354fs	0.51	0.23
PIK3CA	c.3140A>G	p.H1047R	0.48	0.13

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PIK3R1	c.1727_1729del	p.T576del	0.58	0.25
PMS2*	c.2243_2246del	p.K748fs	0.44	ND
PTEN	c.741dup	p.P248fs	0.41	0.21
PTEN	c.800del	p.K267fs	0.41	0.24
RAD51B	c.321dup	p.G108fs	0.39	ND
RAD51C	c.706-2A>G	Unknown	0.49	0.39
RAD51D	c.694_715delinsTGAGAGCTGAAGACCCTGGCCT	p.R232*	0.47	0.43
RAD54L	c.636_637dup	p.K213fs	0.51	0.33
RB1	c.751C>T	p.R251*	0.51	0.21
SLC7A8	c.-231_-224delTTTTTTTT	MSI NR-21	0.44	N/A
SPOP	c.44_47dup	p.P17fs	0.57	0.22
TP53	c.743G>A	p.R248Q	0.51	0.18
ZNF2	c.*1525_*1530delTTTTTT	MSI NR-24	0.48	N/A

N/A = not applicable; NGS assay does not cover specified variant.

ND = not detected; NGS assay did not reveal specified variant above 0.1%.

*This construct for the PMS2 variant also contains a synonymous single nucleotide change (c.2253T>C).

Approval:



17 SEP 2024

Prepared By

Date