

# Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description	Seraseq® ctDNA Prostate Mix WT		
Material Number:	0710-3327	Batch Number:	10709659
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385		
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: 12.4 ng/µL		
Average fragment size			
(Agilent Bioanalyzer High	207 bp		
Sensitivity DNA Analysis):			
Acceptance criteria for			
average fragment size:	150 – 220 bp		
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 (NGS)	Gene	Total Copies (NGS)
TMPRSS2-ERG	ND	CCDN1	ND
SLC45A3-ETV1	ND	MYC	ND

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

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Gene	Nucleic Acid Change	Amino Acid Change	% Allele Frequency (NGS)
PIK3R1	c.1727_1729del	p.T576del	ND
PMS2*	c.2243_2246del; c.2253T>C	p.K748fs	ND
PTEN	c.741dup	p.P248fs	ND
PTEN	c.800del	p.K267fs	ND
RAD51B	c.321dup	p.G108fs	ND
RAD51C	c.706-2A>G	Unknown	ND
RAD51D	c.694_715delinsTGAGAGCTGAAGACCCTGGCCT	p.R232*	ND
RAD54L	c.636_637dup	p.K213fs	ND
RB1	c.751C>T	p.R251*	ND
SLC7A8	c.-231_-224delTTTTTTTT	MSI NR-21	N/A
SPOP	c.44_47dup	p.P17fs	ND
TP53	c.743G>A	p.R248Q	ND
ZNF2	c.*1525_*1530delTTTTTT	MSI NR-24	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%.

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

**Approval:**



17 SEP 2024

Prepared By

Date

