

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF0.1%

Material Number: 0710-3992

Batch Number: 10775976

Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs in plasma-like matrix

Fill Volume: 5 mL

Date of Manufacture: 26 AUG 2025

Expiration Date: 26 AUG 2027

Storage: -20°C

Concentration (Qubit dsDNA BR Assay): Nominal value: 25 ng/mL
Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 32.3 ng/mL

Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis): 210 bp

Acceptance criteria for average size: 150 – 230 bp

Digital PCR Method: Bio-Rad QX200™ Droplet Digital™ PCR System

Digital PCR release criteria: 0.060 – 0.140% for variant allele frequency (VAF) and 2.10 – 2.73 total copies for copy number variants
Note: 95% confidence interval examined if reported estimate does not fall within this range; confidence intervals reported in parentheses in table below.

NGS Method: Illumina TruSight™ Oncology 500 ctDNA sequenced on NovaSeqX Plus 10B/25B (150PE)

NGS release criteria: The extracted cfDNA is made into a library that is successfully sequenced

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SNVs and Indels

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	0.13 (0.10-0.16)	NA
AR	c.2623C>T	p.H875Y	0.26 (0.16-0.34) ¹	0.17 ¹
ATM	c.1058_1059del	p.C353Sfs*5	0.11 (0.06-0.14)	NA
BRAF	c.1799T>A	p.V600E	0.12 (0.08-0.15)	0.09
BRCA1	c.1961del	p.K654Sfs*47	0.10 (0.07-0.13)	NA
BRCA2	c.7934del	p.R2645Nfs*3	0.11 (0.08-0.14)	0.14
CDKN2A	c.9_32dup	p.A4_P11dup	0.12 (0.09-0.15)	NA
CHEK1	c.676del	p.T226Hfs*14	0.15 (0.11-0.19)	NA
CHEK2	c.1029_1030delinsGT	p.K373*	0.13 (0.09-0.17)	NA
EGFR	c.2369C>T	p.T790M	0.15 (0.11-0.18)	0.22
EGFR	c.2303G>T	p.S768I	0.11 (0.06-0.15)	NA
EGFR	c.2389T>A	p.C797S	0.15 (0.11-0.18)	0.22
EGFR	c.2573T>G	p.L858R	0.12 (0.09-0.15)	0.07
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.11 (0.06-0.15)	NA
EGFR	c.2235_2249del	p.E746_A750del	0.12 (0.09-0.15)	0.09
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.14 (0.11-0.17)	NA
ESR1	c.1613A>G	p.D538G	0.15 (0.11-0.18)	NA
FGFR3	c.746C>G	p.S249C	0.08 (0.05-0.10)	0.07
HRAS	c.37G>C	p.G13R	0.11 (0.08-0.14)	0.17
HRAS	c.182A>G	p.Q61R	0.11 (0.08-0.14)	0.22
IDH1	c.394C>T	p.R132C	0.15 (0.10-0.19)	NA
IDH2	c.419G>A	p.R140Q	0.12 (0.09-0.16)	0.13
IDH2	c.515G>A	p.R172K	0.12 (0.09-0.15)	0.14
KIT	c.2361+67_2361+72delTTTTTT	N/A	0.10 (0.07-0.13)	NA
KIT	c.2447A>T	p.D816V	0.12 (0.08-0.15)	0.07
KRAS	c.183A>C	p.Q61H	0.12 (0.09-0.15)	0.12
KRAS	c.34G>T	p.G12C	0.12 (0.07-0.16)	0.12
KRAS	c.35G>A	p.G12D	0.15 (0.11-0.18)	0.20
MAP2K1	c.370C>T	p.P124S	0.13 (0.09-0.17)	NA
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	0.11 (0.08-0.14)	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	0.12 (0.09-0.15)	NA
MET	c.3082+1del	N/A	0.14 (0.11-0.16)	NA
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	0.15 (0.11-0.18)	NA
MSH2	c.1662-12_1677del	N/A	0.13 (0.09-0.16)	NA
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	0.10 (0.07-0.13)	NA

¹The AR variant is present on the X chromosome and the genomic background of this product is male, thus VAF will be ~2-fold higher than other variants.

NA = not assayed; not covered by NGS test panel

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MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	0.09 (0.06-0.12)	0.12
MTOR	c.6644C>A	p.S2215Y	0.12 (0.09-0.16)	NA
NF1	c.3738_3747del	p.F1247Gfs*16	0.11 (0.07-0.13)	NA
NRAS	c.182A>G	p.Q61R	0.12 (0.08-0.15)	0.22
NTRK1	c.1783G>A	p.G595R	0.13 (0.09-0.16)	NA
NTRK2	c.1915G>A	p.G639R	0.17 (0.12-0.22)	NA
NTRK3	c.1867G>A	p.G623R	0.15 (0.08-0.20)	NA
PALB2	c.839del	p.N280Tfs*8	0.13 (0.09-0.16)	NA
PDGFRA	c.2525A>T	p.D842V	0.15 (0.10-0.19)	0.14
PIK3CA	c.3140A>G	p.H1047R	0.14 (0.09-0.17)	0.08
PIK3CA	c.3203dup	p.N1068Kfs*5	0.14 (0.09-0.17)	NA
PIK3CA	c.1633G>A	p.E545K	0.09 (0.06-0.11)	0.17
PIK3R1	c.1727_1729del	p.T576del	0.09 (0.06-0.12)	NA
PMS2	c.861_864del	p.R287Sfs*19	0.10 (0.07-0.13)	NA
PTCH1	c.2307_2308delinsTT	p.R770*	0.10 (0.06-0.13)	NA
PTEN	c.800del	p.K267Rfs*9	0.11 (0.03-0.18)	NA
PTEN	c.741dup	p.P248Tfs*5	0.11 (0.03-0.18)	0.14
RAD51C	c.338dup	p.G114Wfs*25	0.13 (0.09-0.16)	NA
RAD51C	c.242C>A	p.S81*	0.13 (0.09-0.16)	NA
RAD51D	c.392dup	p.N131Kfs*23	0.09 (0.06-0.11)	NA
RAD51D	c.271A>T	p.K91*	0.09 (0.06-0.11)	0.11
RAF1	c.770C>T	p.S257L	0.13 (0.05-0.20)	NA
RB1	c.751C>T	p.R251*	0.11 (0.08-0.14)	NA
RET	c.2753T>C	p.M918T	0.09 (0.06-0.12)	0.13
SLC7A8	c.-231_-224delTTTTTTTT	N/A	0.10 (0.06-0.13)	NA
SMARCB1	c.118C>T	p.R40*	0.10 (0.06-0.13)	NA
STK11	c.734+1G>T	N/A	0.11 (0.08-0.14)	NA
TERT	c.-124C>T	N/A	0.13 (0.09-0.17)	NA
TERT	c.-146C>T	N/A	0.13 (0.09-0.17)	NA
TP53	c.723del	p.C242Afs*5	0.14 (0.08-0.19)	0.12
TP53	c.743G>A	p.R248Q	0.14 (0.08-0.19)	0.08
TP53	c.818G>A	p.R273H	0.14 (0.08-0.19)	NA
TSC1	c.1263+1G>T	N/A	0.08 (0.03-0.11)	NA
TSC2	c.2640-1G>A	N/A	0.13 (0.09-0.17)	NA
VHL	c.481C>T	p.R161*	0.10 (0.07-0.13)	NA
ZNF2	c.*1525_*1530delTTTTTT	N/A	0.11 (0.08-0.15)	NA

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Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	0.10 (0.07-0.13)	NA
CD74::ROS1	Intron 6::Intron 34	0.11 (0.08-0.15)	NA
COL1A1::PDGFB	Intron 25::Intron 1	0.14 (0.09-0.18)	NA
EML4::ALK	Intron 13::Intron 19	0.11 (0.08-0.14)	†
ETV6::NTRK3	Intron 5::Intron 14	0.11 (0.06-0.15)	NA
FGFR2::BICC1	Intron 17::Intron 2	0.12 (0.08-0.15)	NA
FGFR3::TACC3	Exon 18::Intron 7	0.14 (0.11-0.18)	†
NCOA4::RET	Intron 7::Intron 11	0.11 (0.08-0.14)	NA
PML::NTRK2	Intron 2::Intron 12	0.12 (0.06-0.16)	NA
TPM3::NTRK1	Intron 7::Intron 9	0.13 (0.08-0.17)	NA

NA = not assayed

† ≥ 3 supporting reads detected

Copy Number Variants

Gene	dPCR Total Copies	NGS AF Total Copies
AKT2	2.28 (2.20-2.35)	NA
CCND1	2.43 (2.35-2.50)	NA
CCNE1	2.09 (2.02-2.15)	NA
CDK4	2.34 (2.41-2.51)	2.36
ERBB2	2.34 (2.29-2.38)	NA
FGF19	2.43 (2.35-2.50)	NA
FGF3	2.31 (2.23-2.38)	NA
FGF4	2.31 (2.23-2.38)	1.65
FGFR1	2.38 (2.33-2.43)	NA
MET	2.35 (2.27-2.42)	2.34
MYC	2.29 (2.24-2.34)	NA
MYCN	2.05 (1.98-2.13)	NA

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Approval:

Sandhya Jaminden

10 SEP 2025

Prepared By

Date