

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® ctDNA v4 Reference Material AF0.5%		
Material Number:	0710-3991	Batch Number:	10775975
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: 32.4 ng/mL		
Average fragment size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	216 bp		
Acceptance criteria for average size:	150 – 230 bp		
Digital PCR Method:	Bio-Rad QX200™ Droplet Digital™ PCR System		
Digital PCR release criteria:	0.400 – 0.625% for variant allele frequency (VAF) and 2.50 – 3.25 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		

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF0.5%

SNVs and Indels

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	0.58 (0.46-0.68)	0.39
AR	c.2623C>T	p.H875Y	1.19 (0.95-1.42) ¹	0.71 ¹
ATM	c.1058_1059del	p.C353Sfs*5	0.64 (0.56-0.71)	0.72
BRAF	c.1799T>A	p.V600E	0.58 (0.50-0.65)	0.61
BRCA1	c.1961del	p.K654Sfs*47	0.57 (0.50-0.64)	NA
BRCA2	c.7934del	p.R2645Nfs*3	0.56 (0.49-0.62)	0.26
CDKN2A	c.9_32dup	p.A4_P11dup	0.69 (0.61-0.76)	NA
CHEK1	c.676del	p.T226Hfs*14	0.56 (0.49-0.63)	NA
CHEK2	c.1029_1030delinsGT	p.K373*	0.56 (0.48-0.64)	NA
EGFR	c.2369C>T	p.T790M	0.69 (0.60-0.78)	0.39
EGFR	c.2303G>T	p.S768I	0.56 (0.42-0.69)	0.59
EGFR	c.2389T>A	p.C797S	0.69 (0.60-0.78)	0.33
EGFR	c.2573T>G	p.L858R	0.55 (0.47-0.61)	0.64
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.56 (0.47-0.64)	0.55
EGFR	c.2235_2249del	p.E746_A750del	0.56 (0.47-0.64)	0.44
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.62 (0.54-0.69)	0.45
ESR1	c.1613A>G	p.D538G	0.60 (0.53-0.68)	0.52
FGFR3	c.746C>G	p.S249C	0.38 (0.32-0.43)	0.33
HRAS	c.37G>C	p.G13R	0.59 (0.51-0.66)	0.50
HRAS	c.182A>G	p.Q61R	0.59 (0.51-0.66)	0.62
IDH1	c.394C>T	p.R132C	0.58 (0.51-0.65)	0.34
IDH2	c.419G>A	p.R140Q	0.51 (0.44-0.57)	0.39
IDH2	c.515G>A	p.R172K	0.47 (0.37-0.57)	0.64
KIT	c.2361+67_2361+72delTTTTTT	N/A	0.48 (0.42-0.55)	NA
KIT	c.2447A>T	p.D816V	0.51 (0.43-0.59)	0.32
KRAS	c.183A>C	p.Q61H	0.52 (0.43-0.60)	0.60
KRAS	c.34G>T	p.G12C	0.54 (0.47-0.60)	0.26
KRAS	c.35G>A	p.G12D	0.52 (0.46-0.59)	0.21
MAP2K1	c.370C>T	p.P124S	0.49 (0.40-0.57)	0.49
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	0.45 (0.39-0.51)	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	0.55 (0.48-0.61)	NA
MET	c.3082+1del	N/A	0.54 (0.49-0.59)	0.48
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	0.66 (0.56-0.76)	0.32
MSH2	c.1662-12_1677del	N/A	0.64 (0.56-0.71)	0.82
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	0.52 (0.46-0.59)	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

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF0.5%

SNVs and Indels, continued

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	0.48 (0.42-0.54)	0.31
MTOR	c.6644C>A	p.S2215Y	0.51 (0.43-0.58)	0.52
NF1	c.3738_3747del	p.F1247Gfs*16	0.52 (0.42-0.62)	0.13
NRAS	c.182A>G	p.Q61R	0.61 (0.54-0.68)	0.62
NTRK1	c.1783G>A	p.G595R	0.68 (0.60-0.75)	0.45
NTRK2	c.1915G>A	p.G639R	0.59 (0.52-0.66)	0.41
NTRK3	c.1867G>A	p.G623R	0.58 (0.48-0.68)	0.35
PALB2	c.839del	p.N280Tfs*8	0.58 (0.51-0.65)	0.59
PDGFRA	c.2525A>T	p.D842V	0.61 (0.50-0.71)	0.41
PIK3CA	c.3140A>G	p.H1047R	0.54 (0.47-0.61)	0.36
PIK3CA	c.3203dup	p.N1068Kfs*5	0.54 (0.47-0.61)	0.47
PIK3CA	c.1633G>A	p.E545K	0.54 (0.47-0.61)	0.52
PIK3R1	c.1727_1729del	p.T576del	0.52 (0.43-0.59)	0.39
PMS2	c.861_864del	p.R287Sfs*19	0.53 (0.45-0.61)	0.23
PTCH1	c.2307_2308delinsTT	p.R770*	0.59 (0.51-0.68)	0.46
PTEN	c.800del	p.K267Rfs*9	0.63 (0.56-0.71)	0.43
PTEN	c.741dup	p.P248Tfs*5	0.63 (0.56-0.71)	0.54
RAD51C	c.338dup	p.G114Wfs*25	0.46 (0.39-0.53)	0.18
RAD51C	c.242C>A	p.S81*	0.46 (0.39-0.53)	NA
RAD51D	c.392dup	p.N131Kfs*23	0.53 (0.45-0.60)	0.43
RAD51D	c.271A>T	p.K91*	0.53 (0.45-0.60)	0.36
RAF1	c.770C>T	p.S257L	0.51 (0.44-0.57)	0.47
RB1	c.751C>T	p.R251*	0.56 (0.47-0.64)	0.36
RET	c.2753T>C	p.M918T	0.53 (0.37-0.67)	0.50
SLC7A8	c.-231_-224delTTTTTTTT	N/A	0.56 (0.48-0.64)	NA
SMARCB1	c.118C>T	p.R40*	0.47 (0.36-0.57)	0.58
STK11	c.734+1G>T	N/A	0.48 (0.40-0.55)	0.34
TERT	c.-124C>T	N/A	0.59 (0.50-0.68)	NA
TERT	c.-146C>T	N/A	0.59 (0.50-0.68)	NA
TP53	c.723del	p.C242Afs*5	0.47 (0.36-0.56)	0.56
TP53	c.743G>A	p.R248Q	0.47 (0.36-0.56)	0.49
TP53	c.818G>A	p.R273H	0.47 (0.36-0.56)	0.39
TSC1	c.1263+1G>T	N/A	0.52 (0.43-0.61)	0.45
TSC2	c.2640-1G>A	N/A	0.63 (0.47-0.79)	0.68
VHL	c.481C>T	p.R161*	0.44 (0.36-0.51)	0.52
ZNF2	c.*1525_*1530delTTTTTT	N/A	0.53 (0.44-0.60)	NA

NA = not assayed; not covered by NGS test panel

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA v4 Reference Material AF0.5%

Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	0.57 (0.48-0.66)	†
CD74::ROS1	Intron 6::Intron 34	0.55 (0.48-0.62)	†
COL1A1::PDGFB	Intron 25::Intron 1	0.58 (0.44-0.71)	NA
EML4::ALK	Intron 13::Intron 19	0.51 (0.44-0.57)	†
ETV6::NTRK3	Intron 5::Intron 14	0.50 (0.42-0.58)	NA
FGFR2::BICC1	Intron 17::Intron 2	0.55 (0.48-0.62)	†
FGFR3::TACC3	Exon 18::Intron 7	0.66 (0.59-0.74)	†
NCOA4::RET	Intron 7::Intron 11	0.51 (0.45-0.58)	†
PML::NTRK2	Intron 2::Intron 12	0.46 (0.39-0.54)	NA
TPM3::NTRK1	Intron 7::Intron 9	0.56 (0.47-0.64)	NA

NA = not assayed

† ≥ 3 supporting reads detected

Copy Number Variants

Gene	dPCR Total Copies	NGS AF Total Copies
AKT2	2.61 (2.56-2.67)	2.41
CCND1	2.86 (2.80-2.92)	2.34
CCNE1	2.46 (2.41-2.52)	2.55
CDK4	2.98 (2.86-3.09)	2.76
ERBB2	3.03 (2.94-3.12)	2.78
FGF19	2.86 (2.80-2.92)	2.42
FGF3	2.65 (2.56-2.74)	NA
FGF4	2.65 (2.56-2.74)	NA
FGFR1	2.75 (2.69-2.81)	2.31
MET	2.78 (2.73-2.84)	3.10
MYC	2.75 (2.66-2.83)	2.39
MYCN	2.56 (2.50-2.61)	2.72

NA = not assayed; not covered by NGS test panel

Approval:

Sanchita Samudra

10 SEP 2025

Prepared By

Date