

Certificate of Analysis

Product Description: Seraseq® ctDNA Mutation Mix v4 AF0.1%

Material Number: 0710-3097 **Batch Number:** 10687644

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

Volume: 25 µL

Date of Manufacture: 24 MAY 2024 **Expiration Date:** 25 MAR 2028

Storage: -20°C

Nominal Concentration: 10 ng/µL

Concentration (Qubit dsDNA BR Assay): 13.4 ng/µL

Average Fragment Size (Agilent Bioanalyzer High Sensitivity DNA Analysis): 199 bp

Acceptance Criteria for Fragment Size: 150-220 bp

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

NGS Method: Illumina TruSight™ Oncology 500 ctDNA sequenced on NovaSeq™

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SNVs and Indels

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	0.090	NA
AR	c.2623C>T	p.H875Y	0.203	NA
ATM	c.1058_1059del	p.C353Sfs*5	0.060	NA
BRAF	c.1799T>A	p.V600E	0.053	NA
BRCA1	c.1961del	p.K654Sfs*47	0.035	NA
BRCA2	c.7934del	p.R2645Nfs*3	0.073	NA
CDKN2A	c.9_32dup	p.A4_P11dup	0.047	NA
CHEK1	c.676del	p.T226Hfs*14	0.087	NA
CHEK2	c.1029_1030delinsGT	p.K373*	0.047	NA
EGFR	c.2369C>T	p.T790M	0.054	NA
EGFR	c.2303G>T	p.S768I	0.060	NA
EGFR	c.2389T>A	p.C797S	0.054	NA
EGFR	c.2573T>G	p.L858R	0.053	NA
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.060	NA
EGFR	c.2235_2249del	p.E746_A750del	0.063	0.08
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.070	NA
ESR1	c.1613A>G	p.D538G	0.100	NA
FGFR3	c.746C>G	p.S249C	0.070	NA
HRAS	c.37G>C	p.G13R	0.069	0.11
HRAS	c.182A>G	p.Q61R	0.069	NA
IDH1	c.394C>T	p.R132C	0.140	NA
IDH2	c.419G>A	p.R140Q	0.067	NA
IDH2	c.515G>A	p.R172K	0.060	NA
KIT	c.2361+67_2361+72delTTTTTT	N/A	0.040	NA
KIT	c.2447A>T	p.D816V	0.053	NA
KRAS	c.183A>C	p.Q61H	0.060	0.10
KRAS	c.34G>T	p.G12C	0.073	NA
KRAS	c.35G>A	p.G12D	0.063	0.11
MAP2K1	c.370C>T	p.P124S	0.067	NA
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	0.053	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	0.073	NA
MET	c.3082+1del	N/A	0.042	0.17
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	0.093	NA
MSH2	c.1662-12_1677del	N/A	0.190	NA

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MSH2	c.942+20_942+29delAAAAAAAAA	N/A	0.190	NA
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The 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

SNVs and Indels, continued

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	0.060	NA
MTOR	c.6644C>A	p.S2215Y	0.060	NA
NF1	c.3738_3747del	p.F1247Gfs*16	0.073	NA
NRAS	c.182A>G	p.Q61R	0.083	0.20
NTRK1	c.1783G>A	p.G595R	0.117	NA
NTRK2	c.1915G>A	p.G639R	0.100	NA
NTRK3	c.1867G>A	p.G623R	0.040	NA
PALB2	c.839del	p.N280Tfs*8	0.073	NA
PDGFRA	c.2525A>T	p.D842V	0.081	0.09
PIK3CA	c.3140A>G	p.H1047R	0.074	0.10
PIK3CA	c.3203dup	p.N1068Kfs*5	0.074	NA
PIK3CA	c.1633G>A	p.E545K	0.113	NA
PIK3R1	c.1727_1729del	p.T576del	0.067	NA
PMS2	c.861_864del	p.R287Sfs*19	0.085	NA
PTCH1	c.2307_2308delinsTT	p.R770*	0.086	NA
PTEN	c.800del	p.K267Rfs*9	0.047	NA
PTEN	c.741dup	p.P248Tfs*5	0.047	NA
RAD51C	c.338dup	p.G114Wfs*25	0.053	NA
RAD51C	c.242C>A	p.S81*	0.053	NA
RAD51D	c.392dup	p.N131Kfs*23	0.040	NA
RAD51D	c.271A>T	p.K91*	0.040	NA
RAF1	c.770C>T	p.S257L	0.067	NA
RB1	c.751C>T	p.R251*	0.083	NA
RET	c.2753T>C	p.M918T	0.083	NA
SLC7A8	c.-231_-224delTTTTTTTT	N/A	0.130	NA
SMARCB1	c.118C>T	p.R40*	0.052	NA
STK11	c.734+1G>T	N/A	0.103	0.20
TERT	c.-124C>T	N/A	0.047	NA

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TERT	c.-146C>T	N/A	0.047	NA
TP53	c.723del	p.C242Afs*5	0.046	NA
TP53	c.743G>A	p.R248Q	0.046	NA
TP53	c.818G>A	p.R273H	0.046	NA
TSC1	c.1263+1G>T	N/A	0.082	NA
TSC2	c.2640-1G>A	N/A	0.073	NA
VHL	c.481C>T	p.R161*	0.080	NA
ZNF2	c.*1525_ *1530delTTTTTT	N/A	0.080	NA

NA = not assayed; not covered by NGS test panel

Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	0.060	NA
CD74::ROS1	Intron 6::Intron 34	0.050	NA
COL1A1::PDGFB	Intron 25::Intron 1	0.080	NA
EML4::ALK	Intron 13::Intron 19	0.060	NA
ETV6::NTRK3	Intron 5::Intron 14	0.083	NA
FGFR2::BICC1	Intron 17::Intron 2	0.040	NA
FGFR3::TACC3	Exon 18::Intron 7	0.070	0.17
NCOA4::RET	Intron 7::Intron 11	0.063	NA
PML::NTRK2	Intron 2::Intron 12	0.083	NA
TPM3::NTRK1	Intron 7::Intron 9	0.133	NA

NA = not assayed

Copy Number Variants

Gene	dPCR Total Copies	NGS Total Copies
AKT2	2.10	NA
CCND1	2.15	NA
CCNE1	2.26	2.72
CDK4	2.23	NA
ERBB2	2.20	NA
FGF19	2.15	NA
FGF3	2.33	NA
FGF4	2.33	NA
FGFR1	2.18	NA
MET	2.15	2.42
MYC	2.47	3.75

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Approval:

A handwritten signature in black ink, appearing to be 'BL'.

06/27/2024

Prepared By

Date

A handwritten signature in black ink, appearing to be 'L. D. [unclear]'.

28 JUN 2024

QA Verified By

Date

