

# Certificate of Analysis

**Product Description:** Seraseq® ctDNA Mutation Mix v4 AF5%

**Material Number:** 0710-3100      **Batch Number:** 10687648

**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:** 05 MAY 2024      **Expiration Date:** 22 APR 2028

**Storage:** -20°C

**Nominal Concentration:** 10 ng/µL

**Concentration (Qubit dsDNA BR Assay):** 14.63 ng/µL

**Average Fragment Size (Agilent Bioanalyzer High Sensitivity DNA Analysis):** 187 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	4.19	3.50
AR	c.2623C>T	p.H875Y	7.44*	7.78*
ATM	c.1058_1059del	p.C353Sfs*5	4.57	3.46
BRAF	c.1799T>A	p.V600E	4.00	4.17
BRCA1	c.1961del	p.K654Sfs*47	3.99	4.21
BRCA2	c.7934del	p.R2645Nfs*3	4.01	3.25
CDKN2A	c.9_32dup	p.A4_P11dup	4.05	NA
CHEK1	c.676del	p.T226Hfs*14	3.93	NA
CHEK2	c.1029_1030delinsGT	p.K373*	4.18	1.86
EGFR	c.2369C>T	p.T790M	4.59	4.01
EGFR	c.2303G>T	p.S768I	4.35	3.40
EGFR	c.2389T>A	p.C797S	4.59	3.43
EGFR	c.2573T>G	p.L858R	3.85	3.41
EGFR	c.2310_2311insGGT	p.D770_N771insG	4.35	3.40
EGFR	c.2235_2249del	p.E746_A750del	4.01	2.95
ERBB2	c.2313_2324dup	p.Y772_A775dup	4.18	3.70
ESR1	c.1613A>G	p.D538G	3.97	3.60
FGFR3	c.746C>G	p.S249C	4.21	3.46
HRAS	c.37G>C	p.G13R	3.88	4.10
HRAS	c.182A>G	p.Q61R	3.88	3.34
IDH1	c.394C>T	p.R132C	5.28	3.35
IDH2	c.419G>A	p.R140Q	4.48	3.74
IDH2	c.515G>A	p.R172K	4.80	4.90
KIT	c.2361+67_2361+72delTTTTTT	N/A	5.04	NA
KIT	c.2447A>T	p.D816V	5.25	4.55
KRAS	c.183A>C	p.Q61H	4.53	3.52
KRAS	c.34G>T	p.G12C	4.72	4.35
KRAS	c.35G>A	p.G12D	4.58	3.91
MAP2K1	c.370C>T	p.P124S	4.43	5.00
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	4.74	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	4.87	NA
MET	c.3082+1del	N/A	5.83	6.66
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	5.42	2.66
MSH2	c.1662-12_1677del	N/A	4.31	2.85
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	4.38	NA

\*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

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MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	4.40	NA
MTOR	c.6644C>A	p.S2215Y	4.47	4.24
NF1	c.3738_3747del	p.F1247Gfs*16	4.18	1.44
NRAS	c.182A>G	p.Q61R	5.02	5.06
NTRK1	c.1783G>A	p.G595R	5.52	3.63
NTRK2	c.1915G>A	p.G639R	4.98	4.93
NTRK3	c.1867G>A	p.G623R	4.46	4.56
PALB2	c.839del	p.N280Tfs*8	4.73	4.29
PDGFRA	c.2525A>T	p.D842V	4.17	4.61
PIK3CA	c.3140A>G	p.H1047R	4.16	4.70
PIK3CA	c.3203dup	p.N1068Kfs*5	4.16	4.68
PIK3CA	c.1633G>A	p.E545K	4.01	4.06
PIK3R1	c.1727_1729del	p.T576del	4.03	3.92
PMS2	c.861_864del	p.R287Sfs*19	3.80	1.72
PTCH1	c.2307_2308delinsTT	p.R770*	4.07	4.31
PTEN	c.800del	p.K267Rfs*9	3.80	3.26
PTEN	c.741dup	p.P248Tfs*5	3.80	3.37
RAD51C	c.338dup	p.G114Wfs*25	3.85	1.66
RAD51C	c.242C>A	p.S81*	3.85	1.82
RAD51D	c.392dup	p.N131Kfs*23	3.82	2.67
RAD51D	c.271A>T	p.K91*	3.82	3.71
RAF1	c.770C>T	p.S257L	4.09	4.10
RB1	c.751C>T	p.R251*	3.91	2.92
RET	c.2753T>C	p.M918T	4.30	3.83
SLC7A8	c.-231_-224delTTTTTTTT	N/A	4.12	NA
SMARCB1	c.118C>T	p.R40*	3.90	3.64
STK11	c.734+1G>T	N/A	4.17	3.92
TERT	c.-124C>T	N/A	4.42	5.64
TERT	c.-146C>T	N/A	4.42	7.34
TP53	c.723del	p.C242Afs*5	4.13	3.77
TP53	c.743G>A	p.R248Q	4.13	3.86
TP53	c.818G>A	p.R273H	4.13	4.11
TSC1	c.1263+1G>T	N/A	4.11	4.06
TSC2	c.2640-1G>A	N/A	4.62	3.91
VHL	c.481C>T	p.R161*	4.02	3.92
ZNF2	c.*1525_*1530delTTTTTT	N/A	4.38	NA

NA = not assayed; not covered by NGS test panel

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## Structural Variants


Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	3.99	1.17
CD74::ROS1	Intron 6::Intron 34	3.88	2.22
COL1A1::PDGFB	Intron 25::Intron 1	3.83	NA
EML4::ALK	Intron 13::Intron 19	4.28	2.29
ETV6::NTRK3	Intron 5::Intron 14	3.96	NA
FGFR2::BICC1	Intron 17::Intron 2	3.87	1.11
FGFR3::TACC3	Exon 18::Intron 7	4.26	4.90
NCOA4::RET	Intron 7::Intron 11	4.83	1.92
PML::NTRK2	Intron 2::Intron 12	3.97	NA
TPM3::NTRK1	Intron 7::Intron 9	4.22	NA

NA = not assayed

## Copy Number Variants

Gene	dPCR Total Copies	NGS Total Copies
AKT2	7.91	7.47
CCND1	7.30	7.23
CCNE1	7.49	9.71
CDK4	7.63	7.98
ERBB2	7.86	7.14
FGF19	7.30	6.98
FGF3	7.49	6.35
FGF4	7.49	6.67
FGFR1	7.75	6.86
MET	7.42	11.82
MYC	7.37	8.57

## Approval:


06/25/2024  
 \_\_\_\_\_  
 Prepared By Date


28 JUN 2024  
 \_\_\_\_\_  
 QA Verified By Date