

Certificate of Analysis

Product Description:	Seraseq® ctDNA Mutation Mix v4 AF0.5%		
Material Number:	0710-3099	Batch Number:	10687647
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:	12 APR 2028
Storage	-20°C		
Nominal Concentration:	10 ng/µL		
Concentration (Qubit dsDNA BR Assay):	14.1 ng/µL		
Average Fragment Size (Agilent Bioanalyzer High Sensitivity DNA Analysis):	195 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	0.470	0.57
AR	c.2623C>T	p.H875Y	0.933*	0.00*
ATM	c.1058_1059del	p.C353Sfs*5	0.497	0.38
BRAF	c.1799T>A	p.V600E	0.373	0.70
BRCA1	c.1961del	p.K654Sfs*47	0.677	0.45
BRCA2	c.7934del	p.R2645Nfs*3	0.517	0.59
CDKN2A	c.9_32dup	p.A4_P11dup	0.490	NA
CHEK1	c.676del	p.T226Hfs*14	0.383	NA
CHEK2	c.1029_1030delinsGT	p.K373*	0.470	NA
EGFR	c.2369C>T	p.T790M	0.613	0.50
EGFR	c.2303G>T	p.S768I	0.473	0.54
EGFR	c.2389T>A	p.C797S	0.613	0.54
EGFR	c.2573T>G	p.L858R	0.500	0.56
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.473	0.54
EGFR	c.2235_2249del	p.E746_A750del	0.410	0.50
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.570	0.54
ESR1	c.1613A>G	p.D538G	0.610	0.51
FGFR3	c.746C>G	p.S249C	0.500	0.33
HRAS	c.37G>C	p.G13R	0.367	0.73
HRAS	c.182A>G	p.Q61R	0.367	0.51
IDH1	c.394C>T	p.R132C	0.483	0.33
IDH2	c.419G>A	p.R140Q	0.417	0.49
IDH2	c.515G>A	p.R172K	0.503	0.48
KIT	c.2361+67_2361+72delTTTTTT	N/A	0.423	NA
KIT	c.2447A>T	p.D816V	0.413	0.32
KRAS	c.183A>C	p.Q61H	0.577	0.32
KRAS	c.34G>T	p.G12C	0.503	0.47
KRAS	c.35G>A	p.G12D	0.470	0.55
MAP2K1	c.370C>T	p.P124S	0.493	0.30
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	0.477	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	0.423	NA
MET	c.3082+1del	N/A	0.367	0.42
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	0.497	0.51
MSH2	c.1662-12_1677del	N/A	0.437	NA
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	0.400	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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SNVs and Indels, continued

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MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	0.460	NA
MTOR	c.6644C>A	p.S2215Y	0.407	0.82
NF1	c.3738_3747del	p.F1247Gfs*16	0.500	NA
NRAS	c.182A>G	p.Q61R	0.507	0.44
NTRK1	c.1783G>A	p.G595R	0.470	0.47
NTRK2	c.1915G>A	p.G639R	0.520	0.41
NTRK3	c.1867G>A	p.G623R	0.387	0.64
PALB2	c.839del	p.N280Tfs*8	0.493	0.39
PDGFRA	c.2525A>T	p.D842V	0.717	0.69
PIK3CA	c.3140A>G	p.H1047R	0.517	0.43
PIK3CA	c.3203dup	p.N1068Kfs*5	0.517	0.35
PIK3CA	c.1633G>A	p.E545K	0.500	0.54
PIK3R1	c.1727_1729del	p.T576del	0.417	0.27
PMS2	c.861_864del	p.R287Sfs*19	0.439	0.31
PTCH1	c.2307_2308delinsTT	p.R770*	0.423	0.53
PTEN	c.800del	p.K267Rfs*9	0.430	0.31
PTEN	c.741dup	p.P248Tfs*5	0.430	0.56
RAD51C	c.338dup	p.G114Wfs*25	0.493	0.23
RAD51C	c.242C>A	p.S81*	0.493	0.23
RAD51D	c.392dup	p.N131Kfs*23	0.397	0.48
RAD51D	c.271A>T	p.K91*	0.397	0.71
RAF1	c.770C>T	p.S257L	0.550	0.45
RB1	c.751C>T	p.R251*	0.420	0.28
RET	c.2753T>C	p.M918T	0.490	0.72
SLC7A8	c.-231_-224delTTTTTTTT	N/A	0.493	NA
SMARCB1	c.118C>T	p.R40*	0.590	0.42
STK11	c.734+1G>T	N/A	0.450	0.65
TERT	c.-124C>T	N/A	0.420	NA
TERT	c.-146C>T	N/A	0.420	NA
TP53	c.723del	p.C242Afs*5	0.440	0.58
TP53	c.743G>A	p.R248Q	0.440	0.52
TP53	c.818G>A	p.R273H	0.440	0.52
TSC1	c.1263+1G>T	N/A	0.527	0.40
TSC2	c.2640-1G>A	N/A	0.525	0.35
VHL	c.481C>T	p.R161*	0.503	0.47
ZNF2	c.*1525_*1530delTTTTTT	N/A	0.423	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	0.513	0.27
CD74::ROS1	Intron 6::Intron 34	0.473	0.29
COL1A1::PDGFB	Intron 25::Intron 1	0.510	NA
EML4::ALK	Intron 13::Intron 19	0.497	0.29
ETV6::NTRK3	Intron 5::Intron 14	0.453	NA
FGFR2::BICC1	Intron 17::Intron 2	0.407	NA
FGFR3::TACC3	Exon 18::Intron 7	0.500	0.58
NCOA4::RET	Intron 7::Intron 11	0.447	0.13
PML::NTRK2	Intron 2::Intron 12	0.383	NA
TPM3::NTRK1	Intron 7::Intron 9	0.490	NA

NA = not assayed

Copy Number Variants

Gene	dPCR Total Copies	NGS Total Copies
AKT2	3.00	2.89
CCND1	2.64	2.71
CCNE1	2.66	3.12
CDK4	2.65	2.77
ERBB2	2.56	2.36
FGF19	2.64	2.62
FGF3	2.58	NA
FGF4	2.58	2.35
FGFR1	2.69	2.46
MET	2.79	3.59
MYC	2.96	3.22

Approval:

Prepared By  Date 06/20/2024
 QA Verified By ES Date 28 JUN 2024