Certificate of Analysis

Product Description:	Seraseq® ctDNA Mutation Mix v4 AF0.5%		
Material Number:	0710-3099	Batch Number:	10687645
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):	194 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™		

Certificate of Analysis

Product Description: Seraseq® ctDNA Mutation Mix v4 AF0.5%

Material Number: 0710-3099 Batch Number: 10687645

SNVs and Indels

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	0.437	0.35
AR	c.2623C>T	p.H875Y	0.957[*]	1.08[*]
ATM	c.1058_1059del	p.C353Sfs*5	0.480	0.29
BRAF	c.1799T>A	p.V600E	0.423	0.40
BRCA1	c.1961del	p.K654Sfs*47	0.413	0.57
BRCA2	c.7934del	p.R2645Nfs*3	0.460	0.46
CDKN2A	c.9_32dup	p.A4_P11dup	0.460	NA
CHEK1	c.676del	p.T226Hfs*14	0.453	NA
CHEK2	c.1029_1030delinsGT	p.K373*	0.433	NA
EGFR	c.2369C>T	p.T790M	0.457	0.33
EGFR	c.2303G>T	p.S768I	0.477	0.38
EGFR	c.2389T>A	p.C797S	0.457	0.46
EGFR	c.2573T>G	p.L858R	0.493	0.41
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.477	0.38
EGFR	c.2235_2249del	p.E746_A750del	0.517	0.25
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.480	0.31
ESR1	c.1613A>G	p.D538G	0.417	0.47
FGFR3	c.746C>G	p.S249C	0.510	0.47
HRAS	c.37G>C	p.G13R	0.450	0.44
HRAS	c.182A>G	p.Q61R	0.450	0.24
IDH1	c.394C>T	p.R132C	0.457	0.32
IDH2	c.419G>A	p.R140Q	0.420	0.43
IDH2	c.515G>A	p.R172K	0.387	0.32
KIT	c.2361+67_2361+72delTTTTTT	N/A	0.407	NA
KIT	c.2447A>T	p.D816V	0.403	0.28
KRAS	c.183A>C	p.Q61H	0.397	0.52
KRAS	c.34G>T	p.G12C	0.417	0.50
KRAS	c.35G>A	p.G12D	0.593	0.29
MAP2K1	c.370C>T	p.P124S	0.400	0.23
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	0.397	NA
MAP4K3	c.998-35_998-30delAAAAAA	N/A	0.417	NA
MET	c.3082+1del	N/A	0.617	0.92
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	0.487	0.26
MSH2	c.1662-12_1677del	N/A	0.470	0.31
MSH2	c.942+20_942+29delAAAAAAAAAA	N/A	0.467	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

Certificate of Analysis

Product Description: Seraseq® ctDNA Mutation Mix v4 AF0.5%

Material Number: 0710-3099 Batch Number: 10687645

SNVs and Indels, continued

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	0.407	NA
MTOR	c.6644C>A	p.S2215Y	0.457	0.22
NF1	c.3738_3747del	p.F1247Gfs*16	0.407	0.20
NRAS	c.182A>G	p.Q61R	0.403	0.46
NTRK1	c.1783G>A	p.G595R	0.560	0.39
NTRK2	c.1915G>A	p.G639R	0.507	0.52
NTRK3	c.1867G>A	p.G623R	0.463	0.79
PALB2	c.839del	p.N280Tfs*8	0.460	0.39
PDGFRA	c.2525A>T	p.D842V	0.453	0.52
PIK3CA	c.3140A>G	p.H1047R	0.510	0.39
PIK3CA	c.3203dup	p.N1068Kfs*5	0.510	0.38
PIK3CA	c.1633G>A	p.E545K	0.493	0.55
PIK3R1	c.1727_1729del	p.T576del	0.457	0.54
PMS2	c.861_864del	p.R287Sfs*19	0.487	0.45
PTCH1	c.2307_2308delinsTT	p.R770*	0.490	0.24
PTEN	c.800del	p.K267Rfs*9	0.497	0.36
PTEN	c.741dup	p.P248Tfs*5	0.497	0.55
RAD51C	c.338dup	p.G114Wfs*25	0.487	0.24
RAD51C	c.242C>A	p.S81*	0.487	0.30
RAD51D	c.392dup	p.N131Kfs*23	0.470	0.22
RAD51D	c.271A>T	p.K91*	0.470	0.27
RAF1	c.770C>T	p.S257L	0.477	NA
RB1	c.751C>T	p.R251*	0.463	0.41
RET	c.2753T>C	p.M918T	0.470	0.44
SLC7A8	c.-231_-224delTTTTTTTT	N/A	0.507	NA
SMARCB1	c.118C>T	p.R40*	0.457	NA
STK11	c.734+1G>T	N/A	0.510	0.25
TERT	c.-124C>T	N/A	0.483	NA
TERT	c.-146C>T	N/A	0.483	NA
TP53	c.723del	p.C242Afs*5	0.480	0.38
TP53	c.743G>A	p.R248Q	0.480	0.41
TP53	c.818G>A	p.R273H	0.480	0.60
TSC1	c.1263+1G>T	N/A	0.507	0.18
TSC2	c.2640-1G>A	N/A	0.537	0.20
VHL	c.481C>T	p.R161*	0.477	0.58
ZNF2	c.*1525_*1530delTTTTTT	N/A	0.450	NA

NA = not assayed; not covered by NGS test panel

Certificate of Analysis

Product Description: Seraseq® ctDNA Mutation Mix v4 AF0.5%

Material Number: 0710-3099 Batch Number: 10687645

Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	0.457	0.21
CD74::ROS1	Intron 6::Intron 34	0.477	0.32
COL1A1::PDGFB	Intron 25::Intron 1	0.433	NA
EML4::ALK	Intron 13::Intron 19	0.480	0.20
ETV6::NTRK3	Intron 5::Intron 14	0.487	NA
FGFR2::BICC1	Intron 17::Intron 2	0.467	NA
FGFR3::TACC3	Exon 18::Intron 7	0.540	0.76
NCOA4::RET	Intron 7::Intron 11	0.397	0.23
PML::NTRK2	Intron 2::Intron 12	0.487	NA
TPM3::NTRK1	Intron 7::Intron 9	0.483	NA

NA = not assayed

Copy Number Variants

Gene	dPCR Total Copies	NGS Total Copies
AKT2	3.18	2.83
CCND1	2.86	3.81
CCNE1	2.51	3.01
CDK4	2.8	2.93
ERBB2	2.71	2.82
FGF19	2.86	3.72
FGF3	2.70	2.38
FGF4	2.70	2.46
FGFR1	2.19	2.62
MET	2.99	3.77
MYC	3.22	3.10

Approval:

06/20/2024

Prepared By Date

26Jun2024

QA Verified By Date