

Certificate of Analysis

Product Description: Seraseq® Tumor Mutation DNA Mix v3 AF7%

Material Number: 0710-3461 Batch Number: 10754908

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

Volume: 15 µL

Date of Manufacture: 14 APR 2025 Expiration Date: 14 JAN 2029

Storage: -20 °C

Nominal Concentration: 25 ng/µL

Concentration (Qubit dsDNA BR Assay): 25.6 ng/µL

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

NGS Method: Illumina TruSight™ Oncology 500 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	5.9	4.1
APC	c.4348C>T	p.R1450*	6.0	4.8
APC	c.4666dup	p.T1556Nfs*3	6.0	5.5
AR	c.2623C>T	p.H875Y	5.7	5.8
ARID1A	c.5548del	p.D1850Tfs*33	6.5	7.7
ATM	c.1058 1059del	p.C353Sfs*5	5.8	5.9
BARD1	c.1600 1634delinsGCG	p.T534fs	5.9	5.6
BRAF	c.1799T>A	p.V600E	6.2	6.5
BRCA1	c.1961del	p.K654Sfs*47	5.5	8.1
BRCA2	c.7934del	p.R2645Nfs*3	6.0	6.1
BRIP1	c.157dup	p.S53Kfs*16	5.9	8.3
CDK12	c.4382del	p.G1461Afs*38	6.5	6.6
CDKN2A	c.9 32dup	p.A4 P11dup	5.6	ND
CHEK1	c.676del	p.T226Hfs*14	5.4	ND
CHEK2	c.1116 1117delinsGT	p.K373*	5.8	ND
CTNNB1	c.121A>G	p.T41A	5.4	5.8
EGFR	c.2235 2249del	p.E746 A750del	6.1	4.6
EGFR	c.2236 2250del	p.E746 A750del	6.9	7.3
EGFR	c.2303G>T	p.S768I	6.6	4.8
EGFR	c.2310 2311insGGT	p.D770 N771insG	6.6	4.6
EGFR	c.2369C>T	p.T790M	7.4	5.1
EGFR	c.2389T>A	p.C797S	7.4	5.7
EGFR	c.2573T>G	p.L858R	5.7	5.5
ERBB2	c.2313 2324dup	p.Y772 A775dup	7.4	8.1
ESR1	c.1613A>G	p.D538G	7.1	8.2
EZH2	c.1937A>T	p.Y646F	6.4	5.7
FANCA	c.2778+1G>A	N/A	6.3	3.9
FANCL	c.1096 1099dup	p.T367fs	6.1	ND
FGFR3	c.746C>G	p.S249C	6.4	6.2
FOXL2	c.402C>G	p.C134W	7.1	6.5
HRAS	c.182A>G	p.Q61R	5.4	5.7
HRAS	c.37G>C	p.G13R	5.4	4.9
IDH1	c.394C>T	p.R132C	6.4	4.0
IDH2	c.515G>A	p.R172K	5.7	5.5
IDH2	c.419G>A	p.R140Q	5.0	5.3
KIT	c.2361+67 2361+72delTTTTTT	N/A	5.7	N/A
KIT	c.2447A>T	p.D816V	6.2	8.2
KRAS	c.183A>C	p.Q61H	5.9	7.0
KRAS	c.35G>A	p.G12D	5.1	5.3
KRAS	c.34G>T	p.G12C	5.8	5.3
MAP2K1	c.370C>T	p.P124S	6.4	7.0
MAP4K3	c.998-35 998-30delAAAAAA	N/A	5.9	N/A
MAP4K3	c.246-2475 246-2470delTTTTTT	N/A	5.5	N/A
MET	c.3082+1del	N/A	6.8	6.3
MLH1	c.232 243delinsATGTAAGG	p.E78 T81delinM*	6.1	4.2
MRE11	c.1100 1131del	p.V367fs	6.6	1.8
MSH2	c.942+20 942+29delAAAAAAAAAA	N/A	6.0	N/A
MSH2	c.1662-12 1677del	N/A	5.9	N/A

N/A = not assayed; not covered by NGS test panel

ND = not detected; further investigation revealed low coverage or sequence that is difficult to align.

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SNVs and Indels, continued

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MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	6.9	6.0
MTOR	c.6644C>A	p.S2215Y	5.3	6.2
NBN	c.1396del	p.R466fs	5.9	7.4
NF1	c.3738_3747del	p.F1247Gfs*16	6.9	2.7
NRAS	c.182A>G	p.Q61R	5.1	5.6
NTRK1	c.1783G>A	p.G595R	7.1	6.9
NTRK2	c.1915G>A	p.G639R	5.3	4.0
NTRK3	c.1867G>A	p.G623R	6.5	5.7
PALB2	c.839del	p.N280Tfs*8	6.2	4.9
PDGFRA	c.2525A>T	p.D842V	5.8	6.0
PIK3CA	c.1633G>A	p.E545K	5.6	7.0
PIK3CA	c.3140A>G	p.H1047R	6.5	6.8
PIK3CA	c.3203dup	p.N1068Kfs*5	6.5	8.3
PIK3R1	c.1727_1729del	p.T576del	6.3	6.3
PMS2	c.861_864del	p.R287Sfs*19	5.7	6.3
PTCH1	c.2307_2308delinsTT	p.R770*	5.3	7.1
PTEN	c.741dup	p.P248Tfs*5	4.9	4.6
PTEN	c.800del	p.K267Rfs*9	4.9	4.2
PTPN11	c.226G>A	p.E76K	N/T	7.0
RAD51C	c.242C>A	p.S81*	5.8	5.9
RAD51C	c.338dup	p.G114Wfs*25	5.8	4.8
RAD51D	c.392dup	p.N131Kfs*23	5.8	6.8
RAD51D	c.271A>T	p.K91*	5.8	4.8
RAD54L	c.636_637dup	p.K213fs	5.1	6.3
RAF1	c.770C>T	p.S257L	5.0	5.6
RB1	c.751C>T	p.R251*	5.1	5.1
RET	c.2753T>C	p.M918T	6.7	5.5
SLC7A8	c.-231_-224delTTTTTTTT	N/A	5.3	N/A
SMAD4	c.1394dup	p.A466Gfs*28	6.1	6.7
SMARCB1	c.118C>T	p.R40*	5.6	4.9
STK11	c.734+1G>T	N/A	6.0	5.2
TERT	c.-124C>T	N/A	5.5	6.9
TERT	c.-146C>T	N/A	5.5	7.8
TP53	c.818G>A	p.R273H	4.9	5.0
TP53	c.743G>A	p.R248Q	4.9	6.9
TP53	c.723del	p.C242Afs*5	4.9	7.2
TP53	c.524G>A	p.R175H	4.9	5.0
TP53	c.267del	p.S90Pfs*33	5.8	6.4
TSC1	c.1263+1G>T	N/A	6.5	5.8
TSC2	c.2640-1G>A	N/A	5.2	6.1
VHL	c.481C>T	p.R161*	6.2	6.1
ZNF2	c.*1525_*1530delTTTTTT	N/A	6.1	N/A

N/A = not assayed; not covered by NGS test panel

N/T = not tested; PTPN11 variant digital PCR assay not available.

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Structural Variants

Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	5.8	NR
CD74::ROS1	Intron 6::Intron 34	6.3	NR
COL1A1::PDGFB	Intron 25::Intron 1	5.5	N/A
EML4::ALK	Intron 13::Intron 19	5.9	NR
ETV6::NTRK3	Intron 5::Intron 14	5.3	N/A
FGFR2::BICC1	Intron 17::Intron 2	5.9	NR
FGFR3::TACC3	Exon 18::Intron 7	6.8	NR
NCOA4::RET	Intron 7::Intron 11	6.3	NR
PML::NTRK2	Intron 2::Intron 12	5.9	N/A
TPM3::NTRK1	Intron 7::Intron 9	6.0	NR

N/A = not assayed; not covered by NGS test panel

NR = not reported; vendor that performed TSO 500 testing did not report structural variants.

Copy Number Variants

Gene	dPCR Total Copies	NGS Total Copies
AKT2	7.8	7.8
CCND1	8.2	7.7
CCNE1	8.3	10.6
CDK4	8.3	11.0
ERBB2	7.8	9.3
FGF19	8.2	7.7
FGF3	8.3	8.8
FGF4	8.3	9.2
FGFR1	8.4	8.0
MET	8.6	13.1
MYC	8.0	8.5
MYCN	8.8	10.4

Approval:



Prepared By

19 May 2025

Date



QA Verified By

19 JUN 2025

Date