

Certificate of Analysis

Product Description: Seraseq® Tumor Mutation DNA Mix v3 AF10%
Material Number: 0710-3460 Batch Number: 10754907
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: 26 NOV 2028
Storage: -20 °C
Nominal Concentration: 25 ng/µL
Concentration (Qubit dsDNA BR Assay): 25.9 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	10.1	7.9
APC	c.4348C>T	p.R1450*	10.1	8.6
APC	c.4666dup	p.T1556Nfs*3	10.1	10.0
AR	c.2623C>T	p.H875Y	10.3	12.2
ARID1A	c.5548del	p.D1850Tfs*33	9.8	8.2
ATM	c.1058 1059del	p.C353Sfs*5	10.3	9.9
BARD1	c.1600 1634delinsGCG	p.T534fs	10.0	5.3
BRAF	c.1799T>A	p.V600E	9.9	10.1
BRCA1	c.1961del	p.K654Sfs*47	11.1	11.1
BRCA2	c.7934del	p.R2645Nfs*3	9.1	6.9
BRIP1	c.157dup	p.S53Kfs*16	9.8	10.0
CDK12	c.4382del	p.G1461Afs*38	9.7	9.4
CDKN2A	c.9 32dup	p.A4 P11dup	10.7	ND
CHEK1	c.676del	p.T226Hfs*14	10.3	ND
CHEK2	c.1116 1117delinsGT	p.K373*	9.6	ND
CTNNB1	c.121A>G	p.T41A	10.9	11.2
EGFR	c.2235 2249del	p.E746 A750del	10.1	8.8
EGFR	c.2236 2250del	p.E746 A750del	9.9	7.9
EGFR	c.2303G>T	p.S768I	9.8	7.0
EGFR	c.2310 2311insGGT	p.D770 N771insG	9.8	6.6
EGFR	c.2369C>T	p.T790M	9.8	7.3
EGFR	c.2389T>A	p.C797S	9.8	7.3
EGFR	c.2573T>G	p.L858R	11.0	12.3
ERBB2	c.2313 2324dup	p.Y772 A775dup	11.1	11.8
ESR1	c.1613A>G	p.D538G	11.1	6.5
EZH2	c.1937A>T	p.Y646F	9.9	8.1
FANCA	c.2778+1G>A	N/A	10.0	10.4
FANCL	c.1096 1099dup	p.T367fs	9.7	ND
FGFR3	c.746C>G	p.S249C	10.1	9.1
FOXL2	c.402C>G	p.C134W	10.5	9.4
HRAS	c.182A>G	p.Q61R	10.3	10.9
HRAS	c.37G>C	p.G13R	10.3	8.7
IDH1	c.394C>T	p.R132C	9.2	7.4
IDH2	c.515G>A	p.R172K	9.2	8.2
IDH2	c.419G>A	p.R140Q	9.7	9.2
KIT	c.2361+67 2361+72delTTTTTT	N/A	10.7	N/A
KIT	c.2447A>T	p.D816V	10.4	11.6
KRAS	c.183A>C	p.Q61H	9.5	9.5
KRAS	c.35G>A	p.G12D	10.1	8.7
KRAS	c.34G>T	p.G12C	9.3	6.3
MAP2K1	c.370C>T	p.P124S	9.6	9.0
MAP4K3	c.998-35 998-30delAAAAAA	N/A	9.5	N/A
MAP4K3	c.246-2475 246-2470delTTTTTT	N/A	10.4	N/A
MET	c.3082+1del	N/A	12.4	7.3
MLH1	c.232 243delinsATGTAAGG	p.E78 T81delinM*	9.4	5.2
MRE11	c.1100 1131del	p.V367fs	10.4	2.4
MSH2	c.942+20 942+29delAAAAAAAAAA	N/A	10.0	N/A
MSH2	c.1662-12 1677del	N/A	11.3	ND

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

Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	10.4	6.8
MTOR	c.6644C>A	p.S2215Y	10.4	10.9
NBN	c.1396del	p.R466fs	8.8	13.5
NF1	c.3738_3747del	p.F1247Gfs*16	10.1	4.5
NRAS	c.182A>G	p.Q61R	10.4	10.3
NTRK1	c.1783G>A	p.G595R	9.7	7.1
NTRK2	c.1915G>A	p.G639R	10.6	11.9
NTRK3	c.1867G>A	p.G623R	10.4	10.2
PALB2	c.839del	p.N280Tfs*8	9.3	6.1
PDGFRA	c.2525A>T	p.D842V	9.4	10.6
PIK3CA	c.1633G>A	p.E545K	9.9	6.5
PIK3CA	c.3140A>G	p.H1047R	10.4	10.5
PIK3CA	c.3203dup	p.N1068Kfs*5	10.4	10.0
PIK3R1	c.1727_1729del	p.T576del	9.9	6.4
PMS2	c.861_864del	p.R287Sfs*19	9.4	9.4
PTCH1	c.2307_2308delinsTT	p.R770*	10.4	10.4
PTEN	c.741dup	p.P248Tfs*5	10.2	12.1
PTEN	c.800del	p.K267Rfs*9	10.2	14.0
PTPN11	c.226G>A	p.E76K	N/T	12.4
RAD51C	c.242C>A	p.S81*	9.4	9.2
RAD51C	c.338dup	p.G114Wfs*25	9.4	9.0
RAD51D	c.392dup	p.N131Kfs*23	9.8	10.1
RAD51D	c.271A>T	p.K91*	9.8	10.0
RAD54L	c.636_637dup	p.K213fs	10.3	10.8
RAF1	c.770C>T	p.S257L	10.4	9.1
RB1	c.751C>T	p.R251*	10.6	9.8
RET	c.2753T>C	p.M918T	9.9	7.8
SLC7A8	c.-231_-224delTTTTTTTT	N/A	10.2	N/A
SMAD4	c.1394dup	p.A466Gfs*28	10.2	10.2
SMARCB1	c.118C>T	p.R40*	9.4	6.1
STK11	c.734+1G>T	N/A	10.0	6.8
TERT	c.-124C>T	N/A	10.8	8.5
TERT	c.-146C>T	N/A	10.8	10.5
TP53	c.818G>A	p.R273H	10.2	8.0
TP53	c.743G>A	p.R248Q	10.2	9.1
TP53	c.723del	p.C242Afs*5	10.2	9.7
TP53	c.524G>A	p.R175H	10.5	9.3
TP53	c.267del	p.S90Pfs*33	9.7	10.0
TSC1	c.1263+1G>T	N/A	10.0	9.3
TSC2	c.2640-1G>A	N/A	10.9	9.4
VHL	c.481C>T	p.R161*	10.4	9.2
ZNF2	c.*1525_*1530delTTTTTT	N/A	10.1	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	9.7	NR
CD74::ROS1	Intron 6::Intron 34	10.4	NR
COL1A1::PDGFB	Intron 25::Intron 1	9.3	N/A
EML4::ALK	Intron 13::Intron 19	10.0	NR
ETV6::NTRK3	Intron 5::Intron 14	8.9	N/A
FGFR2::BICC1	Intron 17::Intron 2	10.2	NR
FGFR3::TACC3	Exon 18::Intron 7	9.8	NR
NCOA4::RET	Intron 7::Intron 11	10.8	NR
PML::NTRK2	Intron 2::Intron 12	9.7	N/A
TPM3::NTRK1	Intron 7::Intron 9	9.4	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	14.2	12.7
CCND1	16.8	14.3
CCNE1	14.1	16.5
CDK4	14.5	15.9
ERBB2	13.8	15.5
FGF19	16.8	13.9
FGF3	14.6	13.6
FGF4	14.6	14.0
FGFR1	13.6	14.1
MET	13.4	24.8
MYC	13.4	13.0
MYCN	16.4	72.7 ^y

^yThe copy number measured by TSO 500 for MYCN was higher than expected; when analyzed by WGS, the total copy number was ~17.

Approval:



Prepared By

06 JUN 2025

Date



QA Verified By

19 JUN 2025

Date