

Certificate of Analysis

Product Description: Seraseq® Tumor Mutation DNA Mix v3 Tri-Level
Material Number: 0710-3462 Batch Number: 10754909
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: 28 JAN 2029
Storage: -20 °C
Nominal Concentration: 25 ng/µL
Concentration (Qubit dsDNA BR Assay): 26.0 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

4% Tier				
Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
ARID1A	c.5548del	p.D1850Tfs*33	3.9	4.2
BRAF	c.1799T>A	p.V600E	3.6	3.4
BRCA2	c.7934del	p.R2645Nfs*3	3.7	2.9
CDK12	c.4382del	p.G1461Afs*38	3.9	4.9
EGFR	c.2236_2250del	p.E746_A750del	3.9	3.5
EGFR	c.2303G>T	p.S768I	3.7	3.2
EGFR	c.2310_2311insGGT	p.D770_N771insG	3.7	3.3
EGFR	c.2369C>T	p.T790M	3.9	3.3
EGFR	c.2389T>A	p.C797S	3.9	2.9
ESR1	c.1613A>G	p.D538G	4.3	4.4
EZH2	c.1937A>T	p.Y646F	3.6	3.7
FANCA	c.2778+1G>A	N/A	3.6	4.3
FANCL	c.1096_1099dup	p.T367fs	3.5	ND
FGFR3	c.746C>G	p.S249C	4.2	2.8
FOXL2	c.402C>G	p.C134W	4.0	3.9
IDH1	c.394C>T	p.R132C	3.9	4.0
KRAS	c.34G>T	p.G12C	3.5	3.1
MAP2K1	c.370C>T	p.P124S	3.9	2.6
MLH1	c.232_243delinsATGTAAGG	p.E78_T81delinM*	3.7	3.0
MRE11	c.1100_1131del	p.V367fs	3.9	1.5
MSH6	c.2056_2060delinsCTTCTACCTCAAAAA	p.G686Lfs*10	4.2	3.3
NBN	c.1396del	p.R466fs	3.4	3.3
NF1	c.3738_3747del	p.F1247Gfs*16	3.9	2.3
NTRK1	c.1783G>A	p.G595R	4.3	2.3
PALB2	c.839del	p.N280Tfs*8	3.6	2.4
PIK3CA	c.3140A>G	p.H1047R	3.8	5.6
PIK3CA	c.3203dup	p.N1068Kfs*5	3.8	4.6
PIK3R1	c.1727_1729del	p.T576del	3.8	3.8
RAD51C	c.242C>A	p.S81*	3.5	2.7
RAD51C	c.338dup	p.G114Wfs*25	3.5	3.5
RET	c.2753T>C	p.M918T	4.0	3.2
TP53	c.267del	p.S90Pfs*33	3.7	3.9
TSC1	c.1263+1G>T	N/A	3.7	3.3

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

7% Tier				
Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AR	c.2623C>T	p.H875Y	5.1	7.3
BRCA1	c.1961del	p.K654Sfs*47	5.6	5.7
CDKN2A	c.9_32dup	p.A4_P11dup	5.3	ND
CHEK1	c.676del	p.T226Hfs*14	5.4	ND
CTNNB1	c.121A>G	p.T41A	5.3	5.7
EGFR	c.2573T>G	p.L858R	5.4	6.4
HRAS	c.182A>G	p.Q61R	5.3	5.3
HRAS	c.37G>C	p.G13R	5.3	5.1
IDH2	c.419G>A	p.R140Q	4.9	4.8
KIT	c.2361+67_2361+72delTTTTTT	N/A	5.6	N/A
KRAS	c.35G>A	p.G12D	5.1	4.6
MAP4K3	c.246-2475_246-2470delTTTTTT	N/A	5.2	N/A
MET	c.3082+1del	N/A	7.6	8.2
MSH2	c.1662-12_1677del	N/A	5.8	ND
MTOR	c.6644C>A	p.S2215Y	5.0	6.0
NRAS	c.182A>G	p.Q61R	5.2	6.6
NTRK2	c.1915G>A	p.G639R	5.2	7.1
PTCH1	c.2307_2308delinsTT	p.R770*	5.1	7.2
PTEN	c.741dup	p.P248Tfs*5	4.9	5.9
PTEN	c.800del	p.K267Rfs*9	4.9	7.3
PTPN11	c.226G>A	p.E76K	N/T	5.5
RAD54L	c.636_637dup	p.K213fs	5.1	6.1
RAF1	c.770C>T	p.S257L	5.0	6.7
RB1	c.751C>T	p.R251*	4.9	7.4
SLC7A8	c.-231_-224delTTTTTTTT	N/A	5.1	N/A
TERT	c.-124C>T	N/A	5.2	7.5
TERT	c.-146C>T	N/A	5.2	7.9
TP53	c.818G>A	p.R273H	4.9	4.2
TP53	c.743G>A	p.R248Q	4.9	5.8
TP53	c.723del	p.C242Afs*5	4.9	5.6
TP53	c.524G>A	p.R175H	4.9	5.3
TSC2	c.2640-1G>A	N/A	5.1	7.1

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

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SNVs and Indels, continued

10% Tier				
Gene	Nucleotide Change	Protein Change	dPCR VAF%	NGS VAF%
AKT1	c.49G>A	p.E17K	12.0	10.3
APC	c.4348C>T	p.R1450*	11.3	12.0
APC	c.4666dup	p.T1556Nfs*3	11.3	13.5
ATM	c.1058 1059del	p.C353Sfs*5	11.5	9.3
BARD1	c.1600 1634delinsGCG	p.T534fs	11.7	7.9
BRIP1	c.157dup	p.S53Kfs*16	11.5	14.8
CHEK2	c.1116 1117delinsGT	p.K373*	11.5	ND
EGFR	c.2235 2249del	p.E746 A750del	11.7	10.2
ERBB2	c.2313 2324dup	p.Y772 A775dup	11.2	11.9
IDH2	c.515G>A	p.R172K	10.6	12.0
KIT	c.2447A>T	p.D816V	11.8	14.9
KRAS	c.183A>C	p.Q61H	11.0	14.8
MAP4K3	c.998-35 998-30delAAAAAA	N/A	11.4	N/A
MSH2	c.942+20 942+29delAAAAAAAAAAAA	N/A	11.3	N/A
NTRK3	c.1867G>A	p.G623R	11.9	9.9
PDGFRA	c.2525A>T	p.D842V	10.9	10.3
PIK3CA	c.1633G>A	p.E545K	11.2	11.2
PMS2	c.861 864del	p.R287Sfs*19	11.4	13.1
RAD51D	c.392dup	p.N131Kfs*23	11.2	11.1
RAD51D	c.271A>T	p.K91*	11.2	11.5
SMAD4	c.1394dup	p.A466Gfs*28	12.0	14.7
SMARCB1	c.118C>T	p.R40*	10.9	12.1
STK11	c.734+1G>T	N/A	11.7	10.9
VHL	c.481C>T	p.R161*	11.8	13.4
ZNF2	c.*1525 *1530delTTTTTT	N/A	11.6	N/A

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Structural Variants

10% Tier			
Genes	Junction	dPCR AF%	NGS AF%
CD74::NRG1	Intron 6::Intron 5	11.7	NR
CD74::ROS1	Intron 6::Intron 34	12.2	NR
COL1A1::PDGFB	Intron 25::Intron 1	10.5	N/A
EML4::ALK	Intron 13::Intron 19	11.6	NR
ETV6::NTRK3	Intron 5::Intron 14	10.7	N/A
FGFR2::BICC1	Intron 17::Intron 2	11.8	NR
FGFR3::TACC3	Exon 18::Intron 7	11.8	NR
NCOA4::RET	Intron 7::Intron 11	12.0	NR
PML::NTRK2	Intron 2::Intron 12	11.3	N/A
TPM3::NTRK1	Intron 7::Intron 9	11.2	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

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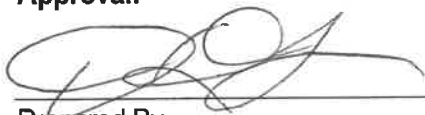
Copy Number Variants

+3 Copies Tier		
Gene	dPCR Total Copies	NGS Total Copies
ERBB2	5.0	6.0
MET	5.3	8.5

+6 Copies Tier		
Gene	dPCR Total Copies	NGS Total Copies
AKT2	8.5	8.6
CCNE1	8.5	10.9
CDK4	8.7	11.5
MYC	9.1	9.7

+12 Copies Tier		
Gene	dPCR Total Copies	NGS Total Copies
CCND1	18.3	17.3
FGF19	18.3	17.5
FGF3	16.3	17.4
FGF4	16.3	18.2
FGFR1	14.2	14.7
MYCN	15.9	18.2

Approval:



Prepared By

19 May 2025

Date



QA Verified By

19 JUN 2025

Date