

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® ctDNA Mutation Mix v2 AF0.125%		
Material Number:	0710-0143	Batch Number:	10818207
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:	01 JUL 2026	Expiration Date:	01 JUL 2030
Storage:	-20°C		
Concentration (Qubit dsDNA BR Assay):	13.4 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	158 bp		
Acceptance criteria for average fragment size:	140-200 bp		

Digital PCR testing using
BioRad QX200™ Droplet
Digital™ PCR System:

Gene ID	Nucleotide Change	Protein Change	AF%
AKT1	c.49G>A	p.E17K	0.16
APC	c.4348C>T	p.R1450*	0.18
APC	c.4666dup	p.T1556fs	0.11
ATM	c.1058_1059del	p.C353fs	0.16
BRAF	c.1799T>A	p.V600E	0.14
CTNNB1	c.121A>G	p.T41A	0.17
EGFR	c.2236_2250del	p.E746_A750del	0.17
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.18
EGFR	c.2369C>T	p.T790M	0.12
EGFR	c.2573T>G	p.L858R	0.18
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.14
FGFR3	c.746C>G	p.S249C	0.12
FLT3	c.2503G>T	p.D835Y	0.13
FOXL2	c.402C>G	p.C134W	0.14
GNA11	c.626A>T	p.Q209L	0.15
GNAQ	c.626A>C	p.Q209P	0.20
GNAS	c.601C>T	p.R201C	0.20
IDH1	c.394C>T	p.R132C	0.19
JAK2	c.1849G>T	p.V617F	0.12
KIT	c.2447A>T	p.D816V	0.13
KRAS	c.35G>A	p.G12D	0.15
MPL	c.1544G>T	p.W515L	0.14
NPM1	c.860_863dup	p.W288fs	0.10
NRAS	c.182A>G	p.Q61R	0.21
PDGFRA	c.1694_1695insA	p.S566fs	0.14
PDGFRA	c.2525A>T	p.D842V	0.14
PIK3CA	c.1633G>A	p.E545K	0.13
PIK3CA	c.3140A>G	p.H1047R	0.13
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.17
PTEN	c.741dup	p.P248fs	0.10
PTEN	c.800del	p.K267fs	0.10
RET	c.2753T>C	p.M918T	0.14
SMAD4	c.1394dup	p.A466fs	0.18
TP53	c.524G>A	p.R175H	0.20
TP53	c.723del	p.C242fs	0.16
TP53	c.743G>A	p.R248Q	0.20
TP53	c.818G>A	p.R273H	0.14
TP53	c.267del	p.S90fs	Not Tested ¹
NCOA4:RET	N/A	Translocation	0.13
TPR:ALK	N/A	Translocation	0.13

¹ NGS testing alone is used for QC of variant TP53 c.267del.

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Seraseq[®] ctDNA Mutation Mix v2 AF0.125%

Next Generation
Sequencing testing using
Archer[®] Reveal ctDNA[™]
28 Kit run on an
Illumina[®] NextSeq 2000
using v2 (2x150 bp) PE
chemistry reagents:

Gene	Nucleotide Change	Protein Change	AF%
AKT1	c.49G>A	p.E17K	0.16
BRAF	c.1799T>A	p.V600E	0.16
CTNNB1	c.121A>G	p.T41A	0.09
EGFR	c.2236_2250del	p.E746_A750del	0.11
EGFR	c.2310_2311insGGT	p.D770_N771insG	0.10
EGFR	c.2369C>T	p.T790M	0.15
EGFR	c.2573T>G	p.L858R	0.12
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.19
IDH1	c.394C>T	p.R132C	0.19
KIT	c.2447A>T	p.D816V	0.11
KRAS	c.35G>A	p.G12D	0.15
NRAS	c.182A>G	p.Q61R	0.21
PDGFRA	c.1694_1695insA	p.S566fs	0.28
PDGFRA	c.2525A>T	p.D842V	0.16
PIK3CA	c.1633G>A	p.E545K	0.18
PIK3CA	c.3140A>G	p.H1047R	0.14
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.09
RET	c.2753T>C	p.M918T	0.18
TP53	c.267del	p.S90fs	0.21
TP53	c.524G>A	p.R175H	0.21
TP53	c.723del	p.C242fs	0.19
TP53	c.743G>A	p.R248Q	0.25
TP53	c.818G>A	p.R273H	0.20

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Product Description: Seraseq® ctDNA Mutation Mix v2 AF0.125%
NGS was performed as an orthogonal verification step. Parameters used:

NGS Parameters:

DNA input = 50 ng

of samples / flow cell = 6

of total reads / sample = 14.9 M

Average read depth = 12486X

On-target reads = ~96%

Q30 score = ~91%

Analysis = Archer Analysis Suite v6.2.2

Default analysis settings except for the following:

- ERROR_CORRECTION is turned to ON (default=OFF; cfDNA pipeline)
- NORMALIZATION_LEVEL is set to 10000000 (default is 3500000; cfDNA pipeline)
- VARIANT_DOWNSTREAM_ROI_SIZE is set to 150 (default=400; cfDNA pipeline)

Approval:

A handwritten signature in black ink, appearing to be "MMA", written over a horizontal line.

31 JUL 2026

Prepared By

Date