

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	SeraSeq® ctDNA Complete Mutation Mix AF0.5%		
Material Number:	0710-0531	Batch Number:	10818523
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	25 µL		
Date of Manufacture:	17 JUL 2026	Expiration Date:	17 JUL 2030
Storage:	-20°C		
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 16.3 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	142 bp		
Acceptance criteria for average fragment size:	140 – 200 bp		

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

Gene ID	Nucleotide Change	Amino Acid Change	Average AF%
AKT1	c.49G>A	p.E17K	0.58
ALK	c.3522C>A	p.F1174L	0.48
ALK	c.3604G>A	p.G1202R	0.48
BRAF	c.1799T>A	p.V600E	0.55
BRCA1	c.1961del	p.K654fs	0.53
BRCA2	c.7934del	p.R2645fs	0.50
EGFR	c.2235_2249del	p.E746_A750del	0.60
EGFR	c.2240_2257del	p.L747_P753delinsS	0.47
EGFR	c.2254_2277del	p.S752_I759del	0.51
EGFR	c.2369C>T	p.T790M	0.48
EGFR	c.2573T>G	p.L858R	0.56
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.41
KIT	c.2447A>T	p.D816V	0.52
KRAS	c.183A>C	p.Q61H	0.49
KRAS	c.34G>T	p.G12C	0.45
KRAS	c.35G>A	p.G12D	0.57
NRAS	c.182A>G	p.Q61R	0.58
PIK3CA	c.3140A>G	p.H1047R	0.52
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.52
CD74/ROS1	NA	Translocation	0.53
EML4/ALK	NA	Translocation	0.48
NCOA4/RET	NA	Translocation	0.45

Gene ID	Average CNV in ctDNA ¹	Average Additional Copies (per cell) in ctDNA
ERBB2	2.31	0.31
MET	2.21	0.21
MYC	2.60	0.60

NA = not applicable

¹Compare to a normal CN of 2.00.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents¹:

Gene ID	Nucleotide Change	Amino Acid Change	AF%
AKT1	c.49G>A	p.E17K	0.55
ALK	c.3522C>A	p.F1174L	0.49
ALK	c.3604G>A	p.G1202R	0.49
BRAF	c.1799T>A	p.V600E	0.44
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	0.62
EGFR	c.2240_2257del	p.L747_P753delinsS	0.54
EGFR	c.2254_2277del	p.S752_I759del	0.51
EGFR	c.2369C>T	p.T790M	0.56
EGFR	c.2573T>G	p.L858R	0.44
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.29
KIT	c.2447A>T	p.D816V	0.58
KRAS	c.183A>C	p.Q61H	0.47
KRAS	c.34G>T	p.G12C	0.43
KRAS	c.35G>A	p.G12D	0.64
NRAS	c.182A>G	p.Q61R	0.32
PIK3CA	c.3140A>G	p.H1047R	0.42
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.30
CD74/ROS1	NA	Translocation	NA
NCOA4/RET	NA	Translocation	NA
EML4-ALK	NA	Translocation	NA

Gene ID	CNV in ctDNA ²	Additional Copies (per cell) in ctDNA
ERBB2	2.72	0.72
MET	2.14	0.14
MYC	NA	NA

NA = not applicable; AF% and CNV marked NA were not targeted by the panel.

¹NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng

of samples / flow cell = 8

of total reads / sample = 6.8M

Average read depth = 8714X

On-target reads = 96.4%

Q30 score = 92.89%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: NA)

²Compare to a normal CN of 2.00.

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Note: The MET gene is amplified using two synthetic constructs with a small region of overlap between the constructs (see package insert for genomic coordinates). Assays which target this region of overlap may report higher amplification levels.

Approval:

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

29 JUL 2026

Prepared By

Date