

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF0.1%		
Material Number:	0710-0532	Batch Number:	10809776
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:	06 APR 2026	Expiration Date:	06 APR 2030
Storage:	-20°C		
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 16.8 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	183 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	0.12
ALK	c.3522C>A	p.F1174L	0.10
ALK	c.3604G>A	p.G1202R	0.10
BRAF	c.1799T>A	p.V600E	0.10
BRCA1	c.1961del	p.K654fs	0.10
BRCA2	c.7934del	p.R2645fs	0.11
EGFR	c.2235_2249del	p.E746_A750del	0.12
EGFR	c.2240_2257del	p.L747_P753delinsS	0.11
EGFR	c.2254_2277del	p.S752_I759del	0.11
EGFR	c.2369C>T	p.T790M	0.12
EGFR	c.2573T>G	p.L858R	0.11
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.09
KIT	c.2447A>T	p.D816V	0.10
KRAS	c.183A>C	p.Q61H	0.11
KRAS	c.34G>T	p.G12C	0.09
KRAS	c.35G>A	p.G12D	0.12
NRAS	c.182A>G	p.Q61R	0.11
PIK3CA	c.3140A>G	p.H1047R	0.11
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.11
CD74/ROS1	NA	Translocation	0.11
EML4/ALK	NA	Translocation	0.08
NCOA4/RET	NA	Translocation	0.09

Gene ID	Average CNV in ctDNA ¹	Average Additional Copies (per cell) in ctDNA
ERBB2	2.18	0.18
MET	2.05	0.05
MYC	2.09	0.09

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	0.05
ALK	c.3522C>A	p.F1174L	0.08
ALK	c.3604G>A	p.G1202R	0.04
BRAF	c.1799T>A	p.V600E	0.14
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	0.12
EGFR	c.2240_2257del	p.L747_P753delinsS	0.10
EGFR	c.2254_2277del	p.S752_I759del	0.09
EGFR	c.2369C>T	p.T790M	0.11
EGFR	c.2573T>G	p.L858R	0.07
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.05
KIT	c.2447A>T	p.D816V	0.16
KRAS	c.183A>C	p.Q61H	0.10
KRAS	c.34G>T	p.G12C	0.14
KRAS	c.35G>A	p.G12D	0.12
NRAS	c.182A>G	p.Q61R	0.13
PIK3CA	c.3140A>G	p.H1047R	0.12
PIK3CA	c.3204_3205insA	p.N1068fs*4p	0.12
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	2.28	0.28
MET	ND	ND
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 = 2

of total reads / sample = 7.2M

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Average read depth = 6739X

On-target reads = 96.2%

Q30 score = 89.3%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: N/A)

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 blue ink, appearing to be 'M. H.', written over a horizontal line.

14 APR 2026

Prepared By

Date