Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 5%		
Material Number:	0710-0669	Batch Number:	10809331
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	5.0 mL		
Date of Manufacture:	24 MAR 2026	Expiration Date:	24 MAR 2030
Storage:	2-8°C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulation Nucleic Acid Kit: 29.4 ng/mL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	168bp		
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	4.88
ALK	c.3522C>A	p.F1174L	4.37
ALK	c.3604G>A	p.G1202R	4.37
BRAF	c.1799T>A	p.V600E	4.55
BRCA1	c.1961del	p.K654fs	4.56
BRCA2	c.7934del	p.R2645fs	4.65
EGFR	c.2235_2249del	p.E746_A750del	5.16
EGFR	c.2240_2257del	p.L747_P753delinsS	5.12
EGFR	c.2254_2277del	p.S752_I759del	5.15
EGFR	c.2369C>T	p.T790M	4.14
EGFR	c.2573T>G	p.L858R	4.56
ERBB2	c.2313_2324dup	p.Y772_A775dup	5.23
KIT	c.2447A>T	p.D816V	4.40
KRAS	c.183A>C	p.Q61H	4.33
KRAS	c.34G>T	p.G12C	4.25
KRAS	c.35G>A	p.G12D	4.68
NRAS	c.182A>G	p.Q61R	4.74
PIK3CA	c.3140A>G	p.H1047R	4.41
PIK3CA	c.3204_3205insA	p.N1068fs*4	4.41
CD74/ROS1	NA	Translocation	4.71
EML4/ALK	NA	Translocation	4.54
NCOA4/RET	NA	Translocation	4.09

Gene ID	Average CNV in ctDNA[1]	Average Additional Copies (per cell) in ctDNA
ERBB2	7.92	5.92
MET	6.27	4.27
MYC	6.85	4.85

NA = not applicable

[1] Compare to a normal CNV of 2.00.

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Product Description: Seraseq® ctDNA Complete Reference Material AF 5%

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents[1]

Gene ID	Nucleotide Change	Amino Acid Change	AF%
AKT1	c.49G>A	p.E17K	4.56
ALK	c.3522C>A	p.F1174L	3.89
ALK	c.3604G>A	p.G1202R	3.94
BRAF	c.1799T>A	p.V600E	4.05
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	4.31
EGFR	c.2240_2257del	p.L747_P753delinsS	4.21
EGFR	c.2254_2277del	p.S752_I759del	3.80
EGFR	c.2369C>T	p.T790M	4.02
EGFR	c.2573T>G	p.L858R	3.36
ERBB2	c.2313_2324dup	p.Y772_A775dup	5.17
KIT	c.2447A>T	p.D816V	4.51
KRAS	c.183A>C	p.Q61H	3.81
KRAS	c.34G>T	p.G12C	3.13
KRAS	c.35G>A	p.G12D	3.90
NRAS	c.182A>G	p.Q61R	4.02
PIK3CA	c.3140A>G	p.H1047R	4.05
PIK3CA	c.3204_3205insA	p.N1068fs*4	3.72
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	7.94	5.94
MET	8.20	6.20
MYC	NA	NA

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

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

DNA input = 50 ng
# of samples / flow cell = 3
# of total reads / sample = 21.2 M
Average read depth = 10918X
On-target reads = 97.4%
Q30 score = 84.8%
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: NA)

[2] Compare to a normal CNV 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:

25 March 2026

Prepared By Date