Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF5%		
Material Number:	0710-0528	Batch Number:	10809562
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:	24 MAR 2026	Expiration Date:	24 MAR 2030
Storage:	-20°C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 13.9 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	176 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	4.93
ALK	c.3522C>A	p.F1174L	5.26
ALK	c.3604G>A	p.G1202R	5.26
BRAF	c.1799T>A	p.V600E	5.55
BRCA1	c.1961del	p.K654fs	5.29
BRCA2	c.7934del	p.R2645fs	5.09
EGFR	c.2235_2249del	p.E746_A750del	5.33
EGFR	c.2240_2257del	p.L747_P753delinsS	5.31
EGFR	c.2254_2277del	p.S752_I759del	5.75
EGFR	c.2369C>T	p.T790M	5.56
EGFR	c.2573T>G	p.L858R	5.13
ERBB2	c.2313_2324dup	p.Y772_A775dup	5.12
KIT	c.2447A>T	p.D816V	4.99
KRAS	c.183A>C	p.Q61H	5.00
KRAS	c.34G>T	p.G12C	5.80
KRAS	c.35G>A	p.G12D	5.38
NRAS	c.182A>G	p.Q61R	5.75
PIK3CA	c.3140A>G	p.H1047R	5.12
PIK3CA	c.3204_3205insA	p.N1068fs*4	5.12
CD74/ROS1	NA	Translocation	4.99
EML4/ALK	NA	Translocation	5.11
NCOA4/RET	NA	Translocation	4.90

Gene ID	Average CNV in ctDNA[1]	Average Additional Copies (per cell) in ctDNA
ERBB2	8.13	6.13
MET	6.40	4.40
MYC	7.37	5.37

NA = not applicable

[1] Compare to a normal CN of 2.00.

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Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® NextSeq™ 2000 using v2 (2x150 bp) PE chemistry reagents[1]:

Gene ID	Nucleotide Change	Amino Acid Change	AF%
AKT1	c.49G>A	p.E17K	4.57
ALK	c.3522C>A	p.F1174L	4.60
ALK	c.3604G>A	p.G1202R	5.19
BRAF	c.1799T>A	p.V600E	6.51
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	4.54
EGFR	c.2240_2257del	p.L747_P753delinsS	4.91
EGFR	c.2254_2277del	p.S752_I759del	5.92
EGFR	c.2369C>T	p.T790M	5.78
EGFR	c.2573T>G	p.L858R	4.11
ERBB2	c.2313_2324dup	p.Y772_A775dup	4.63
KIT	c.2447A>T	p.D816V	5.56
KRAS	c.183A>C	p.Q61H	4.56
KRAS	c.34G>T	p.G12C	5.01
KRAS	c.35G>A	p.G12D	5.09
NRAS	c.182A>G	p.Q61R	5.22
PIK3CA	c.3140A>G	p.H1047R	5.16
PIK3CA	c.3204_3205insA	p.N1068fs*4	4.75
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	7.76	5.76
MET	7.96	5.96
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 = 9.7M
Average read depth = 17248X
On-target reads = 97.5%
Q30 score = 84.8%
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: Variant Downstream ROI Size of 150 and Rad depth Normalization of 10,000,000)

[2] Compare 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:

Shuang Yang 26 MAR 2026
Prepared By Date