Revised Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF1%		
Material Number:	0710-0530	Batch Number:	10771057
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:	07 AUG 2025	Expiration Date:	07 AUG 2029
Storage:	-20°C		
Concentration: (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 15.1 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	169 bp		
Acceptance criteria for average fragment size:	150 – 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	1.09
ALK	c.3522C>A	p.F1174L	0.86
ALK	c.3604G>A	p.G1202R	0.86
BRAF	c.1799T>A	p.V600E	1.06
BRCA1	c.1961del	p.K654fs	0.95
BRCA2	c.7934del	p.R2645fs	0.93
EGFR	c.2235_2249del	p.E746_A750del	0.91
EGFR	c.2240_2257del	p.L747_P753delinsS	1.19
EGFR	c.2254_2277del	p.S752_I759del	0.81
EGFR	c.2369C>T	p.T790M	0.97
EGFR	c.2573T>G	p.L858R	0.98
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.95
KIT	c.2447A>T	p.D816V	1.02
KRAS	c.183A>C	p.Q61H	0.95
KRAS	c.34G>T	p.G12C	0.94
KRAS	c.35G>A	p.G12D	1.11
NRAS	c.182A>G	p.Q61R	1.19
PIK3CA	c.3140A>G	p.H1047R	1.10
PIK3CA	c.3204_3205insA	p.N1068fs*4	1.04
CD74/ROS1	NA	Translocation	0.97
EML4/ALK	NA	Translocation	0.93
NCOA4/RET	NA	Translocation	0.76

Gene ID	Average CNV in ctDNA[1]	Average Additional Copies (per cell) in ctDNA
ERBB2	3.10	1.10
MET	2.70	0.70
MYC	2.84	0.84

NA = not applicable
[1]Compare 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 reagents[1]:

Gene ID	Nucleotide Change	Amino Acid Change	AF%
AKT1	c.49G>A	p.E17K	0.95
ALK	c.3522C>A	p.F1174L	0.89
ALK	c.3604G>A	p.G1202R	0.90
BRAF	c.1799T>A	p.V600E	1.07
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	0.84
EGFR	c.2240_2257del	p.L747_P753delinsS	0.92
EGFR	c.2254_2277del	p.S752_I759del	0.70
EGFR	c.2369C>T	p.T790M	1.20
EGFR	c.2573T>G	p.L858R	0.84
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.82
KIT	c.2447A>T	p.D816V	0.94
KRAS	c.183A>C	p.Q61H	0.79
KRAS	c.34G>T	p.G12C	0.94
KRAS	c.35G>A	p.G12D	1.08
NRAS	c.182A>G	p.Q61R	0.97
PIK3CA	c.3140A>G	p.H1047R	0.88
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.56
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	1.70	1.40
MET	1.52	1.00
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 = 6
# of total reads / sample = 13.6M
Average read depth = 11213X
On-target reads = 96.6%
Q30 score = 87.9%
Analysis = Archer Analysis Suite v6.2.2 (default settings except for: N/A)

[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:

Prepared By

20 April 2026
Date