

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:	10816836
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:	10 JUL 2026	Expiration Date:	10 JUL 2030
Storage:	-20°C		
Concentration:	Nominal value: 10 ng/µL		
(Qubit dsDNA BR Assay):	Average measured value: 20.2 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	163 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	1.04
ALK	c.3522C>A	p.F1174L	1.00
ALK	c.3604G>A	p.G1202R	1.00
BRAF	c.1799T>A	p.V600E	0.92
BRCA1	c.1961del	p.K654fs	0.99
BRCA2	c.7934del	p.R2645fs	1.02
EGFR	c.2235_2249del	p.E746_A750del	1.12
EGFR	c.2240_2257del	p.L747_P753delinsS	1.05
EGFR	c.2254_2277del	p.S752_I759del	1.04
EGFR	c.2369C>T	p.T790M	0.96
EGFR	c.2573T>G	p.L858R	1.02
ERBB2	c.2313_2324dup	p.Y772_A775dup	1.02
KIT	c.2447A>T	p.D816V	0.96
KRAS	c.183A>C	p.Q61H	0.75
KRAS	c.34G>T	p.G12C	0.94
KRAS	c.35G>A	p.G12D	1.04
NRAS	c.182A>G	p.Q61R	1.11
PIK3CA	c.3140A>G	p.H1047R	0.92
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.92
CD74/ROS1	NA	Translocation	0.94
EML4/ALK	NA	Translocation	0.93
NCOA4/RET	NA	Translocation	0.93

Gene ID	Average CNV in ctDNA ¹	Average Additional Copies (per cell) in ctDNA
ERBB2	3.50	1.50
MET	3.04	1.04
MYC	3.22	1.22

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	0.92
ALK	c.3522C>A	p.F1174L	0.78
ALK	c.3604G>A	p.G1202R	0.84
BRAF	c.1799T>A	p.V600E	0.97
BRCA1	c.1961del	p.K654fs	NA
BRCA2	c.7934del	p.R2645fs	NA
EGFR	c.2235_2249del	p.E746_A750del	0.91
EGFR	c.2240_2257del	p.L747_P753delinsS	0.80
EGFR	c.2254_2277del	p.S752_I759del	0.80
EGFR	c.2369C>T	p.T790M	1.03
EGFR	c.2573T>G	p.L858R	0.89
ERBB2	c.2313_2324dup	p.Y772_A775dup	0.73
KIT	c.2447A>T	p.D816V	0.64
KRAS	c.183A>C	p.Q61H	0.66
KRAS	c.34G>T	p.G12C	0.91
KRAS	c.35G>A	p.G12D	0.85
NRAS	c.182A>G	p.Q61R	0.94
PIK3CA	c.3140A>G	p.H1047R	0.79
PIK3CA	c.3204_3205insA	p.N1068fs*4	0.52
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	3.3	1.3
MET	3.2	1.2
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 = 6

of total reads / sample = 23.3M

Average read depth = 12491X

On-target reads = 97.1%

Q30 score = 90.5%

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

²Compare to a normal CN of 2.00.

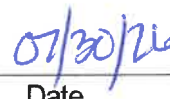
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Note: The MET gene is amplified using two synthetic constructs with a small region of overlap between the constructs (see package insert for genomic coordinates). Assays which target this region of overlap may report higher amplification levels.

Approval:

A handwritten signature in blue ink that reads "Patricia Helzel".A handwritten date in blue ink that reads "07/30/16".

Prepared By

Date