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:	10775745
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:	14 AUG 2025	Expiration Date:	14 AUG 2029
Storage:	-20°C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 15.2 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	157 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	COSMIC Identifier	Amino Acid Change	Average AF%
AKT1	COSM33765	p.E17K	4.46
BRAF	COSM476	p.V600E	4.73
EGFR	COSM6224	p.L858R	4.88
EGFR	COSM6240	p.T790M	5.02
ERBB2	COSM20959	p.A775_G776insYVMA	4.19
KIT	COSM1314	p.D816V	4.75
KRAS	COSM521	p.G12D	4.98
NCOA4/RET	NA	Translocation	4.78
NRAS	COSM584	p.Q61R	4.89
PIK3CA	COSM775	p.H1047R	4.87
PIK3CA	COSM12464[1]	p.N1068fs*4	4.87
EML4-ALK	NA	Translocation	4.67
ALK	COSM144250	p.G1202R	4.91
ALK	COSM28055	p.F1174L	4.91
BRCA1	COSM1383519	p.K654fs*47	4.75
BRCA2	COSM1738242	p.R2645fs*3	4.89
EGFR	COSM12370	p.L747_P753>S	5.47
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.39
EGFR	COSM6223	p.E746_A750delELREA	5.59
KRAS	COSM516	p.G12C	4.77
CD74/ROS1	NA	Translocation	5.04
KRAS	COSM554	p.Q61H	4.53

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	7.50	5.50
MET	5.75	3.75
MYC	6.64	4.64

NA = not applicable

[1]As of June 2019, this mutation is no longer listed in the COSMIC database.

[2]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	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	3.69
BRAF	COSM476	p.V600E	4.30
EGFR	COSM6224	p.L858R	4.23
EGFR	COSM6240	p.T790M	4.83
ERBB2	COSM20959	p.A775_G776insYVMA	3.79
KIT	COSM1314	p.D816V	5.15
KRAS	COSM521	p.G12D	4.24
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	4.68
PIK3CA	COSM775	p.H1047R	4.65
PIK3CA	COSM12464[2]	p.N1068fs*4	3.88
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	4.65
ALK	COSM28055	p.F1174L	4.74
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	4.69
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.06
EGFR	COSM6223	p.E746_A750delELREA	4.83
KRAS	COSM516	p.G12C	4.07
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	4.22

Gene ID	CNV in ctDNA[3]	Additional Copies (per cell) in ctDNA
ERBB2	6.88	4.88
MET	9.62	7.62
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 = 1
# of total reads / sample = 90M
Average read depth = 13871X
On-target reads = 86.7%
Q30 score = 89.3%
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]As of June 2019, this mutation is no longer listed in the COSMIC database.

[3]Compare to a normal CN of 2.00.

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.

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Approval:

Shuang Yang — Prepared By

25 AUG 2025 — Date