

# Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description: Seraseq® ctDNA Complete Mutation Mix AF0.5%

Material Number: 0710-0531                      Batch Number: 10601109

Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs

Concentration  
(Qubit dsDNA BR Assay): Nominal value: 10 ng/μL; Average measured value: 13.9 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 14 JAN 2022                      Expiration Date: 14 JAN 2024

Storage: -20°C

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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	0.51
BRAF	COSM476	p.V600E	0.48
EGFR	COSM6224	p.L858R	0.54
EGFR	COSM6240	p.T790M	0.46
ERBB2	COSM20959	p.A775_G776insYVMA	0.42
KIT	COSM1314	p.D816V	0.53
KRAS	COSM521	p.G12D	0.56
NCOA4/RET	NA	Translocation	0.56
NRAS	COSM584	p.Q61R	0.54
PIK3CA	COSM775	p.H1047R	0.55
PIK3CA	COSM12464 <sup>1</sup>	p.N1068fs*4	0.55
EML4-ALK	NA	Translocation	0.49
ALK	COSM144250	p.G1202R	0.56
ALK	COSM28055	p.F1174L	0.56
BRCA1	COSM1383519	p.K654fs*47	0.46
BRCA2	COSM1738242	p.R2645fs*3	0.50
EGFR	COSM12370	p.L747_P753>S	0.59
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.50
EGFR	COSM6223	p.E746_A750delELREA	0.64
KRAS	COSM516	p.G12C	0.52
CD74/ROS1	NA	Translocation	0.53
KRAS	COSM554	p.Q61H	0.56

Gene ID	Average CNV in ctDNA <sup>2</sup>	Average Additional Copies (per cell) in ctDNA
ERBB2	2.56	0.56
MET	2.41	0.41
MYC	2.37	0.37

NA = not applicable

<sup>1</sup>As of June 2019, this mutation is no longer listed in the COSMIC database.

<sup>2</sup>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<sup>1</sup>:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.73
BRAF	COSM476	p.V600E	0.55
EGFR	COSM6224	p.L858R	0.56
EGFR	COSM6240	p.T790M	0.42
ERBB2	COSM20959	p.A775_G776insYVMA	0.25
KIT	COSM1314	p.D816V	0.57
KRAS	COSM521	p.G12D	0.64
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.82
PIK3CA	COSM775	p.H1047R	0.52
PIK3CA	COSM12464 <sup>3</sup>	p.N1068fs*4	0.41
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.51
ALK	COSM28055	p.F1174L	0.35
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.58
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.41
EGFR	COSM6223	p.E746_A750delELREA	0.59
KRAS	COSM516	p.G12C	0.67
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.46

Gene ID	CNV in ctDNA <sup>4</sup>	Additional Copies (per cell) in ctDNA
ERBB2	2.68	0.68
MET	2.32	0.32
MYC	NA	NA

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

<sup>1</sup>NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng  
 # of samples / flow cell = 1  
 # of total reads / sample = 10M  
 Average read depth = 9100X  
 On-target reads = 95.8%  
 Q30 score = 90.0%

Analysis = Archer Analysis Suite v6.2.7 (default settings)

<sup>2</sup>Please see the poster from NIST for more information about assay sensitivity:

<https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018>

<sup>3</sup>As of June 2019, this mutation is no longer listed in the COSMIC database.

<sup>4</sup>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:

A handwritten signature in black ink, appearing to be "ERL".

20 JAN 2022

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Prepared By

Date