

# Technical Product Report

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

Product Description: Seraseq® ctDNA Complete Reference Material AF 5%  
 Material Number: 0710-0669 Batch Number: 10702080  
 Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs  
 Fill Volume: 5.0 mL  
 Date of Manufacture: 02 APR 2024 Expiration Date: 02 APR 2028  
 Storage: 2-8°C  
 Concentration (Qubit dsDNA BR Assay): Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulation Nucleic Acid Kit: 30 ng/mL  
 Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis): 151bp  
 Acceptance criteria for average fragment size: 150-200 bp

Digital PCR testing using BioRad QX200™ Droplet Digital™ PCR System:

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF%
AKT1	COSM33765	p.E17K	5.22
BRAF	COSM476	p.V600E	5.26
EGFR	COSM6224	p.L858R	5.30
EGFR	COSM6240	p.T790M	5.03
ERBB2	COSM20959	p.A775_G776insYVMA	5.12
KIT	COSM1314	p.D816V	5.18
KRAS	COSM521	p.G12D	5.35
NCOA4/RET	NA	Translocation	5.07
NRAS	COSM584	p.Q61R	5.47
PIK3CA	COSM775	p.H1047R	4.98
PIK3CA	COSM12464 <sup>1</sup>	p.N1068fs*4	4.98
EML4-ALK	NA	Translocation	4.58
ALK	COSM144250	p.G1202R	4.88
ALK	COSM28055	p.F1174L	4.88
BRCA1	COSM1383519	p.K654fs*47	4.79
BRCA2	COSM1738242	p.R2645fs*3	4.61
EGFR	COSM12370	p.L747_P753>S	6.02
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.14
EGFR	COSM6223	p.E746_A750delIELREA	5.72
KRAS	COSM516	p.G12C	5.28
CD74/ROS1	NA	Translocation	4.88
KRAS	COSM554	p.Q61H	4.89

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Gene ID	Average CNV in ctDNA <sup>2</sup>	Average Additional Copies (per cell) in ctDNA
ERBB2	7.67	5.67
MET	6.11	4.11
MYC	6.27	4.27

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 CNV 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>1,2</sup>:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	5.0
BRAF	COSM476	p.V600E	5.0
EGFR	COSM6224	p.L858R	4.0
EGFR	COSM6240	p.T790M	4.8
ERBB2	COSM20959	p.A775_G776insYVMA	4.1
KIT	COSM1314	p.D816V	5.9
KRAS	COSM521	p.G12D	5.7
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	5.7
PIK3CA	COSM775	p.H1047R	5.3
PIK3CA	COSM12464 <sup>3</sup>	p.N1068fs*4	5.2
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	4.7
ALK	COSM28055	p.F1174L	4.7
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	5.2
EGFR	COSM6256	p.S752_I759delSPKANKEI	4.5
EGFR	COSM6223	p.E746_A750delELREA	4.5
KRAS	COSM516	p.G12C	5.0
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	4.3

Gene ID	CNV in ctDNA <sup>4</sup>	Additional Copies (per cell) in ctDNA
ERBB2	6.22	4.22
MET	7.12	5.12
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:

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Product Description: Seraseq® ctDNA Complete Reference Material AF 5%

DNA input = 50 ng  
# of samples / flow cell = 7  
# of total reads / sample = 5.5M  
Average read depth = 10368X  
On-target reads = 96.7%  
Q30 score = 91.49%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: N/A)

<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 CNV 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.

Approval:



6/19/2024

Prepared By

Date

