



# Technical Product Report

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

Product Description: Seraseq® ctDNA Complete Reference Material AF 0.1%

Material Number: 0710-0673      Batch Number: 10694216

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: 08 APR 2024      Expiration Date: 08 APR 2028

Storage: 2-8 °C

Concentration (Qubit dsDNA BR Assay): Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 29 ng/mL

Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis): 179bp

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	0.118
BRAF	COSM476	p.V600E	0.104
EGFR	COSM6224	p.L858R	0.106
EGFR	COSM6240	p.T790M	0.116
ERBB2	COSM20959	p.A775_G776insYVMA	0.089
KIT	COSM1314	p.D816V	0.100
KRAS	COSM521	p.G12D	0.115
NCOA4/RET	NA	Translocation	0.094
NRAS	COSM584	p.Q61R	0.114
PIK3CA	COSM775	p.H1047R	0.106
PIK3CA	COSM12464 <sup>1</sup>	p.N1068fs*4	0.106
EML4-ALK	NA	Translocation	0.083
ALK	COSM144250	p.G1202R	0.100
ALK	COSM28055	p.F1174L	0.100
BRCA1	COSM1383519	p.K654fs*47	0.103
BRCA2	COSM1738242	p.R2645fs*3	0.106
EGFR	COSM12370	p.L747_P753>S	0.113
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.109
EGFR	COSM6223	p.E746_A750delELREA	0.120
KRAS	COSM516	p.G12C	0.089
CD74/ROS1	NA	Translocation	0.107
KRAS	COSM554	p.Q61H	0.106



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Gene ID	Average CNV in ctDNA <sup>2</sup>	Average Additional Copies (per cell) in ctDNA
ERBB2	1.22	0.44
MET	0.85	-0.3
MYC	N/A	N/A

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.

NGS was performed as an orthogonal verification step. Results confirm all variants were detected in the expected range given the parameters used for testing. Numerical data is not included for this product as assay sensitivity is not sufficient for confidence in measured AF values.

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>:

**NGS Parameters:**

- DNA input = 50ng
- # of samples / flow cell = 3
- # of total reads / sample = 5.6M
- Average read depth = 8939X
- On-target reads = 95.7%
- Q30 score = 88.5%
- Analysis = Archer Analysis Suite v6.2.7 (default settings)

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

<sup>1</sup>Please see the poster from NIST for more information about assay sensitivity:

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

**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

31 MAY 2024

Date