

# Technical Product Report

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

Product Description:	Seraseq <sup>®</sup> ctDNA Complete Reference Material AF 1%		
Material Number:	0710-0671	Batch Number:	10724377
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:	04 NOV 2024	Expiration Date:	04 NOV 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: 33.7 ng/mL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	143 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	0.97
BRAF	COSM476	p.V600E	1.00
EGFR	COSM6224	p.L858R	1.06
EGFR	COSM6240	p.T790M	1.00
ERBB2	COSM20959	p.A775_G776insYVMA	0.55
KIT	COSM1314	p.D816V	1.03
KRAS	COSM521	p.G12D	1.10
NCOA4/RET	NA	Translocation	0.97
NRAS	COSM584	p.Q61R	1.10
PIK3CA	COSM775	p.H1047R	1.09
PIK3CA	COSM12464 <sup>1</sup>	p.N1068fs*4	1.09
EML4-ALK	NA	Translocation	0.98
ALK	COSM144250	p.G1202R	0.95
ALK	COSM28055	p.F1174L	0.95
BRCA1	COSM1383519	p.K654fs*47	0.90
BRCA2	COSM1738242	p.R2645fs*3	1.01
EGFR	COSM12370	p.L747_P753>S	1.23
EGFR	COSM6256	p.S752_I759delSPKANKEI	1.09
EGFR	COSM6223	p.E746_A750delELREA	1.06
KRAS	COSM516	p.G12C	1.00
CD74/ROS1	NA	Translocation	0.96
KRAS	COSM554	p.Q61H	1.06

Gene ID	Average CNV in ctDNA <sup>2</sup>	Average Additional Copies (per cell) in ctDNA
ERBB2	2.92	0.92
MET	2.82	0.82
MYC	2.89	0.89

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.

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Product Description: Seraseq<sup>®</sup> ctDNA Complete Reference Material AF 1%

Next Generation Sequencing testing using Archer<sup>®</sup> Reveal ctDNA<sup>™</sup> 28 Kit run on an Illumina<sup>®</sup> MiSeq<sup>™</sup> using v2 (2x150 bp) PE chemistry reagents<sup>1</sup>

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	1.03
BRAF	COSM476	p.V600E	1.15
EGFR	COSM6224	p.L858R	0.78
EGFR	COSM6240	p.T790M	1.22
ERBB2	COSM20959	p.A775_G776insYVMA	0.42
KIT	COSM1314	p.D816V	1.13
KRAS	COSM521	p.G12D	0.86
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.96
PIK3CA	COSM775	p.H1047R	0.96
PIK3CA	COSM12464 <sup>2</sup>	p.N1068fs*4	0.83
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.91
ALK	COSM28055	p.F1174L	0.86
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.23
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.76
EGFR	COSM6223	p.E746_A750delELREA	1.32
KRAS	COSM516	p.G12C	1.02
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.82

Gene ID	CNV in ctDNA <sup>3</sup>	Additional Copies (per cell) in ctDNA
ERBB2	3.30	1.30
MET	3.06	1.06
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 = 2

# of total reads / sample = 1.48M

Average read depth = 4755X

On-target reads = 96.3%

Q30 score = 91.3%

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

<sup>2</sup>As of June 2019, this mutation is no longer listed in the COSMIC database.

<sup>3</sup>Compare to a normal CNV 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:**

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Prepared By TM Date 12/26/2024