

Technical Product Report - REVISED

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq[®] ctDNA Complete Reference Material AF 1%

Material Number: 0710-0671 Batch Number: 10634662

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: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 31.3 ng/mL

Fill Volume: 5.0 mL

Date of Manufacture: 24 AUG 2022 Expiration Date: 24 AUG 2025

Storage: 2-8°C

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

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF%
AKT1	COSM33765	p.E17K	1.06
BRAF	COSM476	p.V600E	1.02
EGFR	COSM6224	p.L858R	1.07
EGFR	COSM6240	p.T790M	0.99
ERBB2	COSM20959	p.A775_G776insYVMA	0.94
KIT	COSM1314	p.D816V	1.07
KRAS	COSM521	p.G12D	1.09
NCOA4/RET	NA	Translocation	1.03
NRAS	COSM584	p.Q61R	1.09
PIK3CA	COSM775	p.H1047R	1.09
PIK3CA	COSM12464 ¹	p.N1068fs*4	1.09
EML4-ALK	NA	Translocation	0.97
ALK	COSM144250	p.G1202R	1.03
ALK	COSM28055	p.F1174L	1.03
BRCA1	COSM1383519	p.K654fs*47	0.99
BRCA2	COSM1738242	p.R2645fs*3	0.94
EGFR	COSM12370	p.L747_P753>S	1.15
EGFR	COSM6256	p.S752_I759delSPKANKEI	1.06
EGFR	COSM6223	p.E746_A750delELREA	1.18
KRAS	COSM516	p.G12C	1.04
CD74/ROS1	NA	Translocation	1.02
KRAS	COSM554	p.Q61H	0.97

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	2.87	0.87
MET	2.68	0.68
MYC	3.07	1.07

NA = not applicable

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

²Compare 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^{1,2}:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	1.07
BRAF	COSM476	p.V600E	1.02
EGFR	COSM6224	p.L858R	0.70
EGFR	COSM6240	p.T790M	1.01
ERBB2	COSM20959	p.A775_G776insYVMA	0.58
KIT	COSM1314	p.D816V	1.27
KRAS	COSM521	p.G12D	1.11
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	1.17
PIK3CA	COSM775	p.H1047R	1.00
PIK3CA	COSM12464 ³	p.N1068fs*4	1.07
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.85
ALK	COSM28055	p.F1174L	0.87
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.14
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.89
EGFR	COSM6223	p.E746_A750delELREA	0.90
KRAS	COSM516	p.G12C	0.78
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.96

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	2.84	0.84
MET	2.68	0.68
MYC	NA	NA

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

¹NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng

of samples / flow cell = 6

of total reads / sample = 15M

Average read depth = 9508X

On-target reads = 96.5%

Q30 score = 93.3%

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

²Please see the poster from NIST for more information about assay sensitivity:

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

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

⁴Compare to a normal CNV of 2.00.

Technical Product Report - REVISED

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Reference Material AF 1%

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:

BK

03/29/2024

Prepared By

Date