



Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 0.5%		
Material Number:	0710-0672	Batch Number:	10690580
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:	03 APR 2024	Expiration Date:	03 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: 28.7 ng/mL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	179 bp		
Acceptance criteria for average fragment size:	150-200 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	0.49
BRAF	COSM476	p.V600E	0.56
EGFR	COSM6224	p.L858R	0.60
EGFR	COSM6240	p.T790M	0.58
ERBB2	COSM20959	p.A775_G776insYVMA	0.46
KIT	COSM1314	p.D816V	0.59
KRAS	COSM521	p.G12D	0.61
NCOA4/RET	NA	Translocation	0.50
NRAS	COSM584	p.Q61R	0.59
PIK3CA	COSM775	p.H1047R	0.59
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.54
EML4-ALK	NA	Translocation	0.54
ALK	COSM144250	p.G1202R	0.57
ALK	COSM28055	p.F1174L	0.57
BRCA1	COSM1383519	p.K654fs*47	0.55
BRCA2	COSM1738242	p.R2645fs*3	0.60
EGFR	COSM12370	p.L747_P753>S	0.57
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.58
EGFR	COSM6223	p.E746_A750delELREA	0.58
KRAS	COSM516	p.G12C	0.51
CD74/ROS1	NA	Translocation	0.56
KRAS	COSM554	p.Q61H	0.54

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	2.59	0.59
MET	2.44	0.44
MYC	2.74	0.74

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.

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AKT1	COSM33765	p.E17K	0.49
BRAF	COSM476	p.V600E	0.56
EGFR	COSM6224	p.L858R	0.56
EGFR	COSM6240	p.T790M	0.61
ERBB2	COSM20959	p.A775_G776insYVMA	0.30
KIT	COSM1314	p.D816V	0.72
KRAS	COSM521	p.G12D	0.53
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.46
PIK3CA	COSM775	p.H1047R	0.59
PIK3CA	COSM12464 ³	p.N1068fs*4	0.35
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.68
ALK	COSM28055	p.F1174L	0.61
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.63
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.47
EGFR	COSM6223	p.E746_A750delELREA	0.56
KRAS	COSM516	p.G12C	0.51
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.36

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	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	2.54	0.54
MET	2.6	0.6
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 = 5

of total reads / sample = `8.0M

Average read depth = 9177X

On-target reads = 96.1%

Q30 score = 91.6%

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>

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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:

B/R

04/23/2024

Prepared By

Date