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:	10593229
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: 29.0 ng/mL		
Fill Volume:	5.0 mL		
Date of Manufacture:	22 NOV 2021	Expiration Date:	22 NOV 2024
Storage:	2-8°C		

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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	0.47
BRAF	COSM476	p.V600E	0.52
EGFR	COSM6224	p.L858R	0.56
EGFR	COSM6240	p.T790M	0.46
ERBB2	COSM20959	p.A775_G776insYVMA	0.22
KIT	COSM1314	p.D816V	0.55
KRAS	COSM521	p.G12D	0.66
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.51
PIK3CA	COSM775	p.H1047R	0.48
PIK3CA	COSM12464[3]	p.N1068fs*4	0.45
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.55
ALK	COSM28055	p.F1174L	0.47
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.64
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.40
EGFR	COSM6223	p.E746_A750delELREA	0.67
KRAS	COSM516	p.G12C	0.56
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.48

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	2.78	0.78
MET	2.36	0.36
MYC	NA	NA

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

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

DNA input = 50 ng
# of samples / flow cell = 2
# of total reads / sample = 8M
Average read depth = 9500X
On-target reads = 95.7%
Q30 score = 94.5%
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: Variant Downstream ROI Size of 150 and Read Depth Normalization of 10,000,000)

[2]Please see the poster from NIST for more information about assay sensitivity: https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018

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

[4]Compare to a normal CNV of 2.00.

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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	0.51
BRAF	COSM476	p.V600E	0.48
EGFR	COSM6224	p.L858R	0.54
EGFR	COSM6240	p.T790M	0.46
ERBB2	COSM20959	p.A775_G776insYVMA	0.42
KIT	COSM1314	p.D816V	0.53
KRAS	COSM521	p.G12D	0.56
NCOA4/RET	NA	Translocation	0.56
NRAS	COSM584	p.Q61R	0.54
PIK3CA	COSM775	p.H1047R	0.55
PIK3CA	COSM12464[1]	p.N1068fs*4	0.55
EML4-ALK	NA	Translocation	0.49
ALK	COSM144250	p.G1202R	0.56
ALK	COSM28055	p.F1174L	0.56
BRCA1	COSM1383519	p.K654fs*47	0.46
BRCA2	COSM1738242	p.R2645fs*3	0.50
EGFR	COSM12370	p.L747_P753>S	0.59
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.50
EGFR	COSM6223	p.E746_A750delELREA	0.64
KRAS	COSM516	p.G12C	0.52
CD74/ROS1	NA	Translocation	0.53
KRAS	COSM554	p.Q61H	0.56

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	2.56	0.56
MET	2.41	0.41
MYC	2.37	0.37

NA = not applicable

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

[2]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:

	02 DEC 2021
Prepared By	Date