Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 2.5%		
Material Number:	0710-0670	Batch Number:	10557983
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: 30.4 ng/mL		
Fill Volume:	5.0 mL		
Date of Manufacture:	01 JUN 2021	Expiration Date:	01 JUN 2024
Storage:	2-8°C		

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

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

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF%
AKT1	COSM33765	p.E17K	2.63
BRAF	COSM476	p.V600E	2.59
EGFR	COSM6224	p.L858R	2.61
EGFR	COSM6240	p.T790M	2.49
ERBB2	COSM20959	p.A775_G776insYVMA	2.27
KIT	COSM1314	p.D816V	2.68
KRAS	COSM521	p.G12D	2.79
NCOA4/RET	NA	Translocation	2.51
NRAS	COSM584	p.Q61R	2.85
PIK3CA	COSM775	p.H1047R	2.54
PIK3CA	COSM12464[1]	p.N1068fs*4	2.54
EML4-ALK	NA	Translocation	2.47
ALK	COSM144250	p.G1202R	2.37
ALK	COSM28055	p.F1174L	2.37
BRCA1	COSM1383519	p.K654fs*47	2.29
BRCA2	COSM1738242	p.R2645fs*3	2.39
EGFR	COSM12370	p.L747_P753>S	3.04
EGFR	COSM6256	p.S752_I759delSPKANKEI	2.51
EGFR	COSM6223	p.E746_A750delELREA	2.97
KRAS	COSM516	p.G12C	2.69
CD74/ROS1	NA	Translocation	2.61
KRAS	COSM554	p.Q61H	2.35

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	4.64	2.64
MET	3.72	1.72
MYC	3.93	1.93

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.

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents1,2:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	1.98
BRAF	COSM476	p.V600E	3.05
EGFR	COSM6224	p.L858R	2.26
EGFR	COSM6240	p.T790M	3.02
ERBB2	COSM20959	p.A775_G776insYVMA	1.80
KIT	COSM1314	p.D816V	2.67
KRAS	COSM521	p.G12D	2.98
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	2.57
PIK3CA	COSM775	p.H1047R	2.64
PIK3CA	COSM12464[3]	p.N1068fs*4	2.18
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	1.98
ALK	COSM28055	p.F1174L	2.27
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	3.25
EGFR	COSM6256	p.S752_I759delSPKANKEI	3.08
EGFR	COSM6223	p.E746_A750delELREA	3.13
KRAS	COSM516	p.G12C	1.95
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	2.48

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	4.16	2.16
MET	4.54	2.54
MYC	NA	NA

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

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

[1]NGS was performed as an orthogonal verification step. Parameters used:
DNA input = 50 ng
# of samples / flow cell = 3
# of total reads / sample = 1.8M
Average read depth = 5111X
On-target reads = 94.6%
Q30 score = 92.7%
Analysis = Archer Analysis Suite v6.2.2 (default settings except for: error correction was on, MAPQ threshold for variant call was 10, minimum allele fraction for variant call of 0.00026, minimum base quality for variant call of 30, the normalization level was set to 10,000,000 and the variant downstream ROI size was set to 150.)

[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.

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	Date
	18 JUN 2021