Technical Product Report

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:	10426589
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: 29.8 ng/mL		
Fill Volume:	5.0 mL		
Date of Manufacture:	11 JUN 2019	Expiration Date:	11 JUN 2022
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
[1]As of June 2019, this mutation is no longer listed in the COSMIC database.
[2]Compare 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	0.97
BRAF	COSM476	p.V600E	0.97
EGFR	COSM6224	p.L858R	1.14
EGFR	COSM6240	p.T790M	1.01
ERBB2	COSM20959	p.A775_G776insYVMA	0.71
KIT	COSM1314	p.D816V	0.93
KRAS	COSM521	p.G12D	0.97
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.87
PIK3CA	COSM775	p.H1047R	0.83
PIK3CA	COSM12464[3]	p.N1068fs*4	0.93
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.92
ALK	COSM28055	p.F1174L	0.80
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.16
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.88
EGFR	COSM6223	p.E746_A750delELREA	1.06
KRAS	COSM516	p.G12C	1.03
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	1.12

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	2.80	0.80
MET	2.78	0.78
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 = 3
# of total reads / sample = 3.5 M
Average read depth = 6400X
On-target reads = 95.0%
Q30 score = 92.24%
Analysis = Archer Analysis Suite v5.1.7 (default settings except for: Error correction on, MAPQ threshold for variant call of 10, minimum allele fraction for variant call of 0.00025, minimum base quality for variant call of 30)

[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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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:

Prepared By

26 JUN 2019
Date