Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 5%		
Material Number:	0710-0669	Batch Number:	10438801
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: 31.4 ng/mL		
Fill Volume:	5.0 mL		
Date of Manufacture:	06 AUG 2019	Expiration Date:	06 AUG 2022
Storage:	2-8°C		

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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	5.22
BRAF	COSM476	p.V600E	5.26
EGFR	COSM6224	p.L858R	5.30
EGFR	COSM6240	p.T790M	5.03
ERBB2	COSM20959	p.A775_G776insYVMA	5.12
KIT	COSM1314	p.D816V	5.18
KRAS	COSM521	p.G12D	5.35
NCOA4/RET	NA	Translocation	5.07
NRAS	COSM584	p.Q61R	5.47
PIK3CA	COSM775	p.H1047R	4.98
PIK3CA	COSM12464[1]	p.N1068fs*4	4.98
EML4-ALK	NA	Translocation	4.58
ALK	COSM144250	p.G1202R	4.88
ALK	COSM28055	p.F1174L	4.88
BRCA1	COSM1383519	p.K654fs*47	4.79
BRCA2	COSM1738242	p.R2645fs*3	4.61
EGFR	COSM12370	p.L747_P753>S	6.02
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.14
EGFR	COSM6223	p.E746_A750delELREA	5.72
KRAS	COSM516	p.G12C	5.28
CD74/ROS1	NA	Translocation	4.88
KRAS	COSM554	p.Q61H	4.89

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	7.67	5.67
MET	6.11	4.11
MYC	6.27	4.27

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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Product Description: Seraseq® ctDNA Complete Reference Material AF 5%

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	4.81
BRAF	COSM476	p.V600E	5.18
EGFR	COSM6224	p.L858R	4.36
EGFR	COSM6240	p.T790M	5.49
ERBB2	COSM20959	p.A775_G776insYVMA	3.34
KIT	COSM1314	p.D816V	5.81
KRAS	COSM521	p.G12D	6.03
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	6.13
PIK3CA	COSM775	p.H1047R	4.65
PIK3CA	COSM12464[3]	p.N1068fs*4	3.28
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	3.72
ALK	COSM28055	p.F1174L	5.18
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	5.86
EGFR	COSM6256	p.S752_I759delSPKANKEI	6.06
EGFR	COSM6223	p.E746_A750delELREA	5.22
KRAS	COSM516	p.G12C	4.19
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	4.57

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	7.54	5.54
MET	8.22	6.22
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 = 2.1M
Average read depth = 6570X
On-target reads = 95.5%
Q30 score = 92.7%
Analysis = Archer Analysis Suite v5.1.7 (default settings except for: Error correction was on, MAPQ threshold for variant call was 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.

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[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

07 AUG 2019
Date