Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 0.1%		
Material Number:	0710-0673	Batch Number:	10439592
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: 33.1 ng/mL		
Fill Volume:	5.0 mL		
Date of Manufacture:	30 AUG 2019	Expiration Date:	30 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	0.118
BRAF	COSM476	p.V600E	0.104
EGFR	COSM6224	p.L858R	0.106
EGFR	COSM6240	p.T790M	0.116
ERBB2	COSM20959	p.A775_G776insYVMA	0.089
KIT	COSM1314	p.D816V	0.100
KRAS	COSM521	p.G12D	0.115
NCOA4/RET	NA	Translocation	0.094
NRAS	COSM584	p.Q61R	0.114
PIK3CA	COSM775	p.H1047R	0.106
PIK3CA	COSM12464[1]	p.N1068fs*4	0.106
EML4-ALK	NA	Translocation	0.083
ALK	COSM144250	p.G1202R	0.100
ALK	COSM28055	p.F1174L	0.100
BRCA1	COSM1383519	p.K654fs*47	0.103
BRCA2	COSM1738242	p.R2645fs*3	0.106
EGFR	COSM12370	p.L747_P753>S	0.113
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.109
EGFR	COSM6223	p.E746_A750delELREA	0.120
KRAS	COSM516	p.G12C	0.089
CD74/ROS1	NA	Translocation	0.107
KRAS	COSM554	p.Q61H	0.106

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	2.18	0.18
MET	2.05	0.05
MYC	2.09	0.09

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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NGS was performed as an orthogonal verification step. Results confirm all variants were detected in the expected range given the parameters used for testing. Numerical data is not included for this product as assay sensitivity is not sufficient for confidence in measured AF values.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents[1]:

NGS Parameters:

DNA input = 50 ng
# of samples / flow cell = 3
# of total reads / sample = 4.0M
Average read depth = 5147X
On-target reads = 93.9%
Q30 score = 92.9%
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)

NA = not applicable; AF% and CNV marked NA were not targeted by the panel.
[1]Please see the poster from NIST for more information about assay sensitivity: https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018

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

05 - SEP - 2019
Date