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: 10723440
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs
Fill Volume:	5.0 mL
Date of Manufacture:	09 OCT 2024 Expiration Date: 09 OCT 2028
Storage:	2-8°C
Concentration (Qubit dsDNA BR Assay):	Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 29.2 ng/mL
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	181bp
Acceptance criteria for average fragment size:	150-200 bp

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

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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.

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	2.13
BRAF	COSM476	p.V600E	2.29
EGFR	COSM6224	p.L858R	2.42
EGFR	COSM6240	p.T790M	2.51
ERBB2	COSM20959	p.A775_G776insYVMA	2.04
KIT	COSM1314	p.D816V	2.37
KRAS	COSM521	p.G12D	2.05
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	2.82
PIK3CA	COSM775	p.H1047R	2.27
PIK3CA	COSM12464[3]	p.N1068fs*4	2.75
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	2.46
ALK	COSM28055	p.F1174L	2.42
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	2.80
EGFR	COSM6256	p.S752_I759delSPKANKEI	2.53
EGFR	COSM6223	p.E746_A750delELREA	2.48
KRAS	COSM516	p.G12C	2.32
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	2.33

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

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	2.18	0.18
MET	2.26	0.26
MYC	NA	NA

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

1NGsS was performed as an orthogonal verification step. Parameters used:
DNA input = 50 ng
# of samples / flow cell = 3
# of total reads / sample = 7.08M
Average read depth = 7319X
On-target reads = 96.3%
Q30 score = 88.5%
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: N/A)

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

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

4Compare 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: 01 Nov 2024