Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF0.5%		
Material Number:	0710-0531	Batch Number:	10636957
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: 10 ng/µL; Average measured value: 14.4 ng/µL		
Fill Volume:	25 µL		
Date of Manufacture:	22 AUG 2022	Expiration Date:	22 AUG 2024
Storage:	-20°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	0.58
BRAF	COSM476	p.V600E	0.55
EGFR	COSM6224	p.L858R	0.56
EGFR	COSM6240	p.T790M	0.48
ERBB2	COSM20959	p.A775_G776insYVMA	0.41
KIT	COSM1314	p.D816V	0.52
KRAS	COSM521	p.G12D	0.57
NCOA4/RET	NA	Translocation	0.45
NRAS	COSM584	p.Q61R	0.58
PIK3CA	COSM775	p.H1047R	0.52
PIK3CA	COSM12464[1]	p.N1068fs*4	0.52
EML4-ALK	NA	Translocation	0.48
ALK	COSM144250	p.G1202R	0.48
ALK	COSM28055	p.F1174L	0.48
BRCA1	COSM1383519	p.K654fs*47	0.53
BRCA2	COSM1738242	p.R2645fs*3	0.50
EGFR	COSM12370	p.L747_P753>S	0.47
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.51
EGFR	COSM6223	p.E746_A750delELREA	0.60
KRAS	COSM516	p.G12C	0.45
CD74/ROS1	NA	Translocation	0.53
KRAS	COSM554	p.Q61H	0.49

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	2.31	0.31
MET	2.21	0.21
MYC	2.60	0.60

NA = not applicable
[1]As of June 2019, this mutation is no longer listed in the COSMIC database.
[2]Compare to a normal CN 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]:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.49
BRAF	COSM476	p.V600E	0.63
EGFR	COSM6224	p.L858R	0.34
EGFR	COSM6240	p.T790M	0.48
ERBB2	COSM20959	p.A775_G776insYVMA	0.20
KIT	COSM1314	p.D816V	0.65
KRAS	COSM521	p.G12D	0.39
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.56
PIK3CA	COSM775	p.H1047R	0.59
PIK3CA	COSM12464[3]	p.N1068fs*4	0.45
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.40
ALK	COSM28055	p.F1174L	0.44
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.50
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.44
EGFR	COSM6223	p.E746_A750delELREA	0.74
KRAS	COSM516	p.G12C	0.46
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.30

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	2.70	0.70
MET	2.16	0.16
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 = 1
# of total reads / sample = 10M
Average read depth = 9845X
On-target reads = 96%
Q30 score = 90%
Analysis = Archer Analysis Suite v6.2.7 (default settings)
[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 CN of 2.00.

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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 09/15/2022