Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF1%		
Material Number:	0710-0530	Batch Number:	10456864
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:	10 JAN 2020	Expiration Date:	11 MAY 2021
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	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 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	1.07
BRAF	COSM476	p.V600E	1.33
EGFR	COSM6224	p.L858R	0.80
EGFR	COSM6240	p.T790M	1.17
ERBB2	COSM20959	p.A775_G776insYVMA	0.72
KIT	COSM1314	p.D816V	1.32
KRAS	COSM521	p.G12D	1.46
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	1.33
PIK3CA	COSM775	p.H1047R	1.11
PIK3CA	COSM12464[3]	p.N1068fs*4	1.19
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	1.14
ALK	COSM28055	p.F1174L	1.03
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.09
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.96
EGFR	COSM6223	p.E746_A750delELREA	0.77
KRAS	COSM516	p.G12C	0.81
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.84

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	3.02	1.02
MET	2.80	0.80
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 = 4.54M
Average read depth = 4912X
On-target reads = 95.3%
Q30 score = 92.2%
Analysis = Archer Analysis Suite v6.2.2 (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

04 FEB 2020

Date