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:	10482529
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: 13.5 ng/µL		
Fill Volume:	25 µL		
Date of Manufacture:	15 APR 2020	Expiration Date:	15 APR 2022
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® LiquidPlex™ 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	1.02
BRAF	COSM476	p.V600E	1.00
EGFR	COSM6224	p.L858R	0.91
EGFR	COSM6240	p.T790M	1.40
ERBB2	COSM20959	p.A775_G776insYVMA	0.66
KIT	COSM1314	p.D816V	1.08
KRAS	COSM521	p.G12D	1.18
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	1.24
PIK3CA	COSM775	p.H1047R	1.11
PIK3CA	COSM12464[3]	p.N1068fs*4	0.94
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.90
ALK	COSM28055	p.F1174L	0.80
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.08
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.83
EGFR	COSM6223	p.E746_A750delELREA	1.08
KRAS	COSM516	p.G12C	1.28
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.82

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	2.26	0.26
MET	3.40	1.40
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 = 4.4M
Average read depth = ~9500X
On-target reads = 94.6%
Q30 score = 90.3%
Analysis = Archer Analysis Suite v5.1.7 (default settings except for: Error correction was on, the MAPQ threshold for variant call was 10, the minimum alignment score was 10, the minimum base quality for variant call was 30, and outlier detection was off)
[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 CN 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

04/21/2020
Date