Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix WT		
Material Number:	0710-0533	Batch Number:	10521929
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL; Average measured value: 14.4 ng/µL		
Fill Volume:	25 µL		
Date of Manufacture:	28 OCT 2020	Expiration Date:	28 OCT 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%[1]
AKT1	COSM33765	p.E17K	0.005
BRAF	COSM476	p.V600E	0.000
EGFR	COSM6224	p.L858R	0.001
EGFR	COSM6240	p.T790M	0.009
ERBB2	COSM20959	p.A775_G776insYVMA	0.007
KIT	COSM1314	p.D816V	0.002
KRAS	COSM521	p.G12D	0.012
NCOA4/RET	NA	Translocation	0.000
NRAS	COSM584	p.Q61R	0.006
PIK3CA	COSM775	p.H1047R	0.006
PIK3CA	COSM12464[2]	p.N1068fs*4	0.006
EML4-ALK	NA	Translocation	0.001
ALK	COSM144250	p.G1202R	0.000
ALK	COSM28055	p.F1174L	0.000
BRCA1	COSM1383519	p.K654fs*47	0.001
BRCA2	COSM1738242	p.R2645fs*3	0.000
EGFR	COSM12370	p.L747_P753>S	0.000
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.001
EGFR	COSM6223	p.E746_A750delELREA	0.008
KRAS	COSM516	p.G12C	0.001
CD74/ROS1	NA	Translocation	0.000
KRAS	COSM554	p.Q61H	0.004

NA = not applicable

[1] Variant allele frequencies > 0.00% for this wild-type negative control are within the expected range for stochastic positive dPCR reactions.

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

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NGS was performed as an orthogonal verification step. Results confirm no variants were detected above 0.1%.

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 = 2
# of total reads / sample = 3.89M
Average read depth = 7939X
On-target reads = 94.1%
Q30 score = 94.5%
Analysis = Archer Analysis Suite v6.2.3 (default settings except for:

- ERROR_CORRECTION is turned to ON (default=OFF; cfDNA pipeline)
- MIN_ALLELE_FRACTION_FOR_VARIANT_CALL is set to 0.0001 (default=0.001)
- NORMALIZATION_LEVEL is set to 10000000 (default is 3500000; cfDNA pipeline))

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

Note: Copy numbers of ERBB2 and MET were assayed by dPCR and found to be normal. They were not assayed by NGS as the wild-type sample is used as a normal control for determining copy number of genes in other samples.

Approval:

Catherine Huang
Prepared By

05 NOV 2020
Date