Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq™ ctDNA Complete™ Mutation Mix AF 0.1%		
Material No:	0710-0532	Batch No:	10346889
Material Description:	Mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Date of Manufacture:	14May2018	Expiration Date:	14May2020
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL; Average measured value: 14.4 ng/µL		
Volume:	25 µL		
Storage:	-20 °C		

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.118
BRAF	COSM476	p.V600E	0.104
EGFR	COSM6224	p.L858R	0.106
EGFR	COSM6240	p.T790M	0.116
ERBB2	COSM682/20959	p.A775_G776insYVMA	0.089
KIT	COSM1314	p.D816V	0.100
KRAS	COSM521	p.G12D	0.115
NCOA4/RET	NA	Translocation	0.094
NRAS	COSM584	p.Q61R	0.114
PIK3CA	COSM775	p.H1047R	0.106
PIK3CA	COSM12464	p.N1068fs*4	0.106
EML4-ALK	NA	Translocation	0.083
ALK	COSM144250	p.G1202R	0.100
ALK	COSM28055	p.F1174L	0.100
BRCA1	COSM1383519	p.K654fs*47	0.103
BRCA2	COSM1738242	p.R2645fs*3	0.106
EGFR	COSM12370	p.L747_P753>S	0.113
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.109
EGFR	COSM6223	p.E746_A750delELREA	0.120
KRAS	COSM516	p.G12C	0.089
CD74/ROS1	NA	Translocation	0.107
KRAS	COSM554	p.Q61H	0.106
		Average AF%	**0.105**

Digital PCR testing using BioRad QX200™ Droplet Digital™ PCR System:

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	2.18	0.18	90
MET	2.05	0.05	25
MYC	2.09	0.09	45

NA = not applicable

[1]Compare to a normal CNV of 2.00.

[2]Calculated based on the ctDNA fraction of 0.2%. Values are within the noise of the copy number changes and just above normal diploid copy number resulting in variability.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents[4]:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%[1]
AKT1	COSM33765	p.E17K	0.110
BRAF	COSM476	p.V600E	0.200
EGFR	COSM6224	p.L858R	0.100
EGFR	COSM6240	p.T790M	0.190
ERBB2	COSM682/20959	p.A775_G776insYVMA	ND
KIT	COSM1314	p.D816V	0.210
KRAS	COSM521	p.G12D	ND
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.070
PIK3CA	COSM775	p.H1047R	0.200
PIK3CA	COSM12464	p.N1068fs*4	ND
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.140
ALK	COSM28055	p.F1174L	0.180
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.100
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.220
EGFR	COSM6223	p.E746_A750delELREA	0.120
KRAS	COSM516	p.G12C	0.140
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.120

Gene ID	CNV in ctDNA[2]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[3]
ERBB2	2.12	0.12	60
MET	2.06	0.06	30
MYC	NA	NA	NA

ND = not detected
NA = not applicable; AF% and CNV marked NA were not targeted by the panel.
[1]Results presented in this table represent a single QC test run. Variants listed as ND here were detected in other rounds of QC testing. Stochastic failures are expected for this 0.1% allele frequency tier under the run conditions used for testing.
[2]Compare to a normal CNV of 2.00.
[3]Calculated based on the ctDNA fraction of 0.2%. Values are within the noise of the copy number changes and just above normal diploid copy number resulting in variability.
[4]NGS was performed using 50 ng input with 4-5M reads per sample (3-4 samples per flow cell). Resulting data had a Q30 score of ~95%, ~8400X average read depth for the variants reported, and about 94% reads on target.

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

03/21/19
Date