Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq™ ctDNA Complete™ Mutation Mix AF 0.5%		
Material No:	0710-0531	Batch No:	10346888
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: 14.8 ng/µL		
Volume:	25 µL		
Storage:	-20 °C		

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

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.51
BRAF	COSM476	p.V600E	0.48
EGFR	COSM6224	p.L858R	0.54
EGFR	COSM6240	p.T790M	0.46
ERBB2	COSM682/20959	p.A775_G776insYVMA	0.42
KIT	COSM1314	p.D816V	0.53
KRAS	COSM521	p.G12D	0.56
NCOA4/RET	NA	Translocation	0.56
NRAS	COSM584	p.Q61R	0.54
PIK3CA	COSM775	p.H1047R	0.55
PIK3CA	COSM12464	p.N1068fs*4	0.55
EML4-ALK	NA	Translocation	0.49
ALK	COSM144250	p.G1202R	0.56
ALK	COSM28055	p.F1174L	0.56
BRCA1	COSM1383519	p.K654fs*47	0.46
BRCA2	COSM1738242	p.R2645fs*3	0.50
EGFR	COSM12370	p.L747_P753>S	0.59
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.50
EGFR	COSM6223	p.E746_A750delELREA	0.64
KRAS	COSM516	p.G12C	0.52
CD74/ROS1	NA	Translocation	0.53
KRAS	COSM554	p.Q61H	0.56
		Average AF%	**0.53**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	2.56	0.56	56
MET	2.41	0.41	41
MYC	2.37	0.37	37

NA = not applicable

[1] Compare to a normal CNV of 2.00.

[2] Calculated based on the ctDNA fraction of 1%.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents[3]:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.72
BRAF	COSM476	p.V600E	0.70
EGFR	COSM6224	p.L858R	0.54
EGFR	COSM6240	p.T790M	0.64
ERBB2	COSM682/20959	p.A775_G776insYVMA	0.33
KIT	COSM1314	p.D816V	0.81
KRAS	COSM521	p.G12D	0.65
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.58
PIK3CA	COSM775	p.H1047R	0.54
PIK3CA	COSM12464	p.N1068fs*4	0.61
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.70
ALK	COSM28055	p.F1174L	0.57
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.65
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.75
EGFR	COSM6223	p.E746_A750delELREA	0.72
KRAS	COSM516	p.G12C	0.71
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.42
		Average AF%	**0.63**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	2.58	0.58	58
MET	2.76	0.76	76
MYC	NA	NA	NA

NA = not applicable; AF% and CNV marked NA were not targeted by the panel.

[1] Compare to a normal CNV of 2.00.

[2] Calculated based on the ctDNA fraction of 1%.

[3] 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%, ~8200X 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