Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq™ ctDNA Complete™ Mutation Mix AF 2.5%		
Material No:	0710-0529	Batch No:	10346886
Material Description:	Mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Date of Manufacture:	11May2018	Expiration Date:	11May2020
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL; Average measured value: 14.6 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	2.63
BRAF	COSM476	p.V600E	2.59
EGFR	COSM6224	p.L858R	2.61
EGFR	COSM6240	p.T790M	2.49
ERBB2	COSM682/20959	p.A775_G776insYVMA	2.27
KIT	COSM1314	p.D816V	2.68
KRAS	COSM521	p.G12D	2.79
NCOA4/RET	NA	Translocation	2.51
NRAS	COSM584	p.Q61R	2.85
PIK3CA	COSM775	p.H1047R	2.54
PIK3CA	COSM12464	p.N1068fs*4	2.54
EML4-ALK	NA	Translocation	2.47
ALK	COSM144250	p.G1202R	2.37
ALK	COSM28055	p.F1174L	2.37
BRCA1	COSM1383519	p.K654fs*47	2.29
BRCA2	COSM1738242	p.R2645fs*3	2.39
EGFR	COSM12370	p.L747_P753>S	3.04
EGFR	COSM6256	p.S752_I759delSPKANKEI	2.51
EGFR	COSM6223	p.E746_A750delELREA	2.97
KRAS	COSM516	p.G12C	2.69
CD74/ROS1	NA	Translocation	2.61
KRAS	COSM554	p.Q61H	2.35
		Average AF%	**2.57**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	4.64	2.64	53
MET	3.72	1.72	34
MYC	3.93	1.93	39

NA = not applicable

[1] Compare to a normal CNV of 2.00.

[2] Calculated based on the ctDNA fraction of 5%.

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	2.35
BRAF	COSM476	p.V600E	2.65
EGFR	COSM6224	p.L858R	2.28
EGFR	COSM6240	p.T790M	3.08
ERBB2	COSM682/20959	p.A775_G776insYVMA	1.64
KIT	COSM1314	p.D816V	2.60
KRAS	COSM521	p.G12D	2.09
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.24
PIK3CA	COSM775	p.H1047R	2.65
PIK3CA	COSM12464	p.N1068fs*4	2.85
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	2.23
ALK	COSM28055	p.F1174L	2.46
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	3.32
EGFR	COSM6256	p.S752_I759delSPKANKEI	2.97
EGFR	COSM6223	p.E746_A750delELREA	3.45
KRAS	COSM516	p.G12C	2.47
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	2.18
		Average AF%	**2.44**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	4.02	2.02	40
MET	5.12	3.12	62
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 5%.

[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%, ~7000X 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