Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq™ ctDNA Complete™ Mutation Mix AF 5%		
Material No:	0710-0528	Batch No:	10346885
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: 13.4 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	5.22
BRAF	COSM476	p.V600E	5.26
EGFR	COSM6224	p.L858R	5.3
EGFR	COSM6240	p.T790M	5.03
ERBB2	COSM682/20959	p.A775_G776insYVMA	5.12
KIT	COSM1314	p.D816V	5.18
KRAS	COSM521	p.G12D	5.35
NCOA4/RET	NA	Translocation	5.07
NRAS	COSM584	p.Q61R	5.47
PIK3CA	COSM775	p.H1047R	4.98
PIK3CA	COSM12464	p.N1068fs*4	4.98
EML4-ALK	NA	Translocation	4.58
ALK	COSM144250	p.G1202R	4.88
ALK	COSM28055	p.F1174L	4.88
BRCA1	COSM1383519	p.K654fs*47	4.79
BRCA2	COSM1738242	p.R2645fs*3	4.61
EGFR	COSM12370	p.L747_P753>S	6.02
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.14
EGFR	COSM6223	p.E746_A750delELREA	5.72
KRAS	COSM516	p.G12C	5.28
CD74/ROS1	NA	Translocation	4.88
KRAS	COSM554	p.Q61H	4.89
		Average AF%	**5.12**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	7.67	5.67	57
MET	6.11	4.11	41
MYC	6.27	4.27	43

NA = not applicable

[1] Compare to a normal CNV of 2.00.

[2] Calculated based on the ctDNA fraction of 10%.

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	5.23
BRAF	COSM476	p.V600E	5.40
EGFR	COSM6224	p.L858R	4.49
EGFR	COSM6240	p.T790M	5.72
ERBB2	COSM682/20959	p.A775_G776insYVMA	3.36
KIT	COSM1314	p.D816V	5.77
KRAS	COSM521	p.G12D	5.10
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	5.70
PIK3CA	COSM775	p.H1047R	5.49
PIK3CA	COSM12464	p.N1068fs*4	5.02
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	3.92
ALK	COSM28055	p.F1174L	4.93
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	6.90
EGFR	COSM6256	p.S752_I759delSPKANKEI	6.93
EGFR	COSM6223	p.E746_A750delELREA	6.33
KRAS	COSM516	p.G12C	4.05
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	5.09
		Average AF%	**5.26**

Gene ID	CNV in ctDNA[1]	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell[2]
ERBB2	6.36	4.36	44
MET	8.48	6.48	65
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 10%.

[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%, ~9600X 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