Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq™ ctDNA Complete Mutation Mix WT		
Material No:	0710-0533	Batch No:	10346890
Material Description:	Human genomic DNA from the reference cell line, GM24385		
Date of Manufacture:	14May2018	Expiration Date:	14May2020
Concentration (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL; Average measured value: 14.3 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%[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	COSM682/20959	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	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
		Average AF%	**0.003**

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.

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

No variants were called above statistical background. 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%, ~9500X average read depth for the variants reported, and about 94% reads on target.

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:

Prepared By

03/21/19

Date