

# Technical Product Report

*For Research Use Only; Not for use in Diagnostic Procedures*

Product Description: Seraseq™ ctDNA Complete™ Mutation Mix AF 1%

Material No: 0710-0530

Batch No: 10346887

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: 14.1 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	1.06
BRAF	COSM476	p.V600E	1.02
EGFR	COSM6224	p.L858R	1.07
EGFR	COSM6240	p.T790M	0.99
ERBB2	COSM682/20959	p.A775_G776insYVMA	0.94
KIT	COSM1314	p.D816V	1.07
KRAS	COSM521	p.G12D	1.09
NCOA4/RET	NA	Translocation	1.03
NRAS	COSM584	p.Q61R	1.09
PIK3CA	COSM775	p.H1047R	1.09
PIK3CA	COSM12464	p.N1068fs*4	1.09
EML4-ALK	NA	Translocation	0.97
ALK	COSM144250	p.G1202R	1.03
ALK	COSM28055	p.F1174L	1.03
BRCA1	COSM1383519	p.K654fs*47	0.99
BRCA2	COSM1738242	p.R2645fs*3	0.94
EGFR	COSM12370	p.L747_P753>S	1.15
EGFR	COSM6256	p.S752_I759delSPKANKEI	1.06
EGFR	COSM6223	p.E746_A750delELREA	1.18
KRAS	COSM516	p.G12C	1.04
CD74/ROS1	NA	Translocation	1.02
KRAS	COSM554	p.Q61H	0.97
<b>Average AF%</b>			<b>1.04</b>

Gene ID	CNV in ctDNA <sup>1</sup>	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell <sup>2</sup>
ERBB2	2.87	0.87	44
MET	2.68	0.68	34
MYC	3.07	1.07	54

NA = not applicable

<sup>1</sup>Compare to a normal CNV of 2.00.

<sup>2</sup>Calculated based on the ctDNA fraction of 2%.

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

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	0.93
BRAF	COSM476	p.V600E	1.06
EGFR	COSM6224	p.L858R	0.93
EGFR	COSM6240	p.T790M	1.07
ERBB2	COSM682/20959	p.A775_G776insYVMA	0.56
KIT	COSM1314	p.D816V	0.91
KRAS	COSM521	p.G12D	1.09
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	1.27
PIK3CA	COSM775	p.H1047R	0.98
PIK3CA	COSM12464	p.N1068fs*4	0.73
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.87
ALK	COSM28055	p.F1174L	0.91
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	1.62
EGFR	COSM6256	p.S752_I759delSPKANKEI	1.10
EGFR	COSM6223	p.E746_A750delIELREA	1.12
KRAS	COSM516	p.G12C	0.91
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.87
		<b>Average AF%</b>	<b>1.00</b>

Gene ID	CNV in ctDNA <sup>1</sup>	Additional Copies (per cell) in ctDNA	Approx. CNV in Tumor Cell <sup>2</sup>
ERBB2	2.78	0.78	39
MET	2.90	0.90	45
MYC	NA	NA	NA

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


<sup>1</sup>Compare to a normal CNV of 2.00.

<sup>2</sup>Calculated based on the ctDNA fraction of 2%.

<sup>3</sup>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%, ~9000X 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