

# Technical Product Report

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

Product Description: Seraseq® ctDNA Complete Mutation Mix WT

Material Number: 0710-0533      Batch Number: 10576256

Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385

Concentration  
(Qubit dsDNA BR Assay): Nominal value: 10 ng/μL; Average measured value: 14.7 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 10 SEP 2021      Expiration Date: 10 SEP 2023

Storage: -20°C

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

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF% <sup>1</sup>
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	COSM20959	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 <sup>2</sup>	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

NA = not applicable

<sup>1</sup>Variant allele frequencies > 0.00% for this wild-type negative control are within the expected range for stochastic positive dPCR reactions.

<sup>2</sup>As of June 2019, this mutation is no longer listed in the COSMIC database.

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NGS was performed as an orthogonal verification step. Results confirm no variants were detected above 0.08%.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents<sup>1</sup>:

**NGS Parameters:**

DNA input = 50 ng  
# of samples / flow cell = 1  
# of total reads / sample = 19.4M  
Average read depth = 8600X  
On-target reads = 95.8%  
Q30 score = 89.6%  
Analysis = Archer Analysis Suite v6.2.7 (default settings)

<sup>1</sup>Please see the poster from NIST for more information about assay sensitivity:  
<https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018>

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:**

A handwritten signature in black ink, appearing to be "ERL".

20 SEP 2021

Prepared By

Date