

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Mutation Mix AF5%

Material Number: 0710-0528 Batch Number: 10559775

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

Concentration
(Qubit dsDNA BR Assay): Nominal value: 10 ng/μL; Average measured value: 13.7 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 18 MAY 2021 Expiration Date: 18 MAY 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%
AKT1	COSM33765	p.E17K	5.22
BRAF	COSM476	p.V600E	5.26
EGFR	COSM6224	p.L858R	5.30
EGFR	COSM6240	p.T790M	5.03
ERBB2	COSM20959	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 ¹	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

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	7.67	5.67
MET	6.11	4.11
MYC	6.27	4.27

NA = not applicable

¹As of June 2019, this mutation is no longer listed in the COSMIC database.

²Compare to a normal CN of 2.00.

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents¹:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	5.65
BRAF	COSM476	p.V600E	5.33
EGFR	COSM6224	p.L858R	4.59
EGFR	COSM6240	p.T790M	5.56
ERBB2	COSM20959	p.A775_G776insYVMA	3.34
KIT	COSM1314	p.D816V	5.09
KRAS	COSM521	p.G12D	5.09
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	6.04
PIK3CA	COSM775	p.H1047R	5.48
PIK3CA	COSM12464 ³	p.N1068fs*4	4.65
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	5.27
ALK	COSM28055	p.F1174L	4.90
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	5.91
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.28
EGFR	COSM6223	p.E746_A750delELREA	4.97
KRAS	COSM516	p.G12C	4.53
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	4.94

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	7.64	5.64
MET	8.36	6.36
MYC	NA	NA

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

¹NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng

of samples / flow cell = 4

of total reads / sample = 2.5M

Average read depth = 9391X

On-target reads = 96.2%

Q30 score = 94.4%

Analysis = Archer Analysis Suite v6.2.3 (default settings except for: Min Allele Fraction for Variant Call set to 0.001)

²Please see the poster from NIST for more information about assay sensitivity:

<https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018>

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⁴Compare to a normal CN of 2.00.

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:

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

27 MAY 2021

Prepared By

Date