

Revised 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: 10680179

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: 16.4 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 26 JUL 2023 Expiration Date: 26 JUL 2025

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	5.93
BRAF	COSM476	p.V600E	5.76
EGFR	COSM6224	p.L858R	5.90
EGFR	COSM6240	p.T790M	5.37
ERBB2	COSM20959	p.A775_G776insYVMA	3.26
KIT	COSM1314	p.D816V	5.46
KRAS	COSM521	p.G12D	5.73
NCOA4/RET	NA	Translocation	4.95
NRAS	COSM584	p.Q61R	5.75
PIK3CA	COSM775	p.H1047R	5.69
PIK3CA	COSM12464 ¹	p.N1068fs*4	5.69
EML4-ALK	NA	Translocation	5.20
ALK	COSM144250	p.G1202R	5.25
ALK	COSM28055	p.F1174L	5.25
BRCA1	COSM1383519	p.K654fs*47	4.92
BRCA2	COSM1738242	p.R2645fs*3	5.38
EGFR	COSM12370	p.L747_P753>S	6.22
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.39
EGFR	COSM6223	p.E746_A750delELREA	5.97
KRAS	COSM516	p.G12C	5.29
CD74/ROS1	NA	Translocation	5.39
KRAS	COSM554	p.Q61H	5.34

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	7.09	5.09
MET	5.14	3.14
MYC	6.84	4.84

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	4.35
BRAF	COSM476	p.V600E	4.37
EGFR	COSM6224	p.L858R	3.95
EGFR	COSM6240	p.T790M	4.50
ERBB2	COSM20959	p.A775_G776insYVMA	2.54
KIT	COSM1314	p.D816V	5.36
KRAS	COSM521	p.G12D	4.58
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	5.08
PIK3CA	COSM775	p.H1047R	4.84
PIK3CA	COSM12464 ³	p.N1068fs*4	3.41
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	3.86
ALK	COSM28055	p.F1174L	4.64
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	5.14
EGFR	COSM6256	p.S752_I759delSPKANKEI	4.82
EGFR	COSM6223	p.E746_A750delELREA	5.03
KRAS	COSM516	p.G12C	4.69
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	4.28

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	7.88	5.88
MET	6.22	4.22
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 = 1

of total reads / sample = 17.2 M

Average read depth = 9645X

On-target reads = 97.1%

Q30 score = 85.6%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: Variant Downstream ROI Size of 150 and Read Depth Normalization of 10,000,000)

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

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

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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

BSU

Date

04/03/2024