

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Mutation Mix AF0.5%

Material Number: 0710-0531 Batch Number: 10704781

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

Fill Volume: 25 µL

Date of Manufacture: 21 AUG 2024 Expiration Date: 21 AUG 2028

Storage: -20°C

Concentration: Nominal value: 10 ng/µL
(Qubit dsDNA BR Assay): Average measured value: 16.3 ng/µL

Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis): 142 bp

Acceptance criteria for average fragment size: 140 – 200 bp

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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	0.58
BRAF	COSM476	p.V600E	0.55
EGFR	COSM6224	p.L858R	0.56
EGFR	COSM6240	p.T790M	0.48
ERBB2	COSM20959	p.A775_G776insYVMA	0.41
KIT	COSM1314	p.D816V	0.52
KRAS	COSM521	p.G12D	0.57
NCOA4/RET	NA	Translocation	0.45
NRAS	COSM584	p.Q61R	0.58
PIK3CA	COSM775	p.H1047R	0.52
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.52
EML4-ALK	NA	Translocation	0.48
ALK	COSM144250	p.G1202R	0.48
ALK	COSM28055	p.F1174L	0.48
BRCA1	COSM1383519	p.K654fs*47	0.53
BRCA2	COSM1738242	p.R2645fs*3	0.50
EGFR	COSM12370	p.L747_P753>S	0.47
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.51
EGFR	COSM6223	p.E746_A750delELREA	0.60
KRAS	COSM516	p.G12C	0.45
CD74/ROS1	NA	Translocation	0.53
KRAS	COSM554	p.Q61H	0.49

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	2.31	0.31
MET	2.21	0.21
MYC	2.60	0.60

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	0.55
BRAF	COSM476	p.V600E	0.44
EGFR	COSM6224	p.L858R	0.44
EGFR	COSM6240	p.T790M	0.56
ERBB2	COSM20959	p.A775_G776insYVMA	0.29
KIT	COSM1314	p.D816V	0.58
KRAS	COSM521	p.G12D	0.64
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.32
PIK3CA	COSM775	p.H1047R	0.42
PIK3CA	COSM12464 ³	p.N1068fs*4	0.3
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.49
ALK	COSM28055	p.F1174L	0.49
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.54
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.51
EGFR	COSM6223	p.E746_A750delELREA	0.62
KRAS	COSM516	p.G12C	0.43
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.47

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	2.72	0.72
MET	2.14	0.14
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 = 8
- # of total reads / sample = 6.8M
- Average read depth = 8714X
- On-target reads = 96.4%
- Q30 score = 92.89%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: NA)

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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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:

DP

23 SEP 2024

Prepared By

Date