

Technical Product Report - REVISED

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Mutation Mix AF1%

Material Number: 0710-0530 Batch Number: 10646259

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: 23-NOV-2022 Expiration Date: 23-NOV-2024

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	1.06
BRAF	COSM476	p.V600E	1.02
EGFR	COSM6224	p.L858R	1.07
EGFR	COSM6240	p.T790M	0.99
ERBB2	COSM20959	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 ¹	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_A750delIELREA	1.18
KRAS	COSM516	p.G12C	1.04
CD74/ROS1	NA	Translocation	1.02
KRAS	COSM554	p.Q61H	0.97

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	2.87	0.87
MET	2.68	0.68
MYC	3.07	1.07

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	0.74
BRAF	COSM476	p.V600E	0.78
EGFR	COSM6224	p.L858R	0.97
EGFR	COSM6240	p.T790M	1.02
ERBB2	COSM20959	p.A775_G776insYVMA	0.6
KIT	COSM1314	p.D816V	0.99
KRAS	COSM521	p.G12D	0.94
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	1.23
PIK3CA	COSM775	p.H1047R	1.12
PIK3CA	COSM12464 ³	p.N1068fs*4	0.84
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.99
ALK	COSM28055	p.F1174L	0.87
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.90
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.95
EGFR	COSM6223	p.E746_A750delELREA	1.12
KRAS	COSM516	p.G12C	0.99
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.89

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	2.78	0.78
MET	2.9	0.9
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 = 6

of total reads / sample = 13.3M

Average read depth = 7943

On-target reads = 95.8%

Q30 score = 90.9%

Analysis = Archer Analysis Suite v6.2.7 (default settings)

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:

BK	03/29/2024
Prepared By	Date