

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Mutation Mix AF0.1%

Material Number: 0710-0532 Batch Number: 10456867

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: 14.8 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 13 JAN 2020 Expiration Date: 14 MAY 2021

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	0.118
BRAF	COSM476	p.V600E	0.104
EGFR	COSM6224	p.L858R	0.106
EGFR	COSM6240	p.T790M	0.116
ERBB2	COSM20959	p.A775_G776insYVMA	0.089
KIT	COSM1314	p.D816V	0.100
KRAS	COSM521	p.G12D	0.115
NCOA4/RET	NA	Translocation	0.094
NRAS	COSM584	p.Q61R	0.114
PIK3CA	COSM775	p.H1047R	0.106
PIK3CA	COSM12464 ¹	p.N1068fs*4	0.106
EML4-ALK	NA	Translocation	0.083
ALK	COSM144250	p.G1202R	0.100
ALK	COSM28055	p.F1174L	0.100
BRCA1	COSM1383519	p.K654fs*47	0.103
BRCA2	COSM1738242	p.R2645fs*3	0.106
EGFR	COSM12370	p.L747_P753>S	0.113
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.109
EGFR	COSM6223	p.E746_A750delIELREA	0.120
KRAS	COSM516	p.G12C	0.089
CD74/ROS1	NA	Translocation	0.107
KRAS	COSM554	p.Q61H	0.106

Gene ID	Average CNV in ctDNA ²	Average Additional Copies (per cell) in ctDNA
ERBB2	2.18	0.18
MET	2.05	0.05
MYC	2.09	0.09

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	0.22
BRAF	COSM476	p.V600E	0.32
EGFR	COSM6224	p.L858R	ND
EGFR	COSM6240	p.T790M	0.20
ERBB2	COSM20959	p.A775_G776insYVMA	ND
KIT	COSM1314	p.D816V	ND
KRAS	COSM521	p.G12D	0.11
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.12
PIK3CA	COSM775	p.H1047R	0.15
PIK3CA	COSM12464 ³	p.N1068fs*4	ND
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	0.17
ALK	COSM28055	p.F1174L	ND
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.11
EGFR	COSM6256	p.S752_I759delSPKANKEI	ND
EGFR	COSM6223	p.E746_A750delELREA	0.10
KRAS	COSM516	p.G12C	ND
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.13

Gene ID	CNV in ctDNA ⁴	Additional Copies (per cell) in ctDNA
ERBB2	2.28	0.28
MET	ND	ND
MYC	NA	NA

ND = not determined; variants listed as ND were detected in other QC testing. Stochastic failures are expected for this 0.1% allele frequency tier under the run conditions used.

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 = 2

of total reads / sample = 7.8M

Average read depth = 6341X

On-target reads = 95.4%

Q30 score = 92.9%

Analysis = Archer Analysis Suite v6.2.2 (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:

A handwritten signature in black ink, appearing to be "D.J.", written over a horizontal line.

Prepared By

04 FEB 2020

Date