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:	10711284
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 JUN 2024	Expiration Date:	21 JUN 2028
Storage:	-20°C		
Concentration: (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 14.47 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	168 bp		
Acceptance criteria for average fragment size:	150 – 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	4.88
BRAF	COSM476	p.V600E	4.55
EGFR	COSM6224	p.L858R	4.56
EGFR	COSM6240	p.T790M	4.14
ERBB2	COSM20959	p.A775_G776insYVMA	5.23
KIT	COSM1314	p.D816V	4.40
KRAS	COSM521	p.G12D	4.68
NCOA4/RET	NA	Translocation	4.09
NRAS	COSM584	p.Q61R	4.74
PIK3CA	COSM775	p.H1047R	4.41
PIK3CA	COSM12464[1]	p.N1068fs*4	4.41
EML4-ALK	NA	Translocation	4.54
ALK	COSM144250	p.G1202R	4.37
ALK	COSM28055	p.F1174L	4.37
BRCA1	COSM1383519	p.K654fs*47	4.56
BRCA2	COSM1738242	p.R2645fs*3	4.65
EGFR	COSM12370	p.L747_P753>S	5.12
EGFR	COSM6256	p.S752_I759delSPKANKEI	5.15
EGFR	COSM6223	p.E746_A750delELREA	5.16
KRAS	COSM516	p.G12C	4.25
CD74/ROS1	NA	Translocation	4.71
KRAS	COSM554	p.Q61H	4.33

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	7.92	5.92
MET	6.27	4.27
MYC	6.85	4.85

NA = not applicable
[1]As of June 2019, this mutation is no longer listed in the COSMIC database.
[2]Compare 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 reagents[1]:

Gene ID	COSMIC Identifier	Amino Acid Change	AF%
AKT1	COSM33765	p.E17K	3.76
BRAF	COSM476	p.V600E	3.78
EGFR	COSM6224	p.L858R	3.63
EGFR	COSM6240	p.T790M	4.44
ERBB2	COSM20959	p.A775_G776insYVMA	5.17
KIT	COSM1314	p.D816V	4.65
KRAS	COSM521	p.G12D	3.78
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	3.83
PIK3CA	COSM775	p.H1047R	4.09
PIK3CA	COSM12464[3]	p.N1068fs*4	3.39
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	4.14
ALK	COSM28055	p.F1174L	3.85
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	4.37
EGFR	COSM6256	p.S752_I759delSPKANKEI	3.84
EGFR	COSM6223	p.E746_A750delELREA	3.97
KRAS	COSM516	p.G12C	3.17
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	3.98

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	7.24	5.24
MET	7.56	5.56
MYC	NA	NA

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

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

DNA input = 50 ng
# of samples / flow cell = 6
# of total reads / sample = 18.35M
Average read depth = 10430X
On-target reads = 96.9%
Q30 score = 90.54%
Analysis = Archer Analysis Suite v6.2.2 (default settings except for: Variant Downstream ROI Size of 150 and Read depth Normalization of 10,000,000)

[2]Please see the poster from NIST for more information about assay sensitivity: https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018

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

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[4]Compare 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:

Prepared By	Date
	26 JUN 2024