Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF1%		
Material Number:	0710-0530	Batch Number:	10704780
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:	17 JUN 2024	Expiration Date:	17 JUN 2028
Storage:	-20°C		
Concentration: (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 13.9 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	166 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	1.09
BRAF	COSM476	p.V600E	1.06
EGFR	COSM6224	p.L858R	0.98
EGFR	COSM6240	p.T790M	0.97
ERBB2	COSM20959	p.A775_G776insYVMA	0.95
KIT	COSM1314	p.D816V	1.02
KRAS	COSM521	p.G12D	1.11
NCOA4/RET	NA	Translocation	0.76
NRAS	COSM584	p.Q61R	1.19
PIK3CA	COSM775	p.H1047R	1.10
PIK3CA	COSM12464[1]	p.N1068fs*4	1.01
EML4-ALK	NA	Translocation	0.93
ALK	COSM144250	p.G1202R	0.86
ALK	COSM28055	p.F1174L	0.86
BRCA1	COSM1383519	p.K654fs*47	0.96
BRCA2	COSM1738242	p.R2645fs*3	0.98
EGFR	COSM12370	p.L747_P753>S	1.19
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.96
EGFR	COSM6223	p.E746_A750delELREA	0.91
KRAS	COSM516	p.G12C	0.94
CD74/ROS1	NA	Translocation	1.00
KRAS	COSM554	p.Q61H	0.95

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	3.10	1.10
MET	2.69	0.69
MYC	2.84	0.84

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	0.70
BRAF	COSM476	p.V600E	0.87
EGFR	COSM6224	p.L858R	0.80
EGFR	COSM6240	p.T790M	1.13
ERBB2	COSM20959	p.A775_G776insYVMA	0.74
KIT	COSM1314	p.D816V	0.90
KRAS	COSM521	p.G12D	1.09
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	0.89
PIK3CA	COSM775	p.H1047R	1.29
PIK3CA	COSM12464[3]	p.N1068fs*4	0.88
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	1.01
ALK	COSM28055	p.F1174L	0.96
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	0.95
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.72
EGFR	COSM6223	p.E746_A750delELREA	0.95
KRAS	COSM516	p.G12C	0.96
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	0.79

Gene ID	CNV in ctDNA[4]	Additional Copies (per cell) in ctDNA
ERBB2	3.46	1.46
MET	3.0	1.0
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 = 10
# of total reads / sample = 7.95M
Average read depth = 9598X
On-target reads = 96.1%
Q30 score = 90.14%
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: N/A)
[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.
[4]Compare to a normal CN of 2.00.

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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:

	11 JUL 2024
Prepared By	Date