Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Mutation Mix AF2.5%		
Material Number:	0710-0529	Batch Number:	10741933
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:	03-FEB-2025	Expiration Date:	03-FEB-2029
Storage:	-20°C		
Concentration: (Qubit dsDNA BR Assay):	Nominal value: 10 ng/µL Average measured value: 14.97 ng/µL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	169 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	2.77
BRAF	COSM476	p.V600E	2.69
EGFR	COSM6224	p.L858R	2.68
EGFR	COSM6240	p.T790M	2.53
ERBB2	COSM20959	p.A775_G776insYVMA	2.30
KIT	COSM1314	p.D816V	2.66
KRAS	COSM521	p.G12D	2.88
NCOA4/RET	NA	Translocation	2.21
NRAS	COSM584	p.Q61R	2.67
PIK3CA	COSM775	p.H1047R	2.69
PIK3CA	COSM12464[1]	p.N1068fs*4	2.69
EML4-ALK	NA	Translocation	2.51
ALK	COSM144250	p.G1202R	2.68
ALK	COSM28055	p.F1174L	2.68
BRCA1	COSM1383519	p.K654fs*47	2.55
BRCA2	COSM1738242	p.R2645fs*3	2.68
EGFR	COSM12370	p.L747_P753>S	3.13
EGFR	COSM6256	p.S752_I759delSPKANKEI	2.81
EGFR	COSM6223	p.E746_A750delELREA	2.91
KRAS	COSM516	p.G12C	2.60
CD74/ROS1	NA	Translocation	2.67
KRAS	COSM554	p.Q61H	2.42

Gene ID	Average CNV in ctDNA[2]	Average Additional Copies (per cell) in ctDNA
ERBB2	4.94	2.94
MET	4.05	2.05
MYC	4.49	2.49

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	2.57
BRAF	COSM476	p.V600E	2.36
EGFR	COSM6224	p.L858R	2.23
EGFR	COSM6240	p.T790M	2.42
ERBB2	COSM20959	p.A775_G776insYVMA	1.91
KIT	COSM1314	p.D816V	2.45
KRAS	COSM521	p.G12D	2.24
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	2.28
PIK3CA	COSM775	p.H1047R	2.47
PIK3CA	COSM12464[2]	p.N1068fs*4	2.61
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	1.99
ALK	COSM28055	p.F1174L	2.08
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	2.69
EGFR	COSM6256	p.S752_I759delSPKANKEI	1.93
EGFR	COSM6223	p.E746_A750delELREA	2.48
KRAS	COSM516	p.G12C	2.03
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	2.07

Gene ID	CNV in ctDNA[3]	Additional Copies (per cell) in ctDNA
ERBB2	4.6	2.6
MET	4.9	2.9
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 = 7
# of total reads / sample = 17.3M
Average read depth = 14405X
On-target reads = 96.5%
Q30 score = 87.2%
Analysis = Archer Analysis Suite v6.2.2 (default settings except for: N/A)

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

[3] 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:

[redacted] Tm 25-FEB-2025

Prepared By Date