Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description:	Seraseq® ctDNA Complete Reference Material AF 5%		
Material Number:	0710-0669	Batch Number:	10731724
Material Description:	A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs		
Fill Volume:	5.0 mL		
Date of Manufacture:	21 NOV 2024	Expiration Date:	21 NOV 2028
Storage:	2-8°C		
Concentration (Qubit dsDNA BR Assay):	Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulation Nucleic Acid Kit: 32.3 ng/mL		
Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis):	167 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	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 CNV of 2.00.

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Product Description: Seraseq® ctDNA Complete Reference Material AF 5%

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	4.05
BRAF	COSM476	p.V600E	4.10
EGFR	COSM6224	p.L858R	3.52
EGFR	COSM6240	p.T790M	4.43
ERBB2	COSM20959	p.A775_G776insYVMA	5.20
KIT	COSM1314	p.D816V	4.37
KRAS	COSM521	p.G12D	3.86
NCOA4/RET	NA	Translocation	NA
NRAS	COSM584	p.Q61R	4.08
PIK3CA	COSM775	p.H1047R	4.06
PIK3CA	COSM12464[2]	p.N1068fs*4	3.31
EML4-ALK	NA	Translocation	NA
ALK	COSM144250	p.G1202R	3.90
ALK	COSM28055	p.F1174L	4.01
BRCA1	COSM1383519	p.K654fs*47	NA
BRCA2	COSM1738242	p.R2645fs*3	NA
EGFR	COSM12370	p.L747_P753>S	4.42
EGFR	COSM6256	p.S752_I759delSPKANKEI	3.73
EGFR	COSM6223	p.E746_A750delELREA	4.27
KRAS	COSM516	p.G12C	3.72
CD74/ROS1	NA	Translocation	NA
KRAS	COSM554	p.Q61H	3.87

Gene ID	CNV in ctDNA[3]	Additional Copies (per cell) in ctDNA
ERBB2	7.40	5.40
MET	7.62	5.62
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 = 2
- # of total reads / sample = 47.5M
- Average read depth = 11719X
- On-target reads = 96.9%
- Q30 score = 88.3%
- Analysis = Archer Analysis Suite v6.2.7 (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 CNV 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:

Prepared By

12/18/2024
Date