

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

Product Description: Seraseq® ctDNA Complete Mutation Mix WT
 Material Number: 0710-0533 Batch Number: 10704515
 Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385
 Fill Volume: 25 µL
 Date of Manufacture: 22 MAY 2024 Expiration Date: 22 MAY 2028
 Storage: -20°C
 Concentration: Nominal value: 10 ng/µL
 (Qubit dsDNA BR Assay): Average measured value: 12 ng/µL
 Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis): 140 bp
 Acceptance criteria for average fragment size: 140 – 200 bp

Digital PCR testing using BioRad QX200™ Droplet Digital™ PCR System:

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF% ¹
AKT1	COSM33765	p.E17K	0.000
BRAF	COSM476	p.V600E	0.000
EGFR	COSM6224	p.L858R	0.000
EGFR	COSM6240	p.T790M	0.000
ERBB2	COSM20959	p.A775_G776insYVMA	0.000
KIT	COSM1314	p.D816V	0.000
KRAS	COSM521	p.G12D	0.000
NCOA4/RET	NA	Translocation	0.000
NRAS	COSM584	p.Q61R	0.000
PIK3CA	COSM775	p.H1047R	0.003
PIK3CA	COSM12464 ²	p.N1068fs*4	0.000
EML4-ALK	NA	Translocation	0.000
ALK	COSM144250	p.G1202R	0.000
ALK	COSM28055	p.F1174L	0.000
BRCA1	COSM1383519	p.K654fs*47	0.000
BRCA2	COSM1738242	p.R2645fs*3	0.000
EGFR	COSM12370	p.L747_P753>S	0.017
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.016
EGFR	COSM6223	p.E746_A750delELREA	0.000
KRAS	COSM516	p.G12C	0.000
CD74/ROS1	NA	Translocation	0.000
KRAS	COSM554	p.Q61H	0.008

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NA = not applicable

¹Variant allele frequencies > 0.00% for this wild-type negative control are within the expected range for stochastic positive dPCR reactions.

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

NGS was performed as an orthogonal verification step. Results confirm no variants were detected above 0.1%.

NGS Parameters:

DNA input = 50ng

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents¹:

NGS Parameters:

DNA input = 50ng

of samples / flow cell = 2

of total reads / sample = 9.1M

Average read depth = 9859X

On-target reads = 96.4%

Q30 score = 87%

Analysis = Archer Analysis Suite v6.2.7 (default settings except for: NA)

¹Please see the poster from NIST for more information about assay sensitivity:

<https://digital.seracare.com/multilab-assessment-reference-materials-ctdna-poster2018>

Note: Copy numbers of ERBB2 and MET were assayed by dPCR and found to be normal. They were not assayed by NGS as the wild-type sample is used as a normal control for determining copy number of genes in other samples.

Approval:



03 SEP 2024

Prepared By

Date