

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: 10440229

Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385

Concentration (Qubit dsDNA BR Assay): Nominal value: 10 ng/μL; Average measured value: 14.3 ng/μL

Fill Volume: 25 μL

Date of Manufacture: 30 AUG 2019 Expiration Date: 30 AUG 2021

Storage: -20°C

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

Gene ID	COSMIC Identifier	Amino Acid Change	Average AF% ¹
AKT1	COSM33765	p.E17K	0.005
BRAF	COSM476	p.V600E	0.000
EGFR	COSM6224	p.L858R	0.001
EGFR	COSM6240	p.T790M	0.009
ERBB2	COSM20959	p.A775_G776insYVMA	0.007
KIT	COSM1314	p.D816V	0.002
KRAS	COSM521	p.G12D	0.012
NCOA4/RET	NA	Translocation	0.000
NRAS	COSM584	p.Q61R	0.006
PIK3CA	COSM775	p.H1047R	0.006
PIK3CA	COSM12464 ²	p.N1068fs*4	0.006
EML4-ALK	NA	Translocation	0.001
ALK	COSM144250	p.G1202R	0.000
ALK	COSM28055	p.F1174L	0.000
BRCA1	COSM1383519	p.K654fs*47	0.001
BRCA2	COSM1738242	p.R2645fs*3	0.000
EGFR	COSM12370	p.L747_P753>S	0.000
EGFR	COSM6256	p.S752_I759delSPKANKEI	0.001
EGFR	COSM6223	p.E746_A750delELREA	0.008
KRAS	COSM516	p.G12C	0.001
CD74/ROS1	NA	Translocation	0.000
KRAS	COSM554	p.Q61H	0.004

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.

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

NGS Parameters:

DNA input = 50 ng

of samples / flow cell = 2

of total reads / sample = 5.0M

Average read depth = 9939X

On-target reads = 94%

Q30 score = 95%

Analysis = Archer Analysis Suite v5.1.7 (default settings except for: Error correction was on, MAPQ threshold for variant call was 10, minimum allele fraction for variant call of 0.00025, minimum base quality for variant call of 30)

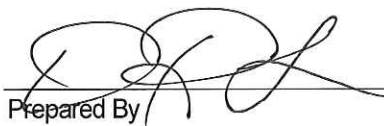
Next Generation Sequencing testing using Archer[®] Reveal ctDNA[™] 28 Kit run on an Illumina[®] MiSeq[™] using v2 (2x150 bp) PE chemistry reagents¹:

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:


Prepared By

06 SEP 2019
Date