

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: 10713204
 Material Description: A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385
 Fill Volume: 25 µL
 Date of Manufacture: 19-JUL-2024 Expiration Date: 19-JUL-2028
 Storage: -20°C
 Concentration: Nominal value: 10 ng/µL
 (Qubit dsDNA BR Assay): Average measured value: 13.6 ng/µL
 Average fragment size (Agilent Bioanalyzer DNA 1000 Analysis): 162 bp
 Acceptance criteria for average fragment size: 150 – 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 | 0.007 |
| EGFR | COSM6240 | p.T790M | 0.006 |
| ERBB2 | COSM20959 | p.A775_G776insYVMA | 0.000 |
| KIT | COSM1314 | p.D816V | 0.002 |
| KRAS | COSM521 | p.G12D | 0.020 |
| NCOA4/RET | NA | Translocation | 0.000 |
| NRAS | COSM584 | p.Q61R | 0.000 |
| PIK3CA | COSM775 | p.H1047R | 0.001 |
| PIK3CA | COSM12464 ² | p.N1068fs*4 | 0.001 |
| 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 | 0.000 |
| EGFR | COSM6256 | p.S752_I759delSPKANKEI | 0.000 |
| EGFR | COSM6223 | p.E746_A750delELREA | 0.000 |
| KRAS | COSM516 | p.G12C | 0.000 |
| CD74/ROS1 | NA | Translocation | 0.000 |
| KRAS | COSM554 | p.Q61H | 0.000 |

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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.

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 = 5

of total reads / sample = 26.5M

Average read depth = 9755X

On-target reads = 96.3%

Q30 score = 89.24%

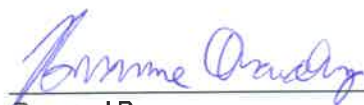
Analysis = Archer Analysis Suite v6.2.7 (default settings except for: N/A)

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

07/24/2024

Date