

Technical Product Report

For Research Use Only; Not for use in Diagnostic Procedures

| | | | |
|---------------------------------------|---|------------------|-------------|
| Product Description: | SeraSeq® ctDNA Complete Reference Material AF 2.5% | | |
| Material Number: | 0710-0670 | Batch Number: | 10656949 |
| Material Description: | A ctDNA-like mixture of human genomic DNA from the reference cell line, GM24385, and synthetic DNA constructs | | |
| Concentration (Qubit dsDNA BR Assay): | Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulating Nucleic Acid Kit: 33.8 ng/mL | | |
| Fill Volume: | 5.0 mL | | |
| Date of Manufacture: | 17 FEB 2023 | Expiration Date: | 17 FEB 2027 |
| Storage: | 2-8°C | | |

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Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

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

| Gene ID | COSMIC Identifier | Amino Acid Change | Average AF% |
|-----------|------------------------|-------------------------|-------------|
| AKT1 | COSM33765 | p.E17K | 2.63 |
| BRAF | COSM476 | p.V600E | 2.59 |
| EGFR | COSM6224 | p.L858R | 2.61 |
| EGFR | COSM6240 | p.T790M | 2.49 |
| ERBB2 | COSM20959 | p.A775_G776insYVMA | 2.27 |
| KIT | COSM1314 | p.D816V | 2.68 |
| KRAS | COSM521 | p.G12D | 2.79 |
| NCOA4/RET | NA | Translocation | 2.51 |
| NRAS | COSM584 | p.Q61R | 2.85 |
| PIK3CA | COSM775 | p.H1047R | 2.54 |
| PIK3CA | COSM12464 ¹ | p.N1068fs*4 | 2.54 |
| EML4-ALK | NA | Translocation | 2.47 |
| ALK | COSM144250 | p.G1202R | 2.37 |
| ALK | COSM28055 | p.F1174L | 2.37 |
| BRCA1 | COSM1383519 | p.K654fs*47 | 2.29 |
| BRCA2 | COSM1738242 | p.R2645fs*3 | 2.39 |
| EGFR | COSM12370 | p.L747_P753>S | 3.04 |
| EGFR | COSM6256 | p.S752_I759delSPKAN KEI | 2.51 |
| EGFR | COSM6223 | p.E746_A750delELREA | 2.97 |
| KRAS | COSM516 | p.G12C | 2.69 |
| CD74/ROS1 | NA | Translocation | 2.61 |
| KRAS | COSM554 | p.Q61H | 2.35 |

| Gene ID | Average CNV in ctDNA ² | Average Additional Copies (per cell) in ctDNA |
|---------|-----------------------------------|---|
| ERBB2 | 4.64 | 2.64 |
| MET | 3.72 | 1.72 |
| MYC | 3.93 | 1.93 |

NA = not applicable

¹As of June 2019, this mutation is no longer listed in the COSMIC database.

²Compare to a normal CNV of 2.00.

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Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

Next Generation Sequencing testing using Archer® Reveal ctDNA™ 28 Kit run on an Illumina® MiSeq™ using v2 (2x150 bp) PE chemistry reagents^{1,2}:

| Gene ID | COSMIC Identifier | Amino Acid Change | AF% |
|-----------|------------------------|-------------------------|------|
| AKT1 | COSM33765 | p.E17K | 2.13 |
| BRAF | COSM476 | p.V600E | 2.29 |
| EGFR | COSM6224 | p.L858R | 2.42 |
| EGFR | COSM6240 | p.T790M | 2.51 |
| ERBB2 | COSM20959 | p.A775_G776insYVMA | 2.04 |
| KIT | COSM1314 | p.D816V | 2.37 |
| KRAS | COSM521 | p.G12D | 2.05 |
| NCOA4/RET | NA | Translocation | NA |
| NRAS | COSM584 | p.Q61R | 2.82 |
| PIK3CA | COSM775 | p.H1047R | 2.27 |
| PIK3CA | COSM12464 ³ | p.N1068fs*4 | 2.75 |
| EML4-ALK | NA | Translocation | NA |
| ALK | COSM144250 | p.G1202R | 2.46 |
| ALK | COSM28055 | p.F1174L | 2.42 |
| BRCA1 | COSM1383519 | p.K654fs*47 | NA |
| BRCA2 | COSM1738242 | p.R2645fs*3 | NA |
| EGFR | COSM12370 | p.L747_P753>S | 2.80 |
| EGFR | COSM6256 | p.S752_I759delSPKAN KEI | 2.53 |
| EGFR | COSM6223 | p.E746_A750delELREA | 2.48 |
| KRAS | COSM516 | p.G12C | 2.32 |
| CD74/ROS1 | NA | Translocation | NA |
| KRAS | COSM554 | p.Q61H | 2.33 |

| Gene ID | CNV in ctDNA ⁴ | Additional Copies (per cell) in ctDNA |
|---------|---------------------------|---------------------------------------|
| ERBB2 | 2.18 | 2.36 |
| MET | 2.26 | 2.52 |
| MYC | NA | NA |

NA = not applicable; AF% and CNV marked NA were not targeted by the panel.

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Product Description: Seraseq® ctDNA Complete Reference Material AF 2.5%

1NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng

of samples / flow cell = 3

of total reads / sample = 7.08M

Average read depth = 7319

On-target reads = 96.3%

Q30 score = 88.5%

Analysis = Archer Analysis Suite v6.2.7 (default settings). Please see the poster from NIST for more information about assay sensitivity:

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

3As of June 2019, this mutation is no longer listed in the COSMIC database.

4Compare to a normal CNV of 2.00.

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

27 FEB 2023

Date