

# 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:    | 10812669    |
| 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:                                                 | 17 JUL 2026                                                                                                                   | Expiration Date: | 17 JUL 2030 |
| Storage:                                                             | 2-8°C                                                                                                                         |                  |             |
| Concentration<br>(Qubit dsDNA BR Assay):                             | Nominal value: 25 ng/mL; Average measured value after extraction using Qiagen QIAamp Circulation Nucleic Acid Kit: 30.1 ng/mL |                  |             |
| Average fragment size<br>(Agilent Bioanalyzer DNA<br>1000 Analysis): | 169 bp                                                                                                                        |                  |             |
| Acceptance criteria for<br>average fragment size:                    | 140-200 bp                                                                                                                    |                  |             |

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

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

| Gene ID   | Nucleotide Change | Amino Acid Change  | Average AF% |
|-----------|-------------------|--------------------|-------------|
| AKT1      | c.49G>A           | p.E17K             | 4.88        |
| ALK       | c.3522C>A         | p.F1174L           | 4.37        |
| ALK       | c.3604G>A         | p.G1202R           | 4.37        |
| BRAF      | c.1799T>A         | p.V600E            | 4.55        |
| BRCA1     | c.1961del         | p.K654fs           | 4.56        |
| BRCA2     | c.7934del         | p.R2645fs          | 4.65        |
| EGFR      | c.2235_2249del    | p.E746_A750del     | 5.16        |
| EGFR      | c.2240_2257del    | p.L747_P753delinsS | 5.12        |
| EGFR      | c.2254_2277del    | p.S752_I759del     | 5.15        |
| EGFR      | c.2369C>T         | p.T790M            | 4.14        |
| EGFR      | c.2573T>G         | p.L858R            | 4.56        |
| ERBB2     | c.2313_2324dup    | p.Y772_A775dup     | 5.23        |
| KIT       | c.2447A>T         | p.D816V            | 4.40        |
| KRAS      | c.183A>C          | p.Q61H             | 4.33        |
| KRAS      | c.34G>T           | p.G12C             | 4.25        |
| KRAS      | c.35G>A           | p.G12D             | 4.68        |
| NRAS      | c.182A>G          | p.Q61R             | 4.74        |
| PIK3CA    | c.3140A>G         | p.H1047R           | 4.41        |
| PIK3CA    | c.3204_3205insA   | p.N1068fs*4        | 4.41        |
| CD74/ROS1 | NA                | Translocation      | 4.71        |
| EML4/ALK  | NA                | Translocation      | 4.54        |
| NCOA4/RET | NA                | Translocation      | 4.09        |

| Gene ID | Average CNV in ctDNA <sup>1</sup> | 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

<sup>1</sup>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<sup>1</sup>

| Gene ID   | Nucleotide Change | Amino Acid Change  | AF%  |
|-----------|-------------------|--------------------|------|
| AKT1      | c.49G>A           | p.E17K             | 3.72 |
| ALK       | c.3522C>A         | p.F1174L           | 3.95 |
| ALK       | c.3604G>A         | p.G1202R           | 3.41 |
| BRAF      | c.1799T>A         | p.V600E            | 4.14 |
| BRCA1     | c.1961del         | p.K654fs           | NA   |
| BRCA2     | c.7934del         | p.R2645fs          | NA   |
| EGFR      | c.2235_2249del    | p.E746_A750del     | 4.22 |
| EGFR      | c.2240_2257del    | p.L747_P753delinsS | 4.40 |
| EGFR      | c.2254_2277del    | p.S752_I759del     | 4.10 |
| EGFR      | c.2369C>T         | p.T790M            | 4.17 |
| EGFR      | c.2573T>G         | p.L858R            | 3.85 |
| ERBB2     | c.2313_2324dup    | p.Y772_A775dup     | 4.91 |
| KIT       | c.2447A>T         | p.D816V            | 4.34 |
| KRAS      | c.183A>C          | p.Q61H             | 3.61 |
| KRAS      | c.34G>T           | p.G12C             | 3.04 |
| KRAS      | c.35G>A           | p.G12D             | 3.94 |
| NRAS      | c.182A>G          | p.Q61R             | 4.41 |
| PIK3CA    | c.3140A>G         | p.H1047R           | 4.23 |
| PIK3CA    | c.3204_3205insA   | p.N1068fs*4        | 3.52 |
| CD74/ROS1 | NA                | Translocation      | NA   |
| NCOA4/RET | NA                | Translocation      | NA   |
| EML4-ALK  | NA                | Translocation      | NA   |

| Gene ID | CNV in ctDNA <sup>2</sup> | Additional Copies (per cell) in ctDNA |
|---------|---------------------------|---------------------------------------|
| ERBB2   | 8.28                      | 6.28                                  |
| MET     | 8.54                      | 6.54                                  |
| MYC     | NA                        | NA                                    |

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

<sup>1</sup>NGS was performed as an orthogonal verification step. Parameters used:

DNA input = 50 ng

# of samples / flow cell = 5

# of total reads / sample = 4.0M

Average read depth = 10452X

On-target reads = 97.1%

Q30 score = 91.4%

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

<sup>2</sup>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:**

A handwritten signature in blue ink that reads "Patricia Hebel".

Prepared By

A handwritten date in blue ink that reads "07/28/26".

Date