



## CERTIFICATE OF COMPLIANCE

This product has been manufactured in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) standards and meets Nova Biomedical product specifications.

| Customer:                                                                                                                                                                                                                                                                                                   | NIA                                                                  |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------|-------------|-------------|----------------|--------|------|----------------|--------|------|--------------|--------|------|----------------------------------------------------------------------------------------------------------------------------------|-------------|-------------|-------------|
| Description:                                                                                                                                                                                                                                                                                                | TEST STRIPS, STATSTRIP LACTATE, PACKAGED                             |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Catalog Number:                                                                                                                                                                                                                                                                                             | 47486                                                                |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Nova Biomedical P/N                                                                                                                                                                                                                                                                                         | 47486                                                                |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| <table border="1"><thead><tr><th>Target Range</th><th>CV (%)</th><th>SD (mmol/L)</th></tr></thead><tbody><tr><td>0.8-2.5 mmol/L</td><td>≤ 6.5%</td><td>±0.3</td></tr><tr><td>3.0-5.0 mmol/L</td><td>≤ 5.5%</td><td>±0.5</td></tr><tr><td>10-14 mmol/L</td><td>≤ 5.0%</td><td>±1.2</td></tr></tbody></table> | Target Range                                                         | CV (%)      | SD (mmol/L) | 0.8-2.5 mmol/L | ≤ 6.5% | ±0.3 | 3.0-5.0 mmol/L | ≤ 5.5% | ±0.5 | 10-14 mmol/L | ≤ 5.0% | ±1.2 | <table border="1"><tbody><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr></tbody></table> | PASS / FAIL | PASS / FAIL | PASS / FAIL |
| Target Range                                                                                                                                                                                                                                                                                                | CV (%)                                                               | SD (mmol/L) |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| 0.8-2.5 mmol/L                                                                                                                                                                                                                                                                                              | ≤ 6.5%                                                               | ±0.3        |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| 3.0-5.0 mmol/L                                                                                                                                                                                                                                                                                              | ≤ 5.5%                                                               | ±0.5        |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| 10-14 mmol/L                                                                                                                                                                                                                                                                                                | ≤ 5.0%                                                               | ±1.2        |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| PASS / FAIL                                                                                                                                                                                                                                                                                                 |                                                                      |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| PASS / FAIL                                                                                                                                                                                                                                                                                                 |                                                                      |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| PASS / FAIL                                                                                                                                                                                                                                                                                                 |                                                                      |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Qty:                                                                                                                                                                                                                                                                                                        | 8,460                                                                |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Lot No.                                                                                                                                                                                                                                                                                                     | 2625091249                                                           |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Mfg. Date:                                                                                                                                                                                                                                                                                                  | 2025-04-01                                                           |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Expiration Date:                                                                                                                                                                                                                                                                                            | 2027-04-01                                                           |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |
| Unique Device Identifier (UDI):                                                                                                                                                                                                                                                                             | (01)20385480 474867<br>(11) 250401<br>(17) 270401<br>(10) 2625091249 |             |             |                |        |      |                |        |      |              |        |      |                                                                                                                                  |             |             |             |

Marc Broome  
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4/16/25  
Date

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