



CERTIFICATE OF ANALYSIS

StatSensor Creatinine Linearity Kit
Lot Number 5525247990

Ref Number 44037
Exp Date 2027-09-04
Date of Manufacture 2025-09-04

Linearity Level 1

Lot:5525247241 Exp: 2027-09-04

| | <u>Spec</u> | <u>Mean Result</u> |
|------------------|-------------|--------------------|
| Creatinine mg/dL | 0.90 - 1.10 | 1.02 |

Linearity Level 2

Lot :5525247242 Exp: 2027-09-04

| | <u>Spec</u> | <u>Mean Result</u> |
|------------------|-------------|--------------------|
| Creatinine mg/dL | 1.95 - 2.25 | 2.02 |

Linearity Level 3

Lot: 5525255243 Exp: 2027-09-12

| | <u>Spec</u> | <u>Mean Result</u> |
|------------------|-------------|--------------------|
| Creatinine mg/dL | 3.80 - 4.30 | 4.09 |

Linearity Level 4

Lot:5525252244 Exp: 2027-09-09

| | <u>Spec</u> | <u>Mean Result</u> |
|------------------|-------------|--------------------|
| Creatinine mg/dL | 5.50 - 7.00 | 5.87 |

Linearity Level 5

Lot: 5525252245 Exp: 2027-09-09

| | <u>Spec</u> | <u>Mean Result</u> |
|------------------|--------------|--------------------|
| Creatinine mg/dL | 9.50 - 11.00 | 9.68 |

This certifies that this product was manufactured and tested at Nova Biomedical Corporation, Waltham MA 02454 U.S.A. in accordance with ISO 13485:2016 Medical Devices Quality Management Systems Requirements, Medical Device Single Audit Program (MDSAP), and conforms to the indicated test specifications.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Approval

QC Inspector

Title

10/22/2025

Date