



CERTIFICATE OF ANALYSIS

Nova Creatinine / BUN / Hct Linearity STD Levels 1 - 4
Lot Number 25254014

Ref Number 61656
Exp Date 2026-09-09
Date of Manufacture 2025-09-09

UDI# (01)00385480616560(11)250909(17)260909(10)25254014

Level 1 L/N 25252007
Level 1 Exp Date 2026-09-09

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	83.9 - 88.2	Pass
Creatinine mg/dL	10.8 - 11.2	Pass
Hct %	13 - 17	Pass

Level 2 L/N 25252008
Level 2 Exp Date 2026-09-09

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	56.6 - 59.5	Pass
Creatinine mg/dL	6.9 - 7.1	Pass
Hct %	27 - 31	Pass

Level 3 L/N 25253006
Level 3 Exp Date 2026-09-10

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	29.3 - 30.8	Pass
Creatinine mg/dL	4.5 - 4.7	Pass
Hct %	44 - 48	Pass

Level 4 L/N 25253007
Level 4 Exp Date 2026-09-10

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	5.9 - 6.2	Pass
Creatinine mg/dL	0.98 - 1.02	Pass
Hct %	62 - 66	Pass

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. All listed analytes are traceable to NIST SRM Materials.

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

Approval

QC Inspector
Title

09/18/2025
Date