



CERTIFICATE OF ANALYSIS

Nova Creatinine / BUN / Hct Linearity STD Levels 1 - 4
Lot Number 25170021

Ref Number 61656
Exp Date 2026-06-17

Date of Manufacture 2025-06-17

UDI# (01)00385480616560(11)250617(17)260617(10)25170021

Level 1 L/N 2516008
Level 1 Exp Date 2026-06-17

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	69.2 - 72.8	Pass
Creatinine mg/dL	9.5 - 9.9	Pass
Hct %	13 - 17	Pass

Level 2 L/N 25168009
Level 2 Exp Date 2026-06-17

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	46.8 - 49.2	Pass
Creatinine mg/dL	6.9 - 7.1	Pass
Hct %	28 - 32	Pass

Level 3 L/N 25169020
Level 3 Exp Date 2026-06-18

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	23.4 - 24.6	Pass
Creatinine mg/dL	4.5 - 4.7	Pass
Hct %	44 - 48	Pass

Level 4 L/N 25170006
Level 4 Exp Date 2026-06-19

	<u>Spec</u>	<u>Pass/Fail</u>
BUN mg/dL	4.9 - 5.1	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

06/27/2025
Date