



**CERTIFICATE OF ANALYSIS**

Nova StatStrip Hb/Hct Linearity Solutions Levels 1 - 3

Ref Number 59826

Lot Number 8124262990

Exp Date 2026-09-18

Date of Manufacture 2024-09-18

UDI# (01)00385480598262(11)240918(17)260918(10)8124262990

Level 1 L/N	8124262241			Level 2 L/N	8124262242		
Level 1 Exp Date	2026-09-18			Level 2 Exp Date	2026-09-18		
	<u>Spec</u>	<u>Mean Result</u>			<u>Spec</u>	<u>Mean Result</u>	
Hb g/dL	8.2 - 8.8	8.6		Hb g/dL	13.4 - 14.6	14.6	
Hct %	24 - 26	26		Hct %	38 - 42	42	
Level 3 L/N	8124262243						
Level 3 Exp Date	2026-09-18						
	<u>Spec</u>	<u>Mean Result</u>					
Hb g/dL	18.4 - 19.6	19.2					
Hct %	52 - 58	56					

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

*Auishi M*

Approval

QC Inspector

Title

10/9/2024

Date