



**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:	N/A												
Description:	TEST STRIPS, STATSTRIP HEMOGLOBIN/HEMATOCRIT, PACKAGED 50 CT												
Catalog Number:	58786												
Nova Biomedical P/N	58786												
<table border="1"> <thead> <tr> <th>Target Range (Hct)</th> <th>CV (%)</th> <th></th> </tr> </thead> <tbody> <tr> <td>28-36 %</td> <td>≤ 8%</td> <td>PASS / FAIL</td> </tr> <tr> <td>38-46 %</td> <td>≤ 8%</td> <td>PASS / FAIL</td> </tr> <tr> <td>48-56%</td> <td>≤ 8%</td> <td>PASS / FAIL</td> </tr> </tbody> </table>	Target Range (Hct)	CV (%)		28-36 %	≤ 8%	PASS / FAIL	38-46 %	≤ 8%	PASS / FAIL	48-56%	≤ 8%	PASS / FAIL	
Target Range (Hct)	CV (%)												
28-36 %	≤ 8%	PASS / FAIL											
38-46 %	≤ 8%	PASS / FAIL											
48-56%	≤ 8%	PASS / FAIL											
Qty:	13,104												
Lot No.	1525265249												
Date of Mfg. (DOM):	2025 / 09 / 22 (YYYY/MM/DD)												
Expiration Date:	2027 / 09 / 22 (YYYY/MM/DD)												
Unique Device Identifier (UDI):	(01)20385480587864 (11)250922 (17)270922 (10)1525265249												

Maureen Boreome  
 Quality Control Manager

10/21/25  
 Date

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454