

OI-922

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Rev. BH

Vialed and Packaged Test Strip Release

Test Strips

nova
biomedical

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></tr></thead><tbody><tr><td>28-36 %</td><td>≤ 8%</td></tr><tr><td>38-46 %</td><td>≤ 8%</td></tr><tr><td>48-56%</td><td>≤ 8%</td></tr></tbody></table>	Target Range (Hct)	CV (%)	28-36 %	≤ 8%	38-46 %	≤ 8%	48-56%	≤ 8%	<table border="1"><tbody><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr><tr><td>PASS / FAIL</td></tr></tbody></table>	PASS / FAIL	PASS / FAIL	PASS / FAIL
Target Range (Hct)	CV (%)											
28-36 %	≤ 8%											
38-46 %	≤ 8%											
48-56%	≤ 8%											
PASS / FAIL												
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Qty:	584											
Lot No.	1522258249											
Date of Mfg. (DOM):	2022/09/15 (YYYY/MM/DD)											
Expiration Date:	2024/09/15 (YYYY/MM/DD)											
Unique Device Identifier (UDI):	(01)20385480587864 (11)220915 (17)240915 (10)1522258249											

Maureen
Quality Control Manager

10/3/2022
Date

Nova Biomedical Corporation

200 Prospect Street

Waltham, MA 02454