

Attachment 3



Certificate of Conformance & Analysis

Nova Biomedical certifies that the following Nova Vet Product has been built and tested in compliance with ISO 13485:2016 and Medical Device Single Audit Program (MDSAP) and meets Nova Biomedical product specifications.

Description: Test strip 25 ct Nova-vet Glu
 Part Number: 53069
 BOM Rev.: C
 Lot Number: 1751023073
 Expiration Date: 2025-03-14
 Date of Manufacture: 2023-03-14
 UDI: (01)20385480 530693
 (11) 230314
 (17) 250314
 (10) 1751023073
 Quantity: 296293 w/ 3/23/23
 Date of Release: 2023-03-23

Release Test Results Summary					
Target Level (mg/dL)	YSI Mean (mg/dL)	Mean (mg/dL)	SD (mg/dL) /CV (%)	SD/CV Specification	P/F
40-80	<u>70.3</u>	<u>80</u>	<u>4.7</u>	≤ 9 mg/dL	<u>P</u>
120-180	<u>176.5</u>	<u>189</u>	<u>3.4</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
220-300	<u>285</u>	<u>282.8</u>	<u>4.0</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
320-440	<u>427.0</u>	<u>413</u>	<u>3.8</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
450-550	<u>494.8</u>	<u>478</u>	<u>2.7</u>	Fail If Both CV of this level and combined CV (L2-L5) >5.0%	<u>P</u>
Total within ISO Zone and %: <u>351/97.5%</u> (per ISO15197:2013)				Total within ISO Zone ≥95%	<u>P</u>

NOTE: Test data in table above taken from completed and approved Data Sheets from TP 139-501 for this lot number.

Marc Browne

Quality Control Manager Signature

Title: QC Manager

Date: 3/23/2023

Nova Biomedical Corporation 200 Prospect Street Waltham, MA 02454