

CERTIFICATE OF ANALYSIS

Allegro HbA1c Test Cartridge Lot Number 24270011

tridge Ref Number 54215 Exp Date 2025-09-26 Date of Manufacture 2024-09-26 UDI# (01)00385480542159(11)240926(17)250926(10)24270011

 Ctl Level 1
 Ctl Level 2

 Spec
 Pass/Fail

 Spec
 Pass/Fail

HbA1c % 4.9 - 6.7 Pass HbA1c % 8.1 - 11.7 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.

Note: Acceptance specifications for this part number are lot dependent and subject to change by the manufacturer

Auishi.M

Approval

QC Inspector Title

10/1/2024 Date