

CERTIFICATE OF ANALYSIS

Allegro Lipids Test Cartridge Lot Number 23304001 Ref Number 54652 Exp Date 2025-04-30 Date of Manufacture 2023-10-31 UDI# (01)00385480546522(11)231031(17)250430(10)23304001

Ctl Level 1

Ctl Level 2

| | <u>Spec</u> | Pass/Fail | | <u>Spec</u> | Pass/Fail |
|--------------------------|----------------------|--------------|--------------------------|-----------------------|--------------|
| HDL mg/dL TCHOL mg/dL | 34 - 56 156 - 226 | Pass Pass | HDL mg/dL TCHOL mg/dL | 68 - 102 285 - 401 | Pass Pass |
| TGL mg/dL | 58 - 134 | Pass | TGL mg/dL | 250 - 390 | 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

Amishi.M

Approval

QC Inspector Title

<u>11/7/2023</u> Date