

CERTIFICATE OF ANALYSIS

Allegro Lipids Test Cartridge Lot Number 24197048 Ref Number 54652 Exp Date 2026-01-15 Date of Manufacture 2024-07-15 UDI# (01)00385480546522(11)240715(17)260115(10)24197048

| Ctl Level 1 | | | | Ctl Level 2 | | |
|-------------|-------------|-----------|-------------|-------------|-----------|--|
| | <u>Spec</u> | Pass/Fail | | <u>Spec</u> | Pass/Fail | |
| HDL mg/dL | 28 - 50 | Pass | HDL mg/dL | 68 - 102 | Pass | |
| TCHOL mg/dL | 155 - 225 | Pass | TCHOL mg/dL | 307 - 423 | Pass | |
| TGL mg/dL | 60 - 136 | Pass | TGL mg/dL | 280 - 420 | 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

Approval

QC Inspector Title

7/24/2024 Date