

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Triglycerides

LOT 26TT0101 DATE MANUFACTURER: 2025-10-22 to 2025-10-29

EXP. DATE: 2027-10-10 (YYYY-MM-DD) REF. # GQ-TT-100

Qty Manufacture: 60 Kits

Physical Inspection:

Labels: Acceptable | QR Code: Acceptable | HPDE Bottle: Acceptable
| Box: Acceptable

Performance Characteristics:

Reagent Triglycerides:

Aspect Liquid Clear Pink (Source Candide Rugose) to pink,
visible particles, with surfactant 1%

Interference blocker

Standard:

Include in the kit – Use Standard of Triglycerides Bialex (GQ-TT-1), (25TT1101)
Concentration 200mg/dL

Reagent

Reagent Triglycerides Abs:

Reagent Triglycerides

Control 1

Control 2

Comparable method with Abbott Alinity c Analyzer (continued)

Values @ 505nm

QCNet (Bio-Rad) Lot 89740

n=20 / 153 mg/dL

n=20 / 77.8 mg/dL

Results @ 505nm

0.014

Results @ 505nm

151.3 mg/dL

75.2 mg/dL

PassCheck -Lot 26PCK0171, 26PCK0172 (REF: GQ-PC1-1,GQ-PC2-1)

Control 1

88.60 mg/dL

Control2

208.43 mg/dL

PassCheck CAL-Lot 26CAL0101 (REF: GQ-CAL-5)

Value 97.84 mg/dL

Linearity: up 1000 mg/dL (PASS)

Stress stability: 3 days (78 hrs) (PASS)

Recommendations: Ultra sensible to cross contamination, keep out of direct light.

Storage 2-8°C

Conclusion: Release for sale

Liable Person: Jean Tankaka

Vector must not be considered pathogenic for livestock or avian species; the kit does not contain genes or express antigens of livestock or poultry disease agents. The kit does not contain any animal derived additives, such as albumin or serum. All Rights Reserved by Bialex®