

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Triglycerides

LOT 25TT0902 DATE MANUFACTURER: 2025-08-21 to 2025-09-04

EXP. DATE: 2027-08-30 (YYYY-MM-DD) REF. # GQ-TT-100, GQ-TT-2X125

Qty Manufacture: 200 KITS (GQ-TT-2X125) +140 KITS (GQ-TT-100)

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),
Concentration 200mg/dL

Reagent

Values @ 505nm

Results @ 505nm

Reagent Triglycerides Abs:

Reagent Triglycerides

Control 1

Control 2

Comparable method with Abbott Alinity c Analyzer (continued)

QCNet (Bio-Rad) Lot 89740

n=20 / 153 mg/dL

n=20 / 77.8 mg/dL

0.021

Results @ 505nm

152.3 mg/dL

79.1 mg/dL

PassCheck -Lot 25PCK0141, 25PCK0142 (REF: GQ-PC1-1,GQ-PC2-1)

Control 1

99.00 mg/dL

Control2

212.17 mg/dL

PassCheck CAL-Lot 24CAL0701 (REF: GQ-CAL-5)

Value 97.96 mg/dL

Linearity: up 1000 mg/dL (PASS)

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

Recommendations: Ultra sensible to cross contaminations, 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®