

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Triglycerides

LOT 24TT1103 DATE MANUFACTURER: 2024-11-07 to 2024-11-12

EXP. DATE: 2026-11-15 REF. # GQ-TT-100

Qty Manufacture: 31L

Physical Inspection:

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

Performance Characteristics:

Reagent Triglycerides:

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

Interference blocker added

Standard:

Include in the kit – Use Standard of Triglycerides Bialex (GQ-TT-1),
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

0.100

Results @ 505nm

156 mg/dL

78 mg/dL

PassCheck -Lot 24PCK0801 (25PCK0814) (REF: GQ-PC1-1,GQ-PC2-1)

Control 1

102 mg/dL

Control 2

216 mg/dL

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

Value 108.83 mg/dl

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

Storage 2-8°C

Conclusion: Release for sale

Liable Person:

