

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Cholesterol Enzymatic Oxidase
LOT 25CHO0302 DATE MANUFACTURER: 2025-02-24 to 2025-03-14
(YYYY-MM-DD) EXP. DATE: 2027-03-10 REF. # GQ-CC-100, GQ-CC-125, GQ-CC-250, GQ-CC-4X125

Qty: 26.4 US gallon / 100 Liters

Physical Inspection:

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

Performance Characteristics:

Reagent Cholesterol:

Translucent, clear pink liquid. Contains visible enzyme microparticles that disappear with increasing temperature and the addition of sample.

Standard:

Include in the kit – Use Standard of Cholesterol Bialex (GQ-CC-1),
Concentration 200mg/dl

Reagent

Reagent Cholesterol

Reagent Cholesterol

Control 1

Control 2

Comparable method with Catachem ChemWell-T

Values @ 510nm

(0.010-0.900)

QCNet (Bio-Rad) Lot 89740

n=20 / 224 mg/dL

n=20 / 96 mg/dL

Results @ 510nm

0.060

Results @ 510nm

226 mg/dL

97 mg/dL

PassCheck Control (Ref: GQ-PC1-01, GQ-PC2-01) -Lot 25PCK0131, 25PCK0132 -@505nm:

Control 1

Control 2

122.40 mg/dL (119.24) 265 mg/dL(260.16)

PassCheck CAL-Lot 24CAL0701 (Ref: GQ-CA-5)

Value: 121.45 mg/dL

Time reader for Abs: 1 hour -Pass

Storage 2-8°C

Conclusion: Release for sale

Liable Person:

A blue circular stamp with "BIALEX LAB" at the top, "QC" in the center, and "QUALITY ASSURANCE" at the bottom. A signature is written over the stamp.