

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Cholesterol Enzymatic Oxidase
LOT 25CHO0901 DATE MANUFACTURER: 2025-08-22 to 2025-09-01
(YYYY-MM-DD) EXP. DATE: 2027-08-30 REF. # GQ-CC-100, GQ-CC-125, GQ-CC-2X125, GQ-CC-250, GQ-CC-4X125

Qty: 300 Liters

Physical Inspection:

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

Performance Characteristics:

Reagent Cholesterol:

Translucent, clear pink liquid. Contains visible 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 @ 505nm

0.053

Results @ 505nm

224.00 mg/dL

92.00 mg/dL

PassCheck Control (Ref: GQ-PC1-01, GQ-PC2-01) -Lot 25PCK0141, 25PCK0142 -@505nm:

Control 1

122.40 mg/dL

Control 2

265 mg/dL

*****Lineality: up 1000 mg/dL, Tested: 1020 mg/dL - pass*****

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

Value: 138.33 mg/dL

Time reader for Abs: 1 hour -Pass

Storage 2-8°C

Conclusion: Release for sale

Liable Person:

