

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Cholesterol Enzymatic Oxidase
LOT 25CHO0601 **DATE MANUFACTURER:** 2025-05-02 (YYYY-MM-DD)
EXP. DATE: 2027-06-01 **REF. #** GQ-CC-100, GQ-CC-125, GQ-CC-2X125,
GQ-CC-250, GQ-CC-4X125

Qty: 400 Kits

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

Abs@ 505nm (against DI Water) = 0.025

Reagent

Reagent Cholesterol

Values @ 510nm

(0.010-0.900)

Reagent Cholesterol

QCNet (Bio-Rad) Lot 89740

Control 1

n=20 / 230 mg/dL

Control 2

n=20 / 85 mg/dL

Comparable method with Abbott Alinity C Analyzer

Results @ 505nm

0.025

Results @ 505nm

230.00 mg/dL

86.40 mg/dL

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

Control 1

129.30 mg/dL

Control 2

266.46 mg/dL

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

Value: 128.52 mg/dL

Time reader for Abs: 1 hour -Pass

Storage 2-8°C

Conclusion: Release for sale

Liable Person:

