Bialex®

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX GGT
LOT: 26GGT0701 MFGDT: 2026.06.29 (YYYY.MM.DD)
EXP. DATE: 2028.06.10 (YYYY.MM.DD) REF: GQ-GGT-4010 / GQ-GGT-6015

BATCH: 100L

Physical Inspection:
Label: Pass QR Code: Pass HPDE Bottle: Pass Vial: NRD Box: Pass

Performance Characteristics:
Reagent: GGT Buffer ph 8.60
Aspect: Liquid Yellow Translucid, non-visible particles with surfactant
Reagent: GGT Substrate
Aspect: Liquid Yellow, non-visible particles w/o surfactant
Speed activity of conversion molar first 25s at 37ºC -Average - PASS
Speed activity of conversion molar 30s to 140s at 37ºC -Average – PASS
Accelerated Stress: PASS

Programmed:
180 read time, Interval Reader: 60s and Lag time: 60s

Factor use in AA Fully Automatic instrument: Use Bialex Calibrator (GQ-CAL-5)

Bialex® PassCheck – Universal Assayed Serum Chemistry Control, Lot 26PCK0171 /26PCK0172
Level 1 = 40 U/L (39) - PASS
Level 2 = 138 U/L (142.00) - PASS
Repeatibility CV<1% (positive bias, which is clinically insignificant)
Optical path 1cm
Lyphochek® - Assayed Chemistry Control, Lot 89740
Level 1 64 (65.00) U/L - PASS
Level 2 136.0 (130.00) U/L - PASS
Beckman Coulter AU System (Continued)
Value for CAL (LOT: 26CAL0101)
47.86

CONCLUSION: REALESE FOR SALE

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