

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX GGT

LOT: 25GGT0401

MFGDT: 2025.04.07 (YYYY.MM.DD)

EXP. DATE: 2027.04.10 (YYYY.MM.DD) **REF:** GQ-GGT-6015

BATCH: 75L

Physical Inspection:

Label: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: NRD

Box: Pass

Performance Characteristics:

Reagent: GGT Buffer ph 8.25

Aspect: Liquid Yellow Translucid, non-visible particles w/o surfactant

Reagent: GGT Substrate

Aspect: Liquid Yellow, non-visible particles w/o surfactant

Speed activity of conversion molar first 30s at 37°C -Average - PASS

Speed activity of conversion molar 31s to 140s at 37°C -Average – PASS

Accelerated Stress: PASS

Programmed:

180 read time, Interval Reader: 60s and Lag time: 30s

Factor use in this lot: 1800 in almost of semi-automatic instruments

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

Bialex® PassCheck – Universal Assayed Serum Chemistry Control, Lot 25PCK0131 /25PCK0132

Level 1 = 40 U/L (44.10) - PASS

Level 2 = 142 U/L (143.22) - PASS

Repeatability CV<1%

Optical path 1cm

Lyphocheck® - Assayed Chemistry Control, Lot 89740

Level 1 49.95 (51.10) U/L - PASS

Level 2 101.75 (102.10) U/L - PASS

Beckman Coulter AU System (Continued)

Value for CAL (LOT: 24CAL0701)

49.22

CONCLUSION: REALESE FOR SALE

