

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX GGT

LOT: 25GGT1101

MFGDT: 2025.10.30 (YYYY.MM.DD)

EXP. DATE: 2027.08.30 (YYYY.MM.DD) REF: GQ-GGT-6015

BATCH: 333 KITS

Physical Inspection:

Label: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: NRD

Box: Pass

Performance Characteristics:

Reagent: GGT Buffer ph 8.56

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 25s at 37°C -Average - PASS

Speed activity of conversion molar 30s to 140s at 37°C -Average – PASS

Accelerated Stress: PASS

Programmed:

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

Factor use in this lot: **1600** 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 25PCK0151 /25PCK0152

Level 1 = 40 U/L (41.00) - PASS

Level 2 = 138 U/L (137.00) - PASS

Repeatability CV<1%

Optical path 1cm

Lyphocheck® - Assayed Chemistry Control, Lot 89740

Level 1 63.6 (63.60) U/L - PASS

Level 2 126.0 (120.00) U/L - PASS

Beckman Coulter AU System (Continued)

Value for CAL (LOT: 24CAL0701)

51.03

CONCLUSION: REALESE FOR SALE

