

## CERTIFICATE OF ANALYSIS

**PRODUCT NAME:** BIALEX LDH

LOT: 25LDH0301

EXP. DATE: 2027.03.10 (YY/MM/DD)

BATCH QTY: 199 KITS

MFGDT: 2025.03.13

REF. GQ-LDH-125

### **Physical Inspection:**

Labels: Pass

QR Code: Pass

HPDE Bottle: Pass

Vial: Pass

Box: Pass

### **Performance Characteristics:**

#### **BUFFER:**

Aspect: Liquid Weak Yellowish Translucid, non visible particles w/o surfactant

pH: 7.4 at 25°C

Reagent Stress: Pass

#### **SUBSTRATE:**

Aspect: Translucid

Reagent Stress: Pass

Work Reagent: 2.5 Abs (Pass)

Work Reagent in 10 Hours: 1.1 Abs (Pass)

Control Lyphocheck Bio-Rad (LOT 89740)

<https://myeinserts-app.qcnet.com/home>

|                        | Result (n=20) | SD    |
|------------------------|---------------|-------|
| Control 1 (144.00 U/L) | 153.80 U/L    | +1.1% |
| Control 2 (287.00 U/L) | 331.90 U/L    | +1.0% |

Comparable Method with BECKMAN COULTER  
SYNCRON/UniCel DxC SERIES (continu

PassCheck Universal Assayed Multicontrol (LOT 25PCK0131/2)

|                        |            |
|------------------------|------------|
| Control 1 (218.56U/L)  | 220.00 U/L |
| Control 2 (530.20 U/L) | 550.00 U/L |

Programming for automatic biochemistry instruments: 120 s (Read Time) / 60 s (Interval Time) / 60 s (Lag time)

Factor at 37°C = Check your Calibrator value (REF: GQ-CAL-5)

Programming for semi-automatic biochemistry instruments: Total time reader 120s, f=8095 (Each factor on the instrument should be calibrated in alignment with the controls)

Conclusion: Released

