

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LDH

LOT: 25LDH0302

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

BATCH QTY: 200 KITS

MFGDT: 2025.03.20

REF. GQ-LDH-100 / 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: 7.54 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: 180 s (Read Time) / 60 s (Interval Time) / 10 s (Lag time)

Factor at 37°C = Check your Calibrator value (REF: GQ-CAL-5) = 253.17

Programming for semi-automatic biochemistry instruments: Total time reader 180s, f=8730 (Each factor on the instrument should be calibrated in alignment with the controls)

Conclusion: Released

