

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LDH

LOT: 25LDH0901

EXP. DATE: 2027.08.30 (YY/MM/DD)

BATCH QTY: 196 KITS

MFGDT: 2025.08.13

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 with surfactant

pH: 7.4 at 25°C

Reagent Stress: Pass

SUBSTRATE:

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

Reagent Stress: Pass

Work Reagent: 2.5 Abs (Pass)

Work Reagent in 10 Hours: 1.2 Abs (Pass)

Control Lyphocheck Bio-Rad (LOT 89740)

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

	Result (n=20)	SD
Control 1 (144.00 U/L)	146.00 U/L	+1.1%
Control 2 (287.00 U/L)	299.30 U/L	+1.0%

Comparable Method with BECKMAN COULTER
SYNCRON/UniCel DxC SERIES (continued)

PassCheck Universal Assayed Multicontrol (LOT 25PCK0141/2)

Control 1 (215.00U/L)	220.00 U/L
Control 2 (556.00 U/L)	550.00 U/L

Programming for automatic biochemistry instruments: 180 s (Read Time) / 60 s (Interval Time) / 60 s (Lag time)
Factor:8095

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

