

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LDH

LOT: 25LDH0701

EXP. DATE: 2027.07.10 (YY/MM/DD)

BATCH QTY: 100 KITS

MFGDT: 2027.07.21

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: 7.50 at 25°C

Reagent Stress: Pass

SUBSTRATE:

Aspect: Translucid

Reagent Stress: Pass

Work Reagent: 2.5 Abs (1.162) - Pass

Substrate: 1.682 - Pass

Control Lyphocheck Bio-Rad (LOT 89740)

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

Result (n=20)

SD

Control 1 (144.00 U/L)

145.60 U/L

+1.0%

Comparable Method with BECKMAN COULTER
SYNCRON/UniCel DxC SERIES

Control 2 (287.00 U/L)

290.10 U/L

+1.0%

PassCheck Universal Assayed Multicontrol (LOT 25PCK0131/2)

Control 1 (210.00U/L)

220.00 U/L

Control 2 (550.20 U/L)

550.00 U/L

Programming for automatic biochemistry instruments: 180 s (Read Time) / 60 s (Interval Time) / 10 s (Lag time),
F=204.28

PassCheck Multicontrol Lot 25PCK0130

Level I: 204.00 (-8% SD)

Level 2: 550 (0% SD) Units: U/L

Programming for semi-automatic biochemistry instruments: 120 s (Read Time) / 60 s (Interval Time) / 20 s (Lag time)

F=8090, PassCheck Multicontrol Lot 25PCK0130

Level I: 194.16, Level II: 560.00 Units: U/L

Factor at 37°C = Check your Calibrator value (REF: GQ-CAL-5) = 204.28

Conclusion: Released

