

CERTIFICATE OF ANALYSIS

PRODUCT NAME: BIALEX LDH

LOT: 26LDH0501

EXP. DATE: 2028.02.10 (YY/MM/DD)

BATCH QTY: 100 KITS

MFGDT: 2026.04.26 - 2026.05.04

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: 7.62 at 25°C

Reagent Stress: Pass

SUBSTRATE:

Aspect: Translucid

Reagent Stress: Pass

Work Reagent: 2.5 Abs (1.30)- Pass

Substrate: 1.600 - Pass

Using: 120s read time, 60s interval reader, 60s lag time

PassCheck Universal Assayed Multicontrol (LOT 26PCK0171/2)

Control 1 (221.95U/L)

220.00 U/L

Control 2 (677.86U/L)

660.00 U/L

(LDH lot shows a negligible positive bias that is clinically insignificant and falls well within the Total Allowable Error (TEa) limits)

Programming for automatic biochemistry instruments: 120 s (Read Time) / 60 s (Interval Time) / 60 s (Lag time),
F=219.21 (Using Bialex Cal Ref: GQ-CAL-5, LOT 26CAL0101)

Programming for semi-automatic biochemistry instruments: 120 s (Read Time) / 60 s (Interval Time) / 60 s (Lag time)
F=7857

Conclusion: Released

