

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex ALT

LOT 25ALT1102 **DATE MANUFACTURER:** 2025.11.21 (YYYY.MM.DD)

EXP. DATE: 2027-10-10 **REF. #** GQ-ALT-100

Qty Manufacture: 700 Kits

Physical Inspection:

Labels: Acceptable | QR Code: Acceptable | HPDE Bottle: Acceptable | Box: Acceptable

☐ x Standard Paperboard Box ☐ x Hospitalary Grade

Performance Characteristics:

Reagent ALT:

Aspect Liquid Translucid clear, non-visible particles.

Reagent

Reagent ALT

Reagent ALT (AA)

Control 1

Control 2

Values @ 340nm

>900

Biorad Lyphocheck Lot 89740

n=20 / 26.8 U/L

n=20 / 100 U/L

Results @ 340nm

1.800

Result:

28.90 SD: 0.9, CV<1.0

101.70 SD<1, CV:1.1

(△ Abs x minute = 3 min)

Run time: 180 s, Interval time: 60 Lag time: 60 s, (Method compare with Abbott Alinity C Analyzer)

Factor: in full automatic instrument, use calibrator (GQ-CAL-5)

Factor: 2450 (Using Jenway 7205)

Factor: 2065 (Most semi-automatic instruments)

Factor: 2100 (Cuvetta x 1cm)

PassCheck Controls -Lot 24PCK0161 & 25PCK0162

Level 1: (45 U/L) 46.00 U/L

LALEVEL 2: (139 U/L) 148.93 U/L

PassCheck CAL-Lot 24CAL0701

Ref: GQ-CAL-5

Value: 57.44(Using 60s of Lag time, and 180s reader)

Linearity: up 1000U/L (1000U/L) Pass

Storage: 2-8°C

Conclusion: Release for sale

Liab Person:



Vector must not be considered pathogenic for livestock or avian species; the kit does not contain genes or express antigens of livestock or poultry disease agents. The kit does not contain any animal derived additives, such as albumin or serum. All Rights Reserved by Bialex®