

## CERTIFICATE OF ANALYSIS

**PRODUCT NAME:** Bialex ALT

LOT 26ALT0301 DATE MANUFACTURER: 2026.01.05-2026.01.14 (YYYY.MM.DD)

EXP. DATE: 2028-01-10 REF. # GQ-ALT-100

**Qty Manufacture:** 400 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          | Values @ 340nm              | Results @ 340nm       |
|------------------|-----------------------------|-----------------------|
| Reagent ALT      | >900                        | 1.900                 |
| Reagent ALT (AA) | Biorad Lyphocheck Lot 89740 | Result:               |
| Control 1        | n=20 / 26.8 U/L             | 23.90 SD: 0.1, CV<1.0 |
| Control 2        | n=20 / 100 U/L              | 103.00 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)

**For best performance, please conduct calibration weekly**

PassCheck Controls -Lot 26PCK0171 & 26PCK0172

Level 1: (45 U/L) 45.07 U/L

LA LEVEL 2: (139 U/L) 142.41 U/L

PassCheck CAL-Lot 26CAL0101

Ref: GQ-CAL-5

Value: 45.59(Using 60s of Lag time, and 180s reader)

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

Storage: 2-8°C

**Conclusion: Release for sale**

Liable 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®