

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex ALT

LOT 25ALT1101 **DATE MANUFACTURER:** 2025.11.13 (YYYY.MM.DD)

EXP. DATE: 2027-09-30 **REF. #** GQ-ALT-100

Qty Manufacture: 600 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	1.800
Reagent ALT (AA)	Biorad Lyphocheck Lot 89740	Result:
Control 1	n=20 / 26.8 U/L	26.90 SD: 0.1, CV<1.0
Control 2	n=20 / 100 U/L	101.30 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) 46.26 U/L

LALEVEL 2: (139 U/L) 149 U/L

PassCheck CAL-Lot 24CAL0701

Ref: GQ-CAL-5

Value: 44(Using 60s of Lag time, and 180s reader)

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

Storage: 2-8°C

Conclusion: Release for sale

Liabe Person:

