

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex ALT

LOT 26ALT0401 **DATE MANUFACTURER:** 2026.04.02 (YYYY.MM.DD)

EXP. DATE: 2027-10-01 **REF. #** GQ-ALT-100

Qty Manufacture: 211 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	1.720
Reagent ALT (AA)	Biorad Lyphocheck Lot 89740	Result:
Control 1	n=20 / 26.8 U/L	27.00 SD: 0.1, CV<1.0
Control 2	n=20 / 100 U/L	109.10 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: 1891 (Using Jenway 7205)

Factor: 2065 (Most semi-automatic instruments)

Factor: 2100 (Cuvetta x 1cm)

PassCheck Controls -Lot 24PCK0171 & 25PCK0172

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

LALEVEL 2: (139 U/L) 140 U/L

PassCheck CAL-Lot 26CAL0101

Ref: GQ-CAL-5

Value: 43.51(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:

