Bialex

CERTIFICATE OF ANALYSIS

PRODUCT INFORMATION

PRODUCT NAME:	Bialex ALT	**REF. #:**	GQ-ALT-100
LOT:	26ALT0701	**QTY MANUFACTURE:**	291 Kits
DATE MANUFACTURE:	2026.07.15 to 2026.07.22 (YYYY.MM.DD)	**EXP. DATE:**	2028-06-30
STORAGE:	2-8 °C	**CONCLUSION:**	Release for sale

PHYSICAL INSPECTION

Labels:	Acceptable	**QR Code:**	Acceptable
HDPE Bottle:	Acceptable	**Box:**	Acceptable (X Standard Paperboard Box)

PERFORMANCE CHARACTERISTICS & REAGENT QUALITY

Reagent ALT:	Hospitalary Grade	**Aspect:**	Liquid Translucid clear, non-visible particles.
Reagent	**Values @ 340nm**	**Results @ 340nm**	
Reagent ALT	>900	1.300	

CONTROL QUALITY TEST (Reagent ALT AA - Biorad Lyphocheck Lot 89750)

Control Level	Target Values	Results
Control 1	n=20 / 26.8 U/L	25.50 (SD: 0.1, CV < 1.0)
Control 2	n=20 / 100 U/L	99.40 (SD > 1, CV: 1.1)

PASSCHECK CONTROLS & CALIBRATORS EVALUATION

PassCheck Controls (Lot 26PCK0171 & 26PCK0172)	PassCheck CAL - Ref: GQ-CAL-5 (Lag: 60s, Reader: 180s)
LEVEL 1: (45 U/L) --> Result: 46.00 U/L	Value (Lot: 26CAL0101): 45.10
LEVEL 2: (139 U/L) --> Result: 137 U/L	Value (Lot: 26CAL0201): 56.62
Linearity Evaluation	Up to 1000 U/L (999 U/L) --> Status: PASS

INSTRUMENT FACTORS & METHOD SPECIFICATIONS

Instrument / Methodology	Assigned Factor / Parameters
In full automatic instrument	Use calibrator (GQ-CAL-5)
Using Jenway 7205	Factor: 2100
Most semi-automatic instruments	Factor: 2045
Cuvetta x 1cm	Factor: 2000
Method Parameters & Comparison	Run time: 180 s | Interval time: 60 s | Lag time: 60 s (Δ Abs x minute = 3 min) Method compared with Abbott Alinity C Analyzer.

LEGAL & MANUFACTURING DECLARATIONS

Pathogen Declaration: 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. **Animal-Derived Additives:** The kit does not contain any animal derived additives, such as albumin or serum. All Rights Reserved by Bialex®

Liable Person: BIALEX LAB
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QUALITY ASSURANCE *Digitally Released*

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