



CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Phosphatase Alkaline

LOT 25PA0901 DATE MANUFACTURER: 2025.08.27 to 2025.09.03
EXP. DATE: 2027-09-03 REF. # GQ-PA-100, GQ-PA-125
Qty: 221 Kits

Physical Inspection:

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

Performance Characteristics:

Buffer:

Aspect Liquid Translucid clear, non-visible particles, w/o surfactant

Substrate:

Aspect yellowish Translucid, non-visible particles.

Reagent Values	@ 405nm	Results @ 405nm
Work Reagent (4:1)	(0.040-0.900)	0.046
Buffer Reagent	(0.010-0.900)	0.020

Reagent Phosphatase Alkaline

	QCNet (Bio-Rad) Lot 89740	Results @ 405nm
Control 1	n=20 / 100 U/L	102.00 U/L
Control 2	n=36 / 446 U/L	448.00 U/L

(Read time: 140s, Read interval: 60s, Leg time: 60s, F=5460)

Comparable method with Roche Cobas Integra

Linearity: 1200 (this lot up to 1201.00 mg/dL) - Pass

Stress Stability: Pass

GQ-PC-1 PassCheck Multicontrol 25PCK0140

Program in instrument:

(Read time: 140s, Read interval: 60s, Leg time: 60s, F=5460)

Control 1 (76 U/L)	76.10 UI/L
Control 2 (210 U/L)	214.00 UI/L

PassCheck CAL-Lot: 24CAL0701 // Ref: GQ-CAL-5

Value Calibrator: 76.10



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.
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