



CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Phosphatase Alkaline

LOT 24PA0801 DATE MANUFACTURER: 2024-08-02

EXP. DATE: 2026-08-01 REF. # GQ-PA-125

Qty: 100 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
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Work Reagent (4:1)	(0.240-0.900)	0.114
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Buffer Reagent	(0.100-0.900)	0.150
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Reagent Phosphatase Alkaline

	QCNet (Bio-Rad) Lot 89730	Results @ 405nm
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Control 1	n=20 / 100 U/L	99.70 U/L
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Control 2	n=36 / 446 U/L	460.00 U/L
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(Read time:60s, Read interval:60s, Leg time:10s, F=5460)

Comparable method with Roche Cobas Integra for Control 2

GQ-PC-1 PassCheck Multicontrol 24PCK0814 (24PCK0401)

Program in instrument:

(Read time:140s, Read interval:60s, Leg time:10s, F=5460)

Control 1	49 UI/L
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Control 2	192 UI/L
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Program in instrument with Δ Abs x 3 minutes

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

Value Calibrator: 82.40



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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