

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirrubin

LOT 25BT0501 DATE MANUFACTURER: 2025-05-13

EXP. DATE: 2027-05-01 REF. # GQ -BT-125

Physical Inspection:

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

Performance Characteristics:

Reagent Total Bilirrubin

Aspect Liquid Translucid, nonvisible particles, with surfactant

Reagent Nitrite:

Aspect Liquid Translucid, nonvisible particles, with surfactant (Lot 25BDT0501)

Reagent	Values @ 550nm	Results @ 550nm
Abs Work Reagent	(0.010-0.200)	0.040 (within the first 4hrs)

T.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 1.30 mg/dL	1.44 (+/- 1.0%)
Control 2	n=20 / 4.10 mg/dL	4.06 (+/- 1.0%)

Comparable with Abaxis Piccolo

	Pediatric Control Liquichek (Bio-Rad) (Lot 74940)	Results @550nm
Control 1	6.43 mg/dL	6.22 (+/-1%)
Control 2	16.40 mg/dL	17.01 (+1%)

Siemens Dimension Vista systems

Comparable with GQ-PC-1 PassCheck Control Lot 25PCK0131 / 24PCK0132

Control 1	Control 2
1.0 mg/dL	6.20mg/dL

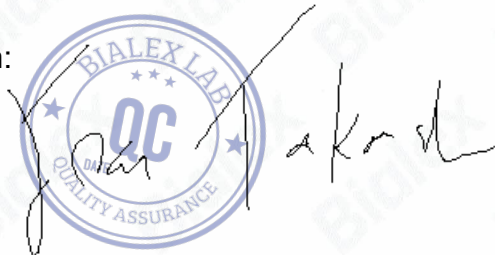
Time reader for Abs:	5 minutes	8 minutes (PASS)
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Factor for this Lot: 36

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 1.37 mg/dL

Storage: 2-25°C

Liable Person:

A circular seal with "BIALEX LAB" at the top, "QC" in the center, and "QUALITY ASSURANCE" at the bottom. A signature is written across the seal.

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. All Rights Reserved by Bialex[®]