

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirubin

LOT 25BT0902 DATE MANUFACTURER: 2025-08-27 to 2025-09-10

EXP. DATE: 2027-09-03 REF. # GQ -BT-100 / GQ-BT-125

Physical Inspection:

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

Performance Characteristics:

Reagent Total Bilirubin

Aspect Liquid Translucid, nonvisible particles, with surfactant

Reagent Nitrite:

Aspect Liquid Translucid, nonvisible particles, with surfactant (Lot 25BDT0902)

Reagent	Values @ 550nm	Results @ 546nm
Abs Work Reagent	(0.010-0.200)	0.190 (within the first 8hrs)

T.Bilirubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 1.02 mg/dL	1.02 (+/- 0.0%)
Control 2	n=20 / 3.92 mg/dL	3.90 (+/- 0.1%)

Comparable with Hitachi Cobac Systems (Continued)

Pediatric Control Liquichek (Bio-Rad) (Lot 74940)

		Results @546nm
Control 1	7.10 mg/dL	6.70 (+/-1%)
Control 2	14.60 mg/dL	13.05 (-1%)

Similar values with Ortho Vitros MicroSlide Series (Calculated)

Comparable with GQ-PC-1 PassCheck Control Lot 25PCK0141 / 24PCK0142

Control 1	Control 2
1.0 mg/dL (1.05)	6.20mg/dL (6.10)

Linearity: up 22 mg/dL

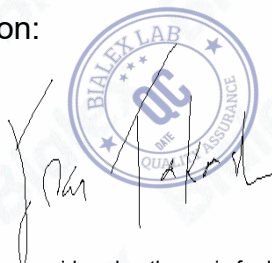
Time reader for Abs: 5 minutes 10 minutes (PASS)

Factor for this Lot: 29

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 0.925

Storage: 2-25°C

Liable Person:



<https://myeinserts-app.qcnet.com/view-pdf?file=blob:https:%2F%2Fmyeinserts-app.qcnet.com%2F5beaec4e-92cf-4a50-9528-3cd642a45e68&fileName=74940>

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®