

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirubin

LOT 25BT1001 DATE MANUFACTURER: 2025-10-22 to 2025-10-30

EXP. DATE: 2027-08-30 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 25BDT0901)

Reagent	Values @ 550nm	Results @ 546nm
Abs Work Reagent	(0.010-0.200)	0.090 (within the first 4hrs)

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	3.96 (+/- 0.0%)

Comparable with Hitachi Cobac Systems (Continued)

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

Control 1	6.18 mg/dL	Results @546nm
Control 2	18.2 mg/dL	6.20 (+/-0.7%)
		18.20 (+0.0%)

Comparable with Ortho Vitros Microslides Series

Comparable with GQ-PC-1 PassCheck Control Lot 25PCK0151 / 24PCK0152

Control 1	Control 2
1.0 mg/dL (1.02)	6.20mg/dL (6.36)

Linearity: up 21 mg/dL

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

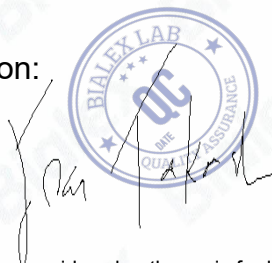
- All samples collected from newborns up to 48 hours of age with Jaundice, should be analyzed using a dilution of 1:10.
- The final results obtained from these diluted samples must be multiplied by 10 to obtain the accurate Total bilirubin level.

Factor for this Lot: 29

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value:1.05

Storage: 2-25°C

Liable Person:



Check reference values of Bio-Rad:

<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®