

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirubin

LOT 26BT1002 DATE MANUFACTURER: 2026-01-05

EXP. DATE: 2028-01-10 (YYYY-MM-DD) REF. # GQ -BT-125, QTY LOT: 195 KITS

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 26BDT1001)

Reagent	Values @ 550nm	Results @ 546nm
Abs Work Reagent	(0.010-0.200)	0.078 (in 24hrs)

T.Bilirubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 1.02 mg/dL	1.12 (+/- 0.1%)
Control 2	n=20 / 3.92 mg/dL	4.06 (+/- 0.9%)

Comparable with Hitachi Cobac Systems (Continued)

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

		Results @546nm
Control 1	6.18 mg/dL	6.18 (+/-0.0%)
Control 2	18.2 mg/dL	17.9 (+0.1%)

Comparable with Ortho Vitros Microslides Series

Comparable with GQ-PC-1 PassCheck Control Lot 25PCK0161 / 25PCK0162

Control 1	Control 2
1.0 mg/dL (1.02)	6.20mg/dL (6.47)

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.

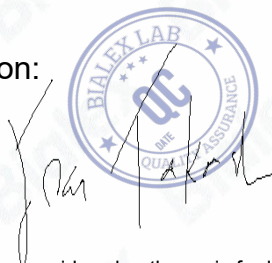
Factor for this Lot: 24.60

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

PassCheck CAL Lot: 26CAL0101 (Ref: GQ-CAL-5) - Value:0.96

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[®]