

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirrubin

LOT 25BT0202 DATE MANUFACTURER: 2025-02-17
EXP. DATE: 2027-02-15 REF. # GQ-BT-100, 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:

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Reagent	Values @ 550nm	Results @ 550nm
Abs Work Reagent	(0.000-0.200)	0.027 (within the first 4hrs)

T.Bilirrubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 1.30 mg/dL	1.36 (+/- 0.0%)
Control 2	n=20 / 4.40 mg/dL	4.39 (+/- 0.1%)
Comparable method with Abbott Architect cSystems		

GQ-PC-1 PassCheck Control Lot 25PCK0821 / 24PCK0821	
Control 1	Control 2
1.15 mg/dL	6.37mg/dL

Time reader for Abs:	5 minutes	8 minutes (PASS)
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Factor for this Lot: 32.10

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 1.14 mg/dL

Liabe Person:

Storage: 2-25°C

