

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Direct Bilirubin

LOT 25BD0901 DATE MANUFACTURER: 2025-08-22
EXP. DATE: 2027-09-04 (YYYY-MM-DD) REF. # GQ-BD-100, GQ-BD-125
LOT QTY: 70L

Physical Inspection:

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

Performance Characteristics:

Reagent Direct Dyazo Bilirubin
Aspect Liquid Translucid, nonvisible particles, with surfactant
Reagent Nitrite:
Aspect Liquid Translucid, nonvisible particles (LOT:25BD0913)

Reagent	Values @ 546nm	Results @ 546nm
Abs Work Reagent	(0.036-0.220)	0.210 (after 8 hours)

D.Bilirubin	QCNet (Bio-Rad) Lot 89740	Results @ 550nm
Control 1	n=20 / 0.379 mg/dL	0.380 (+/- 0.1%)
Control 2	n=20 / 1.680 mg/dL	1.720 (+/- 0.0%)
Comparable result with Beckman Coulter Au Systems		

GQ-PC-1 PassCheck Control Lot 25PCK0141 & 25PCK0142

Control 1	Control 2
0.50 mg/dL	4.70 mg/dL
(0.59 mg/dL)	(4.67mg/dL)

Time reader for Abs:	5 minutes	8 minutes (PASS)
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Pediatric Control - Biorad Liquichek Lot 74940

Siemens ADVIA Chemistry Systems (DBIL_2) (CHEM CAL) (REF 09784096)	mg/dL	4.60	3.78 - 5.41	9.91	8.73 - 11.1
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Bialex Dyazo Direct Bilirubin	mg/dL	4.71	9.39	(Pass)
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FACTOR: 11.20

PassCheck CAL Lot: 24CAL0701 (Ref: GQ-CAL-5) - Value: 0.75 mg/dL

Storage: 2-25°C

Liabe Person:

Yan Tak



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[®]