Bialex®

CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Dyazo Total Bilirrubin	**REF. #:** GQ-BT-100, GQ-BT-125
LOT: 26BT1001	**QTY LOT:** 40L
DATE MANUFACTURER: 2026-10-08	**EXP. DATE:** 2028-10-10 (YYYY-MM-DD)
STORAGE: 2 - 25 °C	**QUALITY STATUS: GMP Quality**

PHYSICAL INSPECTION	STATUS / DESCRIPTION
Labels / QR Code / Box	Acceptable / Acceptable / Acceptable
HPDE Bottle	Acceptable
Reagent Total Bilirrubin Aspect	Liquid Translucid, nonvisible particles, with surfactant
Reagent Nitrite Aspect	Liquid Translucid, nonvisible particles, with surfactant (26BT1001)

PERFORMANCE CHARACTERISTICS	SPECIFICATIONS (@ 546nm)	RESULTS (@ 546nm)
Abs Work Reagent	0.010 - 0.200	0.190 (in 24hrs)

T. BILIRRUBIN CONTROL (Bio-Rad) - Lot 89750	TARGET VALUES	RESULTS (@ 546nm)
Control 1	n = 20 / 1.26 mg/dL	1.30 (+/- 1.0%)
Control 2	n = 20 / 4.90 mg/dL	4.96 (+/- 0.1%)

Method Comparison: Comparable with Beckman Syncron / Unicel

PEDIATRIC CONTROL LIQUICHEK (Bio-Rad) - Lot 74940	TARGET VALUES	RESULTS (@ 546nm)
Control 1	5.39 mg/dL	5.40 (+/- 0.1%)
Control 2	13.30 mg/dL	12.10 (-1.0%)

Method Comparison: Comparable with Roche Cobas Integra
Check reference values of Bio-Rad:
https://myeinserts-app.qcnet.com/view-pdf?file=blob:https:%2F%2Fmyeinserts-app.qcnet.com%2F27ca8b2c-69ff-438a-a189-e4171c568ba9&fileName;=74940

PASSCHECK CONTROL Lot 26PCK170	TARGET VALUES	TIME READER / STATUS
Control 1	1.0 mg/dL (1.10)	5 minutes
Control 2	6.20 mg/dL (6.40)	10 minutes (PASS)

Method Comparison: Comparable with GQ-PC-1 PassCheck Control Lot 26PCK0171 / 25PCK0172

LINEARITY: Up to 20 mg/dL	**FACTOR FOR THIS LOT:** 24.00
PassCheck CAL Lot 26CAL0201 (Ref: GQ-CAL-5) - **Value:** 1.023	**PassCheck CAL Lot 26CAL0101** (Ref: GQ-CAL-5) - **Value:** 0.990

CLINICAL INSTRUCTIONS FOR JAUNDICE IN NEWBORN SAMPLES

- 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.

Liable Person: J.Tanaka

Vector Health Status: *Non-pathogenic for livestock/avian species. Kit does not contain genes or express antigens of livestock or poultry disease agents. Contains no animal-derived additives (albumin/serum).*

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