



CERTIFICATE OF ANALYSIS

PRODUCT NAME: Bialex Direct HDL

LOT 25HDL0901 **DATE MANUFACTURER:** 2025.08.30 to 2025.09.17

EXP. DATE: 2027.08.30 **REF. #** GQ-HDL-6020

Qty Manufacture: 313 Kits

Physical Inspection:

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

Performance Characteristics:

Reagent 1 & 2 Direct HDL :

Aspect Liquid Translucid clear, non-visible particles, w/o surfactant

Calibrator: No include in the kit

Filter Reader for Manual Use: 550nm Filter Reader for AA Use: 600nm

HDL QCNet (Bio-Rad) Lot 89740 Results @ 600nm

Control 1 81.2 mg/dL 81.00 mg/dL

Control 2 28.6 mg/dL 29.00 mg/dL

Comparable method with Siemens Dimensions Series.

PassCheck (Lot 24PCK0141 & 25PCK0142) Ref. Values: 56 - 110 mg/dL

Result: 55.00 - 108.56 mg/dL

Lineality: 200 mg/dl Pass

Time reader for Abs: 180 minutes Pass

Storage 2-8°C

PassCheck CAL (GQ-CAL-5) LOT 25CAL0701 = 61.00

Conclusion: Release for sale

Liable Person:

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®