

Certificate No. 8899-5-2025-1

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

Name of Product(s)

Name of Manufacturer/Distributor, Address

See Attached List

See Attached List

(One Page)

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections.

Sincerely,

CDR Cesar A. Perez, PhD, Director DRP2: Division of Establishment Support

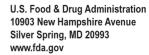
Office of Regulatory Programs

Office of Product Evaluation and Quality Center for Devices and Radiological Health U.S. Food and Drug Administration, DHHS

This certificate is valid from June 13, 2025 to June 12, 2027.









Certificate No. 8899-5-2025-1

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Owner Operator

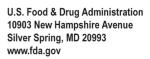
Bialex Lab 717 Ohio Ave Wichita Falls, TX USA 76301

Name of Manufacturer

BIALEX LAB 717 Ohio Ave Wichita Falls, TX USA 76301

----END OF MANUFACTURER/DISTRIBUTOR LIST----







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Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 1

Name of Owner Operator

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Name of Manufacturer

BIALEX LAB 717 Ohio Ave Wichita Falls, TX USA 76301

Name of Product(s)

BIALEX CHOLESTEROL ENZYMATIC OXIDASE - BIOCHEMISTRY REAGENTS

BIALEX TRIGLYCERIDES - BIOCHEMISTRY REAGENTS

BIALEX CREATININE - BIOCHEMISTRY REAGENTS

BIALEX GLUCOSE OXYDASE - BIOCHEMISTRY REAGENTS

BIALEX DYAZO TOTAL BILIRRUBIN - BIOCHEMISTRY REAGENTS

BIALEX DYAZO DIRECT BILIRRUBIN - BIOCHEMISTRY REAGENTS

BIALEX SODIUM - BIOCHEMISTRY REAGENTS

BIALEX POTASSIUM - BIOCHEMISTRY REAGENTS

BIALEX DIRECT HDL - BIOCHEMISTRY REAGENTS

BIALEX ALBUMIN BROMCRESOL - BIOCHEMISTRY REAGENTS

BIALEX AMYLASE - BIOCHEMISTRY REAGENTS

BIALEX PHOSPHATASE ALKALINE -BIOCHEMISTRY REAGENTS

BIALEX TOTAL & DIRECT BILIRUBIN - BIOCHEMISTRY REAGENTS

BIALEX LDL - BIOCHEMISTRY REAGENTS

BIALEX AST - BIOCHEMISTRY REAGENTS

BIALEX ALT - BIOCHEMISTRY REAGENTS

BIALEX EMULSION LIPASE - BIOCHEMISTRY REAGENTS

BIALEX URIC ACID - BIOCHEMISTRY REAGENTS

 ${\tt BIALEX\ PASSCHECK\ BIOCHEMISTRY\ CONTROL\ \&\ CALIBRATOR\ - (IVD\ for\ biochemistry\ analysis)}$

BIALEX HDL Precipitation - BIOCHEMISTRY REAGENTS

BIALEX TOTAL PROTEIN - BIOCHEMISTRY REAGENTS

BIALEX LDH - BIOCHEMISTRY REAGENTS

BIALEX LIPASE KINETIC - BIOCHEMISTRY REAGENTS

BIALEX GGT - BIOCHEMISTRY REAGENTS

BIALEX ASO - BIOCHEMISTRY REAGENTS

BIALEX PHOSPHORUS - BIOCHEMISTRY REAGENTS

BIALEX I-MYCOBACTERIA TEST - BIOCHEMISTRY REAGENTS

BIALEX FERROZINE - BIOCHEMISTRY REAGENTS

BIALEX CHOLINESTERASE - BIOCHEMISTRY REAGENTS

BIALEX BUN - BIOCHEMISTRY REAGENTS

BIALEX CHLORINE - BIOCHEMISTRY REAGENTS

BIALEX CK-MB - BIOCHEMISTRY REAGENTS

BIALEX PROTEINURIA - BIOCHEMISTRY REAGENTS

BIALEX Cu - BIOCHEMISTRY REAGENTS

-----END OF PRODUCT LIST-----

