



**U.S. FOOD & DRUG
ADMINISTRATION**

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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)

See Attached List

(One Page)

Name of Manufacturer/Distributor, Address

See Attached List

(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.



To verify the authenticity of the information on this certificate, you may scan the QR code or visit www.access.fda.gov/fecv/CDRH.



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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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717 Ohio Ave
Wichita Falls, TX
USA 76301

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
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-----

