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. 7608-3-2020

CERTIFICATE OF EXPORTABILITY SECTION 802

The Food and Drug Administration certifies that the product(s) described below is subject to its jurisdiction under the Federal Food, Drug, and Cosmetics Act (the Act). Such product(s), which is not approved for marketing in the United States, may be legally exported to foreign countries provided it meets the requirements of Section 802 of the Act.

Under Section 802 of the Act, a drug or device not approved for marketing in the United States may be exported if it is manufactured, processed, packaged, and held in substantial conformity with current good manufacturing practice requirements. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed below. The company has certified to the Food and Drug Administration that:

* the product(s) accords to the specifications of the foreign purchaser;
* the product(s) is not in conflict with the laws of the country to which it is intended for export;
* the shipping package for the product(s) is labeled on the outside that it is intended for export; and
* the product(s) is not sold or offered for sale in the United States.

Based on the information above, the product(s) listed below may be exported pursuant to Section 802 of the Act.

Name of Product

See Attached List
(One Page)

Manufacturing Location

Diagnostic Automation/ Cortez Diagnostics Inc,.
21250 Califa St Suite 102 and 116
Woodland Hills, CA USA 91367

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 March 31, 2020 to March 30, 2022.

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Certificate of Exportability Section 802 - Name of Product(s) Attachment Page 1 of 1

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Diagnostic Automation/ Cortez Diagnostics Inc,.
21250 Califa St Suite 102 and 116
Woodland Hills, CA USA 91367

Name of Product(s)
HDV Ag
HBcAb IgM
HEV IgM
TB IgM
Gonorrhea
HBsAg
HEV Ab
HAV IgG
HAV IgM
HBcAb
TB IgG
HBeAb
Free PSA
HDV IgG
PSA
HCV Ab
HTLV
HCV IgG
HBsAb
HBeAg
HDV IgM
Rapid and ELISA Test System Kits containing the following analytes
HBV
HCV IgM
AFP
HEV IgG
TB IgA
nCOV
----------END OF PRODUCT LIST----------