



Certificate No. 13496-7-2018

CERTIFICATE OF EXPORTABILITY SECTION 801(e)(1)

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). The products described below may not be sold or offered for sale in the United States. 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 801(e)(1) of the Act.

Name of Product(s)

See Attached List
(Two Pages)

Name of Company, Address

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

CAPT Sean M. Boyd, MPH, USPHS
Deputy Director for Regulatory Affairs
Office of Compliance
Center for Devices and Radiological Health
U.S. Food and Drug Administration, DHHS

This certificate is valid from July 31, 2018 to July 30, 2020.





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

CENTER FOR DEVICES AND RADIATION HEALTH

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

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Name of Company, Address

Diagnostic Automation/ Cortez Diagnostics Inc.,
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Name of Product(s)

CMV IgG/IgM Instatest
Toxoplasma IgG/IgM Instatest
CRP Instatest
SHBG
Salmonella
CKMB ELISA
Leishmania
Beta 2 Glycoprotein IgA
Beta 2 Glycoprotein IgG
Beta 2 Glycoprotein IgM
Intact PTH
Leptospira IgM
Leptospira IgG
Leptospira IgG/IgM
Syphilis (TPA) IgM
Syphilis (TPA) IgM, IgG
Rubella IgA
Toxoplasma IgA ELISA
Cytomegalovirus (CMV) IgA
Herpes Simplex 1 IgM (HSV1 IgM)
Herpes Simplex 1 IgM (HSV1 IgA)
Herpes Simplex 2 IgM (HSV2 IgM)
Herpes Simplex 1 IgM (HSV2 IgA)
Herpes Simplex 1, 2 IgG (HSV1, 2 IgG)
Epstein Bar Virus Early Antigen (EA) IgG
Chlamydia Trachomatis IgA
Chlamydia Trachomatis IgM
Mumps IgM
H. pylori IgA
H. pylori IgM
H. pylori Antigen
Brucella IgG
Brucella IgM
Brucella IgA
EBV VCA IgA
E. coli Verotoxin (Fecal)
E. coli 0157 (Fecal)
Leptin
Micro-Albumin
Anti-Phospholipid
Anti CCP
Anti-Tissue Transglutaminase IgA
Anti-Tissue Transglutaminase IgG
Vitamin B12
STfR-SolubleTransferrin Soluble Receptor
PAPP-A
RSV IgA
RSV IgG
RSV IgM
Adenovirus IgA





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Adenovirus IgG
Adenovirus IgM
Influenza A IgA
Influenza A IgG
Influenza A IgM
Influenza B IgA
Influenza B IgG
Influenza B IgM
Chagas
West Nile IgG
JE IgG ELISA
JE IgM ELISA
Adenovirus (Fecal)
Legionella Urinary Antigen
Campylobacter (Fecal)
Insulin
C-Peptide
Diphtheria Toxoid IgG
Adeno/Rotavirus InstaTest
IgE InstaTest
Chagas InstaTest
Syphilis InstaTest
Leishmania InstaTest
Chlamydia InstaTest
Myoglobin InstaTest
CK-MB InstaTest
Mono InstaTest
HSV 2 IgM IFA
HSV 1 IgM IFA

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

