



Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Certificate No. 28305-11-2015

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  
(4 Pages)

Name of Manufacturer/Distributor, Address

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

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. 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 above.

Carl Fischer, Ph.D.  
Director  
Division of International Compliance Operations  
Office of Compliance  
Center for Devices and Radiological Health

This Certificate is valid from December 16, 2015 to December 16, 2017.



## Certificate to Foreign Government Attachment (Page 1 of 4)

Name Of Product

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**Diagnostic Automation/Cortez Diagnostics, Inc**  
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### **ELISA**

ANA Screen  
ENA Combined Screen  
ENA Profile  
Sm/RNP  
Sm  
Jo-1  
Scl-70  
SS-A (Ro)  
SS-B (La)  
dsDNA G,M  
Cardiolipin IgG, A, M  
Cardiolipin IgG  
Cardiolipin IgM  
Cardiolipin IgA  
Histone  
Rheumatoid Factor I (RF IgM)  
Mitochondria  
Thyroglobulin  
Thyroid Microsomal  
Ribosomal P IgG, A, M  
ANCA Screen Elisa  
Myeloperoxidase MPO (p-ANCA)  
PR3 (C-ANCA)  
Gliadin IgG  
Gliadin IgA  
Beta hCG  
Prostatic Acid Phosphatase (PAP)  
HCG  
HCG Visual  
FSH  
LH  
Prolactin (PRL)  
Dihydro-Testosterone  
Estriol  
T3  
T4  
Sensitive TSH  
TSH  
T Uptake  
Free T3  
Free T4  
Toxoplasma gondii IgG (Toxo IgG)  
Toxoplasma gondii IgM (Toxo IgM)  
Rubella IgG  
Rubella IgM  
Cytomegalovirus IgG (CMV IgG)  
Cytomegalovirus IgM (CMV IgM)  
Herpes Simplex 1 IgG (HSV1 IgG)  
Herpes Simplex 2 IgG (HSV2 IgG)



## Certificate to Foreign Government Attachment (Page 2 of 4)

### Name Of Product

Herpes Simplex 1,2 (HSV 1 & 2 IgM)  
Epstein Barr Virus VCA IgG (EBV, VCA IgG)  
Epstein Barr Virus VCA IgM (EBV, VCA IgM)  
Epstein Barr Virus Nuclear Antigen (EBNA) IgG  
Epstein Barr Virus Nuclear Antigen (EBNA) IgM  
Epstein Barr Virus Early Antigen (EBV-EA) IgG  
Measles IgG  
Measles IgM  
Mumps IgG  
Mycoplasma pneumonia IgG  
Mycoplasma pneumonia IgM  
TPO  
Syphilis (TPA) IgG, TREPONEMAL ANTIBODY  
Legionella pneumophila IgG/IgM  
Legionella Total ( IgG/IgA/IgM)  
Lyme Disease IgG (B.burgdorferi IgG)  
Lyme Disease IgM (B.burgdorferi IgM)  
Lyme Disease IgG/ IgM (B.burgdorferi IgG/IgM)  
Varicella-Zoster IgG (VZV, IgG)  
Varicella-Zoster IgM (VZV, IgM)  
DHEA-S  
Anderostenedione (ASD)  
Estradiol  
Free Testosterone  
Human Growth Hormone (HGH)  
Cortisol  
Ferritin  
Testosterone  
Beta-2 Microglobulin  
PSA  
AFP  
H-Pylori IgG  
C-Reactive Protein (CRP)  
Dixogin  
Troponin I  
Myoglobin  
Cryptosporidium EIA  
Cryptosporidium/Giardia Ag Combo  
Giardia  
C. difficile A+B  
Hepatitis B Surface Antigen (HBsAg)  
Hepatitis B Surface Antibody (HBsAb)  
Hepatitis B Core Total Antibody (HBcAb)  
Hepatitis B Core IgM Antibody (HBcAb IgM)  
Hepatitis B(e) Ag/Ab (HBe Ag/Ab)  
Hepatitis B(e) Antibody (HBeAb)  
Hepatitis B(e) Antigen (HBeAg)  
Hepatitis A Virus IgM Antibody (HAV IgM)  
Hepatitis A Virus Total Antibody (HAV Ab)

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## Certificate to Foreign Government Attachment (Page 3 of 4)

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Neonatal T4  
Neonatal TSH  
Progesterone  
Echinococcus  
Trichinella  
T.Solium (Cysticercosis )  
Schistosoma  
Toxocara  
E.histolytica  
Fasciola  
Strongyloides  
Leptospira IgG  
Ascaris  
Diphtheria  
Chlamydia Trachomatis IgG  
Lipase  
IgE  
Total Human IgE  
FLIPSCREEN (TM) TOTAL E IMMUNOASSAY  
West Nile IgM  
Echinococcus  
Intact PTH  
Rotavirus  
T3U (T-UPTAKE )  
Dengue IgM

### IFA

IFA, ANA HEP-2 (300Tests)  
IFA, ANA HEP-2 (300Tests w/EB)  
IFA, ANA HEP-2 (120Tests)  
IFA, ANA HEP-2 (120Tests w/EB)  
IFA, ANA Mouse Kidney  
IFA, RAT Liver, ANA RAT LIVER  
IFA, Anti-Skin Antibody (ASA)  
IFA, Autoantibody Screen  
(AAS Rat Kidney,Stomach,Liver Tissue Test System)  
IFA, CMV IgG  
IFA, CMV IgM  
IFA, Legionella  
IFA, nDNA  
IFA, EBV -EA IgG  
IFA, EBV-VCA IgG  
IFA, EBV-VCA IgM  
IFA, EBV-NA IgG  
IFA, FTA-ABS  
IFA, FTA-ABS Titratable  
IFA, FTA-ABS Double Stain  
IFA, HSV 2 IgG  
IFA, HSV 1 IgG  
IFA, HSV 1&2 IgG  
IFA, LYME G/M  
IFA, LYME IgG  
IFA,AntiMitochondrial Antibody



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### Name Of Product

IFA, Mycoplasma IgG  
IFA, Mycoplasma CrownTiter IgG  
IFA, Mycoplasma IgM  
IFA, Mycoplasma CrownTiter IgM  
IFA, AntiSmoothmuscle Antibody  
IFA, AntiThyroid Antibody (TA)  
IFA, Toxoplasma IgG  
IFA, Toxoplasma IgM  
IFA, Varicella Zoster  
IFA, Endomysial Antibody  
IFA, Lyme Slide Mounting Media  
IFA, ANCA (P&C)  
IFA, VZV IgG IFA Kits  
IFA, Measles IgG IFA Kits  
IFA Lyme Disease IgG/ IgM (B.burgdorferi IgG/IgM)

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### Instruments

MicroStrip Reader 300 (SF300)  
Chemistry Analyzer 4500 (SF4500)  
Chemistry Analyzer 3300 (SF3300)  
Chemistry Analyzer 1904 (SF1904)  
Incubator/Shaker 2200 (SF2200)  
Microplate washer 2600 (SF2600)  
Microplate Reader 2100 (SF2100)  
Microplate Reader 4200 (SF4200)  
Microwell Washer SWASH (SWASH)  
Microplate Reader 3200 (SF3200)  
Microstrip Luminometer 4100  
Microplate Reader DAR800 (DAR800)  
Microplate Washer DAW50 (DAW50)

END OF PRODUCT LIST

