



Certificate No. 14593-9-2019

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

(Six Pages)

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. 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.

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 September 17, 2019 to September 16, 2021.





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Manufactured for Owner Operator

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

Name of Manufacturer

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

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





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Manufactured for Owner Operator

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

Name of Manufacturer

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

Name of Product(s)

ELISA Test System
ANA IgG
ENA Profile
ENA Combined Screen
Sm/RNP Smith antigen / Ribonucleoprotein
Sm (Smith Antibody)
Jo-1 Antihistidyl Transfer RNA Synthase Antibodies
Scl-70 Anti-Topoisomerase Scleroderma Antibodies
SS-A (Ro) Anti-Sjögren Syndrome A
SS-B (La) Anti-Sjögren Syndrome B
Lipoprotein Lp(a)
Double-Stranded DNA (dsDNA)
Cardiolipin IgG A,M
Cardiolipin IgA
Cardiolipin IgG
Cardiolipin IgM
Histone
Rheumatoid Factor (RF)
Mitochondria
Thyroglobulin
Thyroid Microsomal
Ribosomal
ANCA Screen IgG
MPO, Myeloperoxidase (p-ANCA)
PR3 (cANCA)
Gliadin IgA
Gliadin IgG
Beta hCG
Prostatic Acid Phosphatase (PAP)
hCG
hCG Visual
FSH
LH
Prolactin
Dihydro-Testosterone (DHT)
Free Estriol
T3
T4
Ultra Sensitive TSH
TSH
T Uptake
Free T3
Free T4
Toxoplasma IgG
Toxoplasma IgM
Rubella IgG





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Rubella IgM
Cytomegalovirus IgG (CMV IgG)
Cytomegalovirus IgM (CMV IgM)
Herpes Simplex 1 IgG (HSV 1 IgG)
Herpes Simplex 2 IgG (HSV 1 IgG)
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 Early Antigen (EA) IgG
Epstein-Barr Virus Nuclear Antigen (EBNA) IgM
Epstein-Barr Virus Nuclear Antigen (EBNA) IgG
Measles IgG
Measles IgM
Mumps IgG
Mycoplasma pneumoniae IgG
Mycoplasma pneumoniae IgM
Thyroid Peroxidase (TPO)
Syphilis (TPA) IgG
Syphilis (TPA) IgM
Legionella Total (IgG/M/A)
Legionella IgG/IgM
Lyme Disease IgG (B. burgdorferi IgG)
Lyme Disease IgM (B. burgdorferi IgM)
Lyme Disease IgG/IgM (B. burgdorferi IgG,IgM)
Varicella-Zoster IgG
Varicella-Zoster IgM
DHEA-S
Progesterone
Testosterone
Free Testosterone
Estradiol
Cortisol
Beta-2 Microglobulin
Human prostate-specific antigen (PSA)
Alpha-fetoprotein (AFP)
H. pylori igG
C-Reactive Protein (CRP)
Digoxin
Troponin I
Myoglobin
Cryptosporidium (Fecal)
Crypto/Giardia Ag Combo
Giardia
C. Difficile A+B
HBsAg
HBsAb
HBcAb
HBcAb IgM
HBeAg
HBeAg/Ab
HBeAb
HAV Ab
HAV IgM
Ferritin
Human Growth Hormone (HGH)
Neonatal T4
Neonatal TSH
Echinococcus IgG





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Trichinella IgG
Cysticercosis IgG (T.Solium)
Schistosoma IgG
Toxocara IgG
E. histolytica IgG (Amebiasis)
E. histolytica/dispar
Fasciola IgG
Fasciola gigantica
Strongyloides IgG
Leptospira IgG
Leptospira IgM
Ascaris IgG
Total Human IgE
West Nile IgM
Dengue IgM
Intact PTH
Rotavirus
Chagas
Leishmania
Chlamydia Trachomatis IgG
Diphtheria Toxoid IgG
Anti-Tetanus Toxoid
Campylobacter
Vitamin D
17 OH Progesterone
IFA Test System
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
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
IFA, Mycoplasma IgG
IFA, Mycoplasma CrownTiter IgG
IFA, Mycoplasma IgM
IFA, Mycoplasma CrownTiter IgM
IFA, AntiSmoothmuscle Antibody
IFA, AntiThyroid Antibody (TA)
IFA, Toxoplasma IgG





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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)
Instruments
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
Microplate Reader 3200 (SF3200)
Microstrip Luminometer 4100
Microplate Reader(DAR800)
Microplate Washer (DAW50)
Rapid Test Kits
Hemo Fecal Occult Blood (FOB)
Troponin I Serum
Troponin I Serum/Whole Blood
3 in 1 Troponin I/Myoglobin/CK-MB
Buprenorphine(BUP) Urine RapiCard
Buprenorphine(BUP) Urine RapiDip
Oxycodone (OXY)Urine RapiCard
Oxycodone(OXY) Urine RapiDip
Amphetamine Urine RapiCard
Amphetamine Urine RapiDip
Barbiturates Urine RapiCard
Barbiturates Urine RapiDip
Benzodiazepine Urine RapiCard
Benzodiazepine Urine RapiDip
Cocaine Urine RapiCard™
Cocaine Urine RapiDip
MDMA(Ecstasy) RapiCard
MDMA(Ecstasy) RapiDip
Methamphetamine Urine RapiDip
Methamphetamine Urine RapiCard
EDDP Urine RapiCard
EDDP Urine RapiDip
Marijuana (THC) Urine RapiCard
Marijuana (THC) Urine RapiDip
Opiates/Heroin/Morphine Urine RapiCard
Opiates/Heroin/Morphine Urine RapiDip
Phencyclidine (PCP) Urine RapiCard
Phencyclidine (PCP) Urine RapiDip
Tricyclic Antidepressants(TCA) RapiCard
Tricyclic Antidepressants(TCA) RapiDip
10-Drug RapiCard (Any Drug Combination)
9-Drug RapiCard (Any Drug Combination)
8-Drug RapiCard (Any Drug Combination)
7-Drug RapiCard (Any Drug Combination)
6-Drug RapiCard (Any Drug Combination)
5-Drug RapiCard (Any Drug Combination)





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4-Drug RapiCard (Any Drug Combination)
3-Drug RapiCard (Any Drug Combination)
2-Drug RapiCard (Any Drug Combination)
9-Drug RapiDip(Any Drug Combination)
8-Drug RapiDip(Any Drug Combination)
7-Drug RapiDip(Any Drug Combination)
6-Drug RapiDip (Any Drug Combination)
5-Drug RapiDip (Any Drug Combination)
4-Drug RapiDip (Any Drug Combination)
3-Drug RapiDip (Any Drug Combination)
2-Drug RapiDip (Any Drug Combination)
4-Drug RapiCup (Any Drug Combination)
5-Drug RapiCup (Any Drug Combination)
6-Drug RapiCup (Any Drug Combination)
12-Drug RapiCup (Any Drug Combination)
Alcohol Saliva t
Strep A RapiCard(Swab, Tube & Holder Test)
H. Pylori Cassette Serum/Whole Blood Test)
H. Pylori Ab(Cassette Serum Test)
H. Pylori Ab (Strip Serum Test)
H. Pylori Ab(Cassette Serum/Whole Blood Test)
H. Pylori Ab(Cassette Serum Test)
H. Pylori Ab (Strip Serum Test)
Rotavirus Antigen (Cassette)
Chagas(Cassette)
Malaria (P.f.Vivax) WB-Cassette
Legionella Urinary Antigen
FSH Urine RapiCard
FSH Urine RapiDip
LH Ovulation Urine RapiCard
LH Urine Midstream
LH Urine RapiDip
HCG Midstream Urine RapiCard (OTC)
HCG Urine RapiCard (OTC)
HCG Urine RapiDip (OTC)
HCG Combo (Urine/Serum) (Cassette Test)
HCG Combo (Urine/Serum) (Strip)
URS-1B (Blood)
URS-1G (Glucose)
URS-1P (Protein)
URS-1K (Ketone)
URS-2K (Glucose/Ketone)
URS-2P (Glucose/Protein)
URS-3 (Glucose/Protein/pH)
URS-3K (Glucose/Protein/Ketone)
URS-4B (Glucose/Protein/pH/Blood)
URS-4S (Glucose/Protein/pH/SG)
URS-5K (Blood/Ketone/Glucose/Protein/pH)
URS-5U (Blood/Urobilinogen/Glucose/Protein/pH)
URS-5S (Blood/SG/ Glucose/Protein/pH)
URS-6 (Blood/Ketone/Glucose/Protein/pH/Bilirubin)
URS-6L (Blood/Ketone/Glucose/Protein/Leukocyte/Bilirubin)
URS-7 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin)
URS-8 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin/Nitrite)
URS-9 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite /SG)
URS-10 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes)
URS-11 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes/Ascorbic Acid)
Serology Test Kits





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CRP Latex Test Kit (Complete kit)

RF Latex Test Kit (Complete kit)

ASO Latex Test Kit (complete kit)

Mono Latex Test Kit (Complete kit)

RPR Latex Test Kit (Complete kit)

SLE Latex Test Kit (Complete kit)

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

