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. 11538-8-2026-1

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)	**Name of Manufacturer/Distributor, Address**
See Attached List	See Attached List
(Five Pages)	(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.

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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 August 28, 2026 to August 27, 2028.

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

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)

AccuDiag™ ELISA System
AccuDiag™ Anti-Thyroglobulin Antigen ELISA
AccuDiag™ nDNA Elisa-
AccuDiag™ Pr-3 Elisa
AccuDiag™ Androstenedione Elisa
AccuDiag™ Thyroxine-Binding Globulin (TBG) Elisa
AccuDiag™ Insulin Elisa -
AccuDiag™ C-peptide Elisa
AccuDiag™ 17-Hydroxyprogesterone Elisa
AccuDiag™ TBG - Thyroxine-Binding Globulin Elisa
AccuDiag™ DHEAS Elisa
AccuDiag™ Neonatal 17OHP Elisa
AccuDiag™ Neonatal Thyroxine-Binding Globulin (NTBG)Elisa
AccuDiag™ Legionella Urinary Antigen ELISA
AccuDiag™ Giardia Stool Antigen Detection ELISA
AccuDiag™ Cryptosporidium Stool Antigen Detection Elisa
AccuDiag™ Giardia/Cryptosporidium Combo Stool Antigen Elisa
AccuDiag™ Estrone ELISA
AccuDiag™ Dehydroepiandrosterone Sulfate (DHEAS) ELISA
AccuDiag™ Dehydroepiandrosterone (DHEA) ELISA
AccuDiag™ Rubella Elisa
AccuDiag™ ANA IgG,Elisa Kit
AccuDiag™ ENA Profile-6 Elisa
AccuDiag™ ENA Combined Screen Elisa
AccuDiag™ Scl-70 Anti-Topoisomerase Scleroderma Antibodies Elisa
AccuDiag™ SS-A (Ro) Anti-Sjögren Syndrome A Elisa
AccuDiag™ SS-B (La) Anti-Sjögren Syndrome B Elisa
AccuDiag™ Lipoprotein Lp(a) Elisa
AccuDiag™ Double-Stranded DNA (dsDNA) Elisa
AccuDiag™ Cardiolipin IgA Elisa
AccuDiag™ Cardiolipin IgG Elisa
AccuDiag™ Cardiolipin IgM Elisa
AccuDiag™ Rheumatoid Factor (RF) Elisa
AccuDiag™ Thyroglobulin Elisa
AccuDiag™ Thyroid Autoantibody ELISA
AccuDiag™ ANCA Screen IgG Elisa
AccuDiag™ MPO, Myeloperoxidase (p-ANCA) Elisa
AccuDiag™ PR3 (cANCA) Elisa
AccuDiag™ Gliadin IgA Elisa
AccuDiag™ Gliadin IgG Elisa
AccuDiag™ FSH Elisa
AccuDiag™ LH Elisa
AccuDiag™ Prolactin Elisa
AccuDiag™ T3 Elisa

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AccuDiag™ T4 Elisa
AccuDiag™ TSH Elisa
AccuDiag™ T Uptake Elisa
AccuDiag™ Free T3 Elisa
AccuDiag™ Free T4 Elisa
AccuDiag™ Toxoplasma IgG Elisa
AccuDiag™ Toxoplasma IgM Elisa
AccuDiag™ Rubellla IgG Elisa
AccuDiag™ Rubella IgM Elisa
AccuDiag™ Cytomegalovirus IgG (CMV IgG) Elisa
AccuDiag™ Cytomegalovirus IgM (CMV IgM) Elisa
AccuDiag™ Herpes Simplex 1 IgG (HSV 1 IgG) Elisa
AccuDiag™ Herpes Simplex 2 IgG (HSV 1 IgG) Elisa
AccuDiag™ Herpes Simplex 1,2 (HSV 1,2 IgM) Elisa
AccuDiag™ Epstein-Barr Virus VCA IgG (EBV, VCA IgG) Elisa
AccuDiag™ Epstein-Barr Virus VCA IgM (EBV, VCA IgM) Elisa
AccuDiag™ Epstein-Barr Virus Early Antigen (EA) IgG Elisa
AccuDiag™ Epstein-Barr Virus Nuclear Antigen (EBNA) IgM Elisa
AccuDiag™ Epstein-Barr Virus Nuclear Antigen (EBNA) IgG Elisa
AccuDiag™ Measles IgG Elisa
AccuDiag™ Measles IgM Elisa
AccuDiag™ Mumps IgG Elisa
AccuDiag™ Mumps IgM Elisa
AccuDiag™ Mycoplasma pneumoniae IgG Elisa
AccuDiag™ Mycoplasma pneumoniae IgM Elisa
AccuDiag™ Anti-Thyroperoxidase Antigen Elisa
AccuDiag™ Thyroid Peroxidase (TPO) Elisa
AccuDiag™ Legionella IgG/IgM Elisa
AccuDiag™ Lyme Disease IgG (B. burgdorferi IgG) Elisa
AccuDiag™ Lyme Disease IgM (B. burgdorferi IgM) Elisa
AccuDiag™ Lyme Disease IgG/IgM (B. burgdorferi IgG/IgM) Elisa
AccuDiag™ Varicella-Zoster IgG Elisa
AccuDiag™ Varicella-Zoster IgM Elisa
AccuDiag™ Progesterone Elisa
AccuDiag™ Testosterone Elisa
AccuDiag™ Free Testosterone Elisa
AccuDiag™ Estradiol Elisa
AccuDiag™ H. pylori igG Elisa
AccuDiag™ Digoxin Elisa
AccuDiag™ Cryptosporidium (Fecal) Elisa
AccuDiag™ Crypto/Giardia Ag Combo Elisa
AccuDiag™ Giardia Elisa
AccuDiag™ Ferritin Elisa
AccuDiag™ Human Growth Hormone (HGH) Elisa
AccuDiag™ Neonatal T4 Elisa
AccuDiag™ Neonatal TSH Elisa
AccuDiag™ Echinococcus IgG Elisa
AccuDiag™ Trichinella IgG Elisa
AccuDiag™ Cysticercosis IgG (T.Solium) Elisa
AccuDiag™ Schistosoma IgG Elisa
AccuDiag™ Toxocara IgG Elisa
AccuDiag™ E. histolytica IgG (Amebiasis) Elisa
AccuDiag™ E. histolytica/dispar Elisa
AccuDiag™ Fasciola IgG Elisa
AccuDiag™ Strongyloides IgG Elisa
AccuDiag™ Leptospira IgG Elisa
AccuDiag™ Leptospira IgM Elisa
AccuDiag™ Ascaris IgG Elisa

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AccuDiag™ West Nile IgM Elisa
AccuDiag™ Dengue IgM Elisa
AccuDiag™ Dengue NS1 ELISA
AccuDiag™ Rotavirus Elisa
AccuDiag™ Leishmania Elisa - Not Found
AccuDiag™ Enhanced Toxocara IgG ELISA
AccuDiag™ Chlamydia Trachomatis IgG Elisa
AccuDiag™ ANA HEP-2 (300Tests w/EB) IFA
AccuDiag™ ANA HEP-2 (120Tests) IFA
AccuDiag™ ANA HEP-2 (120Tests w/EB) IFA
AccuDiag™ ANA Mouse Kidney IFA
AccuDiag™ RAT Liver IFA
AccuDiag™ Anti-Skin Antibody (ASA) IFA
AccuDiag™Autoantibody Screen IFA
AccuDiag™ (AAS Rat Kidney,Stomach,Liver Tissue Test System) IFA
AccuDiag™ CMV IgG IFA
AccuDiag™ CMV IgM IFA
AccuDiag™ Legionella IFA
AccuDiag™ nDNA IFA
AccuDiag™ EBV -EA IgG IFA
AccuDiag™ EBV-VCA IgG IFA
AccuDiag™ EBV-VCA IgM IFA
AccuDiag™ EBV-NA IgG IFA
AccuDiag™ FTA-ABS IFA
AccuDiag™ FTA-ABS Titratable IFA
AccuDiag™ FTA-ABS Double Stain IFA
AccuDiag™ HSV 2 IgG IFA
AccuDiag™ HSV 1 IgG IFA
AccuDiag™ HSV 1&2 IgG IFA
AccuDiag™ LYME G/M IFA
AccuDiag™ LYME IgG IFA
AccuDiag™ AntiMitochondrial Antibody IFA
AccuDiag™ AntiSmoothmuscle Antibody IFA
AccuDiag™ AntiThyroid Antibody (TA) IFA
AccuDiag™ Toxoplasma IgG IFA
AccuDiag™ Toxoplasma IgM IFA
AccuDiag™ Varicella Zoster IFA
AccuDiag™ VZV IgG IFA
AccuDiag™ Measles IgG IFA
AccuDiag™ Lyme Disease IgG/ IgM (B.burgdorferi IgG/IgM) IFA
AccuDiag™ Instrument System
Chemistry Analyzer 4500 (SF4500)
Chemistry Analyzer 3300 (SF3300)
Chemistry Analyzer 1904(SF1904)
Incubator/Shaker/Digital Dry Bath 2200(SF2200)
Microplate washer 2600 (SF2600)
Microplate Reader 2100(SF2100)
Microplate Reader 4200 (SF4200)
Microwell Washer SWASH
Microplate Reader 3200 (SF3200)
Microplate Reader(DAR800TS)
Microplate Washer (DAW50TS)
InstaTest™ RapidTest System
InstaTest™ Hemo Fecal Occult Blood (FOB) RapiCard™
InstaTest™ Troponin I Serum RapiCard™
InstaTest™ Troponin I Serum/Whole Blood RapiCard™
InstaTest™ Amphetamine Urine RapiCard™
InstaTest™ Amphetamine Urine RapiDip™

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InstaTest™ Barbiturates Urine RapiCard™
InstaTest™ Barbiturates Urine RapiDip™
InstaTest™ Benzodiazepine Urine RapiCard™
InstaTest™ Benzodiazepine Urine RapiDip™
InstaTest™ Cocaine Urine RapiCard™
InstaTest™ Cocaine Urine RapiDip™
InstaTest™ Methamphetamine Urine RapiDip™
InstaTest™ Methamphetamine Urine RapiCard™
InstaTest™ Marijuana (THC) Urine RapiCard™
InstaTest™ Marijuana (THC) Urine RapiDip™
InstaTest™ Opiates/Heroin/Morphine Urine RapiCard™
InstaTest™ Opiates/Heroin/Morphine Urine RapiDip™
InstaTest™ Phencyclidine (PCP) Urine RapiCard™
InstaTest™ Phencyclidine (PCP) Urine RapiDip™
InstaTest™ Tricyclic Antidepressants(TCA) RapiCard™
InstaTest™ Tricyclic Antidepressants(TCA) RapiDip™
InstaTest™ 10-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 9-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 8-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 7-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 6-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 5-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 4-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 3-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 2-Drug RapiCard™ (Any Drug Combination)
InstaTest™ 9-Drug RapiDip™(Any Drug Combination)
InstaTest™ 8-Drug RapiDip™(Any Drug Combination)
InstaTest™ 7-Drug RapiDip™(Any Drug Combination)
InstaTest™ 6-Drug RapiDip™ (Any Drug Combination)
InstaTest™ 5-Drug RapiDip™ (Any Drug Combination)
InstaTest™ 4-Drug RapiDip™ (Any Drug Combination)
InstaTest™ 3-Drug RapiDip™ (Any Drug Combination)
InstaTest™ 2-Drug RapiDip™ (Any Drug Combination)
InstaTest™ 4-Drug RapiCup™ (Any Drug Combination)
InstaTest™ 5-Drug RapiCup™ (Any Drug Combination)
InstaTest™ 6-Drug RapiCup™ (Any Drug Combination)
InstaTest™ 12-Drug RapiCup™ (Any Drug Combination)
InstaTest™ H. Pylori Serum/Whole Blood Test RapiCard™ ™
InstaTest™ H. Pylori Ag Serum Test RapiCard™ ™
InstaTest™ H. Pylori Ab Serum Test RapiDip™
InstaTest™ H. Pylori Ag Serum Test RapiDip™
InstaTest™ Influ A + B RapiCard™
InstaTest™ Fecal Occult Blood RapidCard
InstaTest™ LH Ovulation Urine RapiCard™
InstaTest™ LH Urine Midstream
InstaTest™ LH Urine RapiDip™
InstaTest™ HCG Midstream Urine RapiCard™ (OTC)
InstaTest™ HCG Urine RapiCard™ (OTC)
InstaTest™ HCG Urine RapiDip™ (OTC)
InstaTest™ HCG Combo Urine/Serum/Plasma RapiCard™
InstaTest™ HCG Combo Urine/Serum RapiDip™
InstaTest™ RPR RapiCard™
InstaTest™ URS-1B (Blood)
InstaTest™ URS-1G (Glucose)
InstaTest™ URS-1P (Protein)
InstaTest™ URS-1K (Ketone)
InstaTest™ URS-2K (Glucose/Ketone)
InstaTest™ URS-2P (Glucose/Protein)

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InstaTest™ URS-3 (Glucose/Protein/pH)
InstaTest™ URS-3K (Glucose/Protein/Ketone)
InstaTest™ URS-4B (Glucose/Protein/pH/Blood)
InstaTest™ URS-4S (Glucose/Protein/pH/SG)
InstaTest™ URS-5K (Blood/Ketone/Glucose/Protein/pH)
InstaTest™ URS-5U (Blood/Urobilinogen/Glucose/Protein/pH)
InstaTest™ URS-5S (Blood/SG/ Glucose/Protein/pH)
InstaTest™ URS-6 (Blood/Ketone/Glucose/Protein/pH/Bilirubin
InstaTest™ URS-6L (Blood/Ketone/Glucose/Protein/Leukocyte/Bilirubin)
InstaTest™ URS-7 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin)
InstaTest™ URS-8 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin/Nitrite)
InstaTest™ URS-9 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH /Bilirubin /Nitrite /SG)
InstaTest™ URS-10 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG /Leukocytes)
InstaTest™ URS-11 (Urobilinogen /Blood /Ketone /Glucose /Protein /pH/Bilirubin /Nitrite /SG
InstaTest™ Serology System
InstaTest™ CRP Latex Test Kit (Complete kit)
InstaTest™ RF Latex Test Kit (Complete kit)
InstaTest™ ASO Latex Test Kit (complete kit)
InstaTest™ RPR Latex Test Kit (Complete kit)
InstaTest™ SLE Latex Test Kit (Complete kit)
InstaTest™ Synthetic VDRL Antigen Test Kit
InstaTest™ Color Staph Test Kit
InstaTest™ Sickle Cell Test Kit
InstaTest™ Color Mono Test Kit
InstaTest™ Staphslide Latex Test Kit
----------END OF PRODUCT LIST----------

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