



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

Certificate No. 28253-10-2015

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

Diagnostic 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 November 17, 2015 to November 17, 2017.



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

**NAME OF MANUFACTURER/DISTRIBUTOR, ADDRESS**  
**NAME OF PRODUCT**  
Diagnostic Automation/Cortez Diagnostics, Inc.  
21250 Califa St, Suite 102 and 116, Woodland Hills, CA 91367

## Hemo Fecal Occult

OneStep Hemo Fecal Occult Blood RapiCard™ InstaTest

## Cardiac Markers

OneStep Troponin I Serum RapiCard™ InstaTest

OneStep Troponin I Serum/Whole Blood RapiCard™ InstaTest

OneStep 3 in 1, Troponin I/Myoglobin/CK-MB Serum/Plasma RapiCard™ InstaTest

## Drug Tests

OneStep Buprenorphine(BUP) Urine RapiCard™ InstaTest

OneStep Buprenorphine(BUP) Urine RapiDip™ InstaTest

OneStep Oxycodone (OXY)Urine RapiCard™ InstaTest

OneStep Oxycodone(OXY) Urine RapiDip™ InstaTest

OneStep Amphetamine Urine RapiCard™ InstaTest

OneStep Amphetamine Urine RapiDip™ InstaTest

OneStep Barbiturates Urine RapiCard™ InstaTest

OneStep Barbiturates Urine RapiDip™ InstaTest

OneStep Benzodiazepine Urine RapiCard™ InstaTest

OneStep Benzodiazepine Urine RapiDip™ InstaTest

OneStep Cocaine Urine RapiCard™ InstaTest

OneStep Cocaine Urine RapiDip™ InstaTest

OneStep MDMA(Ecstasy) RapiCard InstaTest

OneStep MDMA(Ecstasy) RapiDip InstaTest

OneStep Methamphetamine Urine RapiDip™ InstaTest

OneStep Methamphetamine Urine RapiCard™ InstaTest

OneStep EDDP (Methadone) Urine RapiCard™ InstaTest

OneStep EDDP (Methadone) Urine RapiDip™ InstaTest

OneStep Marijuana (THC) Urine RapiCard™ InstaTest

OneStep Marijuana (THC) Urine RapiDip™ InstaTest

OneStep Opiates/Heroin/Morphine Urine RapiCard™

OneStep Opiates/Heroin/Morphine Urine RapiDip™ InstaTest

OneStep Phencyclidine (PCP) Urine RapiCard™ InstaTest

OneStep Phencyclidine (PCP) Urine RapiDip™ InstaTest

OneStep Tricyclic Antidepressants( TCA ) Urine RapiCard™ InstaTest

OneStep Tricyclic Antidepressants( TCA ) Urine RapiDip™ InstaTest

OneStep 6-Drug RapiCard™ InstaTest, (Any Drug Combination)

OneStep 5-Drug RapiCard™ InstaTest, (Any Drug Combination)

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Diagnostic Automation/Cortez Diagnostics, Inc.  
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OneStep 7-Drug RapiDip™ InstaTest, (Any Drug Combination)  
OneStep 6-Drug RapiDip™ InstaTest, (Any Drug Combination)  
OneStep 5-Drug RapiDip™ InstaTest, (Any Drug Combination)  
OneStep 4-Drug RapiDip™ InstaTest, (Any Drug Combination)  
OneStep 3-Drug RapiDip™ InstaTest, (Any Drug Combination)  
OneStep 2-Drug RapiDip™ InstaTest (Any Drug Combination)

## Drug Check RapiCup

OneStep 4-Drug RapiCup™ InstaTest (Any Drug Combination)  
OneStep 5-Drug RapiCup™ InstaTest (Any Drug Combination)  
OneStep 6-Drug RapiCup™ InstaTest (Any Drug Combination)  
OneStep 12-Drug RapiCup™ InstaTest (Any Drug Combination)

## Alcohol

OneStep Alcohol Saliva InstaTest

## Infectious Diseases and Others

### Strep A

OneStep Strep A RapiCard™ InstaTest  
(Swab, Tube & Holder Test)

### H. Pylori

OneStep H. Pylori RapiCard™ InstaTest,(Cassette Serum/Whole Blood Test)  
OneStep H. Pylori RapiCard™ InstaTest (Cassette Serum Test)  
OneStep H. Pylori RapiCard™ InstaTest (Cassette Serum Test)

### Rotavirus

OneStep Rotavirus Antigen RapiCard™ InstaTest

### Malaria (P.f,Vivax)

Malaria (P.f,Vivax) Whole Blood RapiCard™ InstaTest

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### Legionella

Legionella Urinary Antigen RapiCard™ InstaTest

### Fertility (HCG)

OneStep FSH Urine RapiCard™ InstaTest

OneStep FSH Urine RapiDip™ InstaTest

### Ovulation (LH)

OneStep LH Ovulation Urine RapiCard™ InstaTest (6 days Pack)

OneStep LH Ovulation Urine RapiCard™ InstaTest (10 days Pack)

OneStep LH Urine RapiCard™ InstaTest (Cassette Test)

OneStep LH Midstream RapiCard™ InstaTest

OneStep LH Urine RapiDip™ InstaTest (3.5mm Strip)

OneStep LH Urine RapiDip™ InstaTest (5mm Strip)

### Pregnancy

OneStep HCG Midstream Urine RapiCard™ InstaTest (OTC)

OneStep HCG Urine RapiCard™ InstaTest (Cassette) (OTC)

OneStep HCG Urine RapiDip™ InstaTest (2.5mm Strip) (OTC)

OneStep HCG Urine RapiDip™ InstaTest (3.5mm Strip) (OTC)

OneStep HCG Urine RapiDip™ InstaTest (5mm Strip) (OTC)

OneStep HCG Combo (Urine/Serum) RapiCard™ InstaTest (Cassette Test)

OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest (3.5mm Strip)

OneStep HCG Combo (Urine/Serum) RapiDip™ InstaTest (5mm Strip)

### Urine Reagent Strips

URS-1B (Blood)

URS-1G (Glucose)

URS-1P (Protein)

URS-1K (Ketone)

URS-2K (Glucose/Ketone)

URS-2P (Glucose/Protein)

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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

**CRP (C-Reactive Protein)**

CRP Latex Test Kit (Complete kit)

**RF (Rheumatoid Factor)**

RF Latex Test Kit (Complete kit)

**ASO(Anti-Streptolysin-O)**

ASO Latex Test Kit (complete kit)

**Mono(Infected Mononucleosis)**

Mono Latex Test Kit (Complete kit)

**RPR( Rapid Plasma Reagent)**

RPR Latex Test Kit (Complete kit)

RPR Latex Test Kit (Complete kit)

**SLE (Systemic Lupus Erythematosus)**

SLE Latex Test Kit (Complete kit)

**“End of Product list”**

