

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

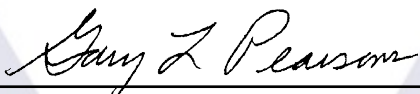
**Diagnostic Automation, Inc.
and Cortez Diagnostics, Inc.
23961 Craftsman Road
Suite D/E/F
Calabasas
California
91302
USA**

Holds Certificate No: **FM 83092**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Please see scope page.

For and on behalf of BSI:

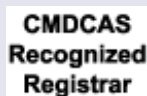


President, BSI Management Systems America, Inc.

Originally registered: **04/09/2004**

Latest Issue: **02/21/2007**

Expiry Date: **03/11/2010**



Page: 1 of 3



This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsi-global.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.

Certificate No: **FM 83092**

Registered Scope:

Manufacture and distribution of test kits used in medical diagnostics (Class II - Indicator OneStep HCG Midstream Urine RapiCard. InstaTest, Indicator OneStep HCG Urine RapiCard. InstaTest (Cassette), Indicator OneStep HCG Urine RapiDip. InstaTest (Strip),Indicator OneStep HCG Combo (Urine/Serum) RapiCard. InstaTest (Cassette Test), Indicator OneStep HCG Combo (Urine/Serum) RapiDip. Indicator OneStep LH Midstream Urine RapiCard. InstaTest, Indicator OneStep LH Urine RapiCard. InstaTest (Cassette), Indicator OneStep LH Urine RapiDip. InstaTest (Strip),Indicator .InstaTest (Strip), Indicator OneStep Strep A RapiCard. InstaTest (Cassette Test), Indicator OneStep Alcohol Saliva InstaTest, RapiCup 5Test InstaCup, (Any Combination), OneStep 6-Drug RapiCard. InstaTest, (Any Drug combination), OneStep 5-Drug RapiCard. InstaTest, ,(Any Drug Combination),OneStep 4-Drug RapiCard. 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 Troponin I Serum RapiCard. InstaTest, One Step Myoglobin Serum RapiCard. InstaTest, One Step 3 in 1 Troponin I/Myoglobin/CK-MB (Serum/Whole Blood RapiCard InstaTest), One Step 3 in 1 Troponin I/Myoglobin/CK-MB Serum RapiCard InstaTest, Cardiolipin IgG ELISA Test Kit, Cardiolipin IgM ELISA Test Kit, Cardiolipin IgA ELISA Test Kit,Cardiolipin IgG, A, M ELISA Test Kit,ANA Screen ELISA Test Kit, ENA Profile ELISA Test Kit, ENA Combined ELISA Test Kit,Histone ELISA Test Kit, Rheumatoid Factor ELISA Test Kit, Mitochondria ELISA Test Kit, Thyroglobulin ELISA Test Kit, Ribosomal ELISA Test Kit, ANCA Screen ELISA Test Kit, Gliadin IgG ELISA Test Kit, Gliadin IgA ELISA Test Kit. Class III -Hemo Fecal Occult Blood RapiCard. InstaTest, Hemo Fecal Occult Blood RapiDip. InstaTest (5mm Strip), Chlamydia (Male) RapiCard. InstaTest (Cassette Swab Test), Chlamydia (Female) RapiCard. InstaTest (Cassette Swab Test), Lyme Disease IgG ELISA Test Kit, Lyme Disease IgM ELISA Test Kit, Lyme Disease IgG, M ELISA Test Kit, Anti Tetanus Toxoid ELISA Test Kit, Diphteria Toxoid IgG ELISA Test Kit).

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Location

Registered Activities

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