



**Certificate Number: 0088/113495/00087**

**EC DESIGN EXAMINATION CERTIFICATE**

***In accordance with the requirements of the  
In Vitro Diagnostic Medical Devices Directive 98/79/EC and  
Medical Devices Regulations 2002:618***

LRQA confirm that the Design Dossier for:

**Product Name:** OneStep LH (Rapid Test) Product Family

**Product Description:** Self Test Luteinising Hormone

**Other Details:** OneStep LH Urine RapiDip™ InstaTest  
OneStep LH Urine RapiCard™ InstaTest  
OneStep LH Urine Midstream InstaTest

**Manufacturer:** Cortez Diagnostics, Inc  
Diagnostic Automation  
23961 Craftsman Road  
Suite D/E/F  
Calabasas, CA 91302  
USA

*Is in conformity with the provisions of Annex III, Clause 6 of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002:618.*

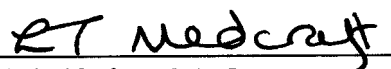
*The manufacturer shall notify LRQA of any modifications or changes to the device design in order to maintain a valid certificate.*

Original Approval: 19 May 2005

Current Certificate: 19 May 2005

Certificate Expiry: 18 May 2010

LRQA Notified Body  
Registration No: 0088

  
on behalf of LRQA Centre

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