



Certificate Number: 0088/113495/00080

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 hCG (Rapid Test) family
Product Description:	Self Test Pregnancy
Other Details:	OneStep hCG Midstream Urine InstaTest, OneStep hCG Urine RapiCard Instatest, OneStep hCG Urine RapiDip InstaTest
Design Dossier:	DOC C - 052003
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.

LRQA Notified Body
Registration No: 0088

Original Approval: 20 October 2004

Current Certificate: 20 October 2004

Certificate Expiry: 19 October 2009


on behalf of LRQA Centre

This document is subject to the provision on the reverse
71 Fenchurch Street, London EC3M 4BS, United Kingdom. Registration Number 1879370
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001
Macro Revision 12

LLOYD'S REGISTER QUALITY ASSURANCE