Lloyd's Register
LRQA

EC DESIGN EXAMINATION CERTIFICATE

This is to certify that Lloyd's Register Quality Assurance, a Notified Body under the terms of:
the In Vitro Diagnostic Medical Devices Directive 98/79/EC;
the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618;
did (in accordance with Annex III clause 6 of the Directive) undertake an EC Design Examination on the stated products to ensure their conformity with the requirements of the Directive which apply to them. The products identified below were shown to comply.

This certificate is issued to:

MANUFACTURER:	**Diagnostics Automation/Cortez Diagnostics, Inc.** **23961 Craftsman Road, Suite D/E/F** **Calabasas, California 91302, USA**
PRODUCT NAME:	**OneStep HCG Midstream Urine RapiCard™ InstaTest Self Testing** **OneStep HCG Urine RapiCard™ InstaTest Self Testing** **OneStep HCG Urine RapiDip™ InstaTest (2.5mm) Self Testing** **OneStep HCG Urine RapiDip™ InstaTest (3.5mm) Self Testing** **OneStep HCG Urine RapiDip™ InstaTest (5mm) Self Testing**
PRODUCT DESCRIPTION:	**A rapid chromatographic immunoassay for the qualitative detection of human chorionic gonadotropin (hCG) in urine to aid in the early detection of pregnancy.**
DESIGN DOSSIER REFERENCE:	**CE DD hCG 01-06-2015**

This Certificate is not valid for products, the design or characteristics of which have been varied from those examined. The manufacturer shall notify LRQA of any modification or changes to the products in order to maintain a valid certificate.

Certificate No:	0088/0113495/00080
Original Approval:	October 20, 2004
Current Certificate:	October 19, 2014
Certificate Expiry:	October 19, 2019

LRQA Notified Body Number 0088

Martha Winfield
Issued by: Lloyd's Register Quality Assurance Limited

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