



October 20, 2006

Edward Tung
Innovacon
4108 Sorrento Valley Blvd.
San Diego, CA 92121 US

Re: k024350/A009
Received: October 6, 2006

C a t e g o r i z a t i o n N o t i f i c a t i o n

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page <http://www.fda.gov/cdrh/clia>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

If you have any questions regarding this complexity categorization, please contact Freddie Poole at 240-276-0496.

Sincerely yours,

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Document Number : k024350/A009

Test System: Clarity H. pylori Rapid Test Device {serum/plasma}

Analyte : Helicobacter Pylori Antibodies

Complexity : MODERATE



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Waiver Granted Notification

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your application for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. We are pleased to inform you that your test system(s) as identified below is waived:

Test System/Analyte (s) : (SEE ATTACHMENT)

Waived status is applicable to test systems and their instructions approved or cleared by the FDA. We recommend that the test system instructions include a statement that the test system is waived under CLIA. Any modification to the test system including test system instructions or a change in the test system name must be submitted to the FDA for the evaluation of waiver. If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above. This complexity categorization is effective as of the date of this notification.

This categorization will be reported on FDA's home page <http://www.fda.gov/cdrh/clia> and categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. This categorization will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

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Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Document Number : k024350/A009

Test System: Clarity H. pylori Rapid Test Device {whole blood}

Analyte : Helicobacter Pylori Antibodies

Complexity : WAIVED