



July 25, 2007

Edward Tung
Innovacon
4106 Sorrento Valley Blvd.
San Diego, CA 92121 US

Re: k024350/A017
Received: June 29, 2007

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/cli> 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.

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/A017

Test System: Polymedco Poly Stat H. Pylori Test (Whole Blood) {H. Pylori}

Analyte : Helicobacter Pylori Antibodies

Complexity : WAIVED

Test System: Henry Schein One Step + H. Pylori Rapid Test Device (Whole Blood) {H. Pylori}

Analyte : Helicobacter Pylori Antibodies

Complexity : WAIVED