



## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30341-3724

JAN 10 2000

Ms. Robin Weiner  
Vice President  
Clinical Development and Regulatory Affairs  
Quidel Corporation  
10165 McKellar Court  
San Diego, California 92121

Dear Ms. Weiner:

We have completed our review of the Quidel submission for waived status under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations and have determined that the Quidel QuickVue H. pylori gII Test is the same test system as the Quidel QuickVue One-Step H. pylori II Test with the exception of modifications that do not affect performance of the tests.

We have reviewed the differences between Quidel QuickVue One-Step H. pylori II Test and the Quidel QuickVue H. pylori gII Test and note that we approved the Quidel QuickVue One-Step H. pylori II Test submission for waived status on August 27, 1999. Accordingly, upon labeling in conformance with the following paragraph the following test system is approved for waived status:

Test System Code and Name:

52120 Quidel QuickVue H. pylori gII (for whole blood)

Analyte Code and Name:

2513 Helicobacter pylori Antibodies

K991747

In addition, our review of the information submitted by Quidel indicates positive and negative external controls must be tested with each new kit, once per kit, and with each change in operator within that test kit. We believe this requirement for running a positive and negative external control is an acceptable fail-safe mechanism. This must be included in all product labeling and the user must be notified regarding this information. The test kit size must not exceed 30. Waived status is only applicable to the

Page 2 - Ms. Robin Weiner

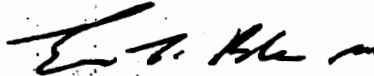
test system and test system instructions reviewed and approved by the Centers for Disease Control and Prevention (CDC). The test system instructions must include a statement that the test system is waived under CLIA. When the final revised copy of the test system instructions is available, we require a complete copy of the product labeling for our records.

Please note: for test systems in use prior to waiver approval, any modifications to the device or instructions that were required for waiver approval must be incorporated into those existing test systems for use of such test systems to be considered waived. (Pending such modifications, the particular test system already in use in a laboratory will retain its prior test categorization.)

Any further modification by the manufacturer or producer to the test system, including test system instructions, must be resubmitted to CDC for evaluation and review. In addition, if the test system is marketed under a different name and/or labeling through agreement with Quidel, this is considered a new test system and is not waived. The new test system must be submitted to CDC for evaluation for waiver.

This categorization is effective as of the date of this notification and may be provided to the user of the test system as specified for the analyte indicated. This categorization will also be published in a Federal Register notice, with an opportunity for public comment. The Department of Health and Human Services reserves the right to reevaluate and recategorize tests based on comments received in response to the Notice.

Sincerely yours,



Edward L. Baker, M.D., M.P.H.  
Assistant Surgeon General  
Director  
Public Health Practice Program Office