



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

September 03, 1999

Categorization Notification

Regulations codified at 42 CFR 493.17, implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems, assays, and examinations by level of complexity. Based upon the categorization criteria, the following test system, assay or examination for the analyte indicated is categorized below:

Test System Code and Name:

52113 Quidel QuickVue H. pylori gII (for Serum/Plasma)

Analyte Code and Name:

2513 Helicobacter pylori Antibodies

FDA 510(k) Number: K991747 Complexity: MODERATE

If the test system indicated above has received clearance through the FDA 510(k) or PMA process, this complexity categorization is effective as of the date of this notification, and this categorization information may be provided to the user of the test system, assay, or examination as specified for the analyte indicated. This determination will also be announced in a Federal Register Notice which will provide opportunity for comment on the decision. CDC reserves the right to reevaluate and recategorize this test based on comments received in response to the Federal Register Notice. It should be noted that a complexity categorization is based upon the unique combination of a test system and analyte; therefore, it cannot be assumed that the same categorization applies to other analytes determined on the test system indicated above. The CDC Identifier Codes referenced above are unique identifiers developed by CDC to facilitate data management. They can be used by CDC, FDA, the Health Care Financing Administration (HCFA), clinical laboratories, and health insurers to track an assay's complexity category.

Edward L. Baker, M.D., M.P.H.

Director

Public Health Practice Program Office