



October 10, 2006

Allan White  
HEMOCUE AB  
40 Empire Drive  
Lake Forest, CA 92630 US

Re: k061047/A001  
Received: June 13, 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   ( W a i v e d )**

Regulations codified at 42 CFR 493.15 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)**

Waived status is applicable to test systems and their instructions approved 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 and will be reported on FDA's home page <http://www.fda.gov/cdrh/cliia>. 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 have any questions regarding this complexity categorization, please contact Josephine Bautista at 240-276-0493 X177.

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 : k061047/A001

Test System: HemoCue Hb 301 System

Analyte : Hemoglobin

Complexity : WAIVED