



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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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 analytes is categorized below:

Test System: QUIDEL QUICKVUE® ONE-STEP hCG URINE TEST

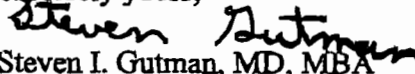
Analyte: URINE HCG BY VISUAL COLOR COMPARISON TESTS

RE: k020799

Complexity: Waived

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>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analytes 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. For questions regarding FDA's categorization procedure, contact Clara A. Sliva, Acting CLIA Coordinator, at (301) 827-0496 or email <http://www.CLIA@CDRH.FDA.GOV>.

Sincerely yours,


Steven I. Gutman, MD, MBA

Director

Division of Clinical Laboratory Devices

Office of Device Evaluation

Center for Devices and Radiological

Health