DEPARTMENT OF HEALTH & HUMAN SERVICES

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Categorization Notification

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 Systems: PHAMATECH OVUCARD LH TEST (CASSETTE)
PHAMATECH OVUSTICK LH TEST (STRIP)

Analyte: OVULATION TEST (LH) BY VISUAL COLOR COMPARISON

Re: k990249/A001 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 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. 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 Gutman

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