DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center - WO66-G609
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

September 14, 2010

Alfa Scientific Designs, Inc.
c/o Suni L Dungan, QA/RA Manager
13200 Gregg St.
Poway, CA 92064 US

Document No: k063545/A038
Re: k063545
Received: September 7, 2010

Categorization Notification (Waived)

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/clia. 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 Zhihao Peter Qiu at 301-827-6924.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

ATTACHMENT

Document Number : k063545

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Amphetamines
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Barbiturates
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Benzodiazepines
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Cocaine Metabolites
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Cannabinoids (THC)
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Methadone
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Methamphetamines
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Methylenedioxymethamphetamine (MDMA)
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Morphine
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Phencyclidine (PCP)
Complexity : WAIVED

Test System: Confirm Biosciences Drugconfirm instant multi-drug test kit, Multi-Drug of Abuse Urine Test
Analyte : Tricyclic Antidepressants
Complexity : WAIVED
