December 6, 2023

Rosa Wu, R&D VP
Hangzhou AllTest Biotech Co., Ltd.
No.550 Yinhai Street, Hangzhou Economic & Technological Development Area
Hangzhou, 310018 CHN

Re: CR230759
CLIA Parent(s): k233417
Applicant: Hangzhou AllTest Biotech Co., Ltd.
Device: CLIAwaived, Inc. Rapid Drug Test Device "RDTD" for Fentanyl in Urine
Dated: November 2, 2023
Received: November 9, 2023
CLIA Effective Date: December 6, 2023

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 in FDA's CLIA Database: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/search.cfm . This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. FDA reserves the right to re-evaluate and re-categorize this test based upon additional information received.

If you have any questions regarding this complexity categorization, please contact Joseph Cleveland at joseph.cleveland@fda.hhs.gov.

Sincerely yours,

Tim Stenzel, MD, PhD
Director
Office of *In Vitro* Diagnostics and
Radiological Health
Center for Devices and Radiological Health

Parent Number : k233417

Test System : CLIAwaived, Inc. Rapid Drug Test Device "RDTD" for Fentanyl in Urine
Analyte : Fentanyl
Complexity : WAIVED