



May 25, 2023

Joe Xia, Regulatory Affairs
LSI International
504 E Diamond Ave, Suite F
Gaithersburg, MD 20877 USA

Re: CR230220
CLIA Parent(s): k153597
Applicant: Healgen Scientific LLC
Device: NEOTEST Drug Test Multi Panel Cup (Urine), NEOTEST Drug Test Dip Card
Dated: April 26, 2023
Received: April 26, 2023
CLIA Effective Date: May 25, 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 Yung Chan at 301-796-6138 or yung.chan@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 : k153597

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Amphetamines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Barbiturates
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Benzodiazepines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Buprenorphine
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Cannabinoids (THC)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Cocaine metabolites
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : EDDP (methadone metabolite)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Methadone
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Methamphetamines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Methylenedioxymethamphetamine (MDMA)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Morphine
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Oxycodone
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Phencyclidine (PCP)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Multi Panel Cup (Urine)
Analyte : Tricyclic antidepressants
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Amphetamines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Barbiturates
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Benzodiazepines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Buprenorphine
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Cannabinoids (THC)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Cocaine metabolites
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : EDDP (methadone metabolite)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Methadone
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Methamphetamines
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Methylenedioxymethamphetamine (MDMA)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Morphine
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Oxycodone
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Phencyclidine (PCP)
Complexity : WAIVED

Test System : Neopharma Technologies Sdn., NEOTEST Drug Test Dip Card
Analyte : Tricyclic antidepressants
Complexity : WAIVED
