Hangzhou AllTest Biotech Co.,Ltd
% Joe Shia
Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K233019
Trade/Device Name: AllTest Multi-Drug Rapid Test Cup; AllTest Multi-Drug Rapid Test Cup Rx, AllTest Multi-Drug Rapid Test Panel, AllTest Multi-Drug Rapid Test Panel Rx
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, NFT, DIS, JXM, DJG, PTH, DIO, DJR, NFV, LAF, DJC, LDJ, NGL, NFY, DNK, LCM, PTG, LFG, NGG, NFW, NGI, NGM, QAW
Dated: September 21, 2023
Received: September 22, 2023

Dear Joe Shia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S
Digitally signed by Joseph A. Kotarek -S
Date: 2023.12.13 17:04:33 -05'00'

Joseph Kotarek, Ph.D.
Toxicology Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
k233019

Device Name
AllTest Multi-Drug Rapid Test Cup
AllTest Multi-Drug Rapid Test Panel

Indications for Use *(Describe)*
AllTest Multi-Drug Rapid Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	500 or 1000 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	150 or 300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	500 or 1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

AllTest Multi-Drug Rapid Test Cup offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
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Methamphetamine (MET)	500 or 1000 ng/mL
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Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL

Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

AllTest Multi-Drug Rapid Test Panel offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

k233019

Device Name
AllTest Multi-Drug Rapid Test Cup Rx
AllTest Multi-Drug Rapid Test Panel Rx

Indications for Use *(Describe)*

AllTest Multi-Drug Rapid Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	d-Amphetamine	500 or 1000
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methamphetamine (MET)	d-Methamphetamine	500 or 1000
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50

AllTest Multi-Drug Rapid Test Cup Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Panel Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	d-Amphetamine	500 or 1000
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methamphetamine (MET)	d-Methamphetamine	500 or 1000
Methylenedioxymethamphetamine	d,l-Methylenedioxymethamphetamine	500

(MDMA)		
Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50

AllTest Multi-Drug Rapid Test Panel Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) SUMMARY
K233019

The purpose of this submission is to add analytes Amphetamine 1000, Cocaine 300, Methamphetamine 1000, to previously cleared devices (k182738). These three new analytes were evaluated in this submission. For other analytes, please refer to k182738 for Buprenorphine, Secobarbital, Benzodiazepines, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Nortriptyline and Marijuana.

1. Date: November 3, 2023

2. Submitter:
Hangzhou Alltest Biotech Co.,Ltd.
#550, Yinhai Street
Hangzhou 310018, China

3. Contact person:
Joe Shia
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com.

4. Device Name:
AllTest Multi-Drug Rapid Test Cup
AllTest Multi-Drug Rapid Test Cup Rx
AllTest Multi-Drug Rapid Test Panel
AllTest Multi-Drug Rapid Test Panel Rx

Classification: Class 2

Product Codes	Class	Regulation Section	Regulation Name	Panel
DKZ, NFT	II	862.3100	Amphetamine Test system	Toxicology (91)
DIS, PTH	II	862.3150	Barbiturate Test system	
JXM, NFV	II	862.3170	Benzodiazepines Test System	
DIO, NFY	II	862.3250	Cocaine and metabolites Test System	
DJR, PTG	II	862.3620	Methadone Test system	
LAF, DJC, NGG	II	862.3610	Methamphetamine Test System	
LDJ, NFW	II	862.3870	Cannabinoids Test System	
DNK, NGI	II	862.3640	Morphine Test System	
DJG, NGL	II	862.3650	Opiate Test System	
LCM, NGM	II	Unclassified	Enzyme immunoassay Phencyclidine	
LFG, QAW	II	862.3910	Tricyclic Antidepressant Drugs Test System	

5. Predicate Devices: K182738

The AllTest Single and Multi-Drug Rapid Test Cup (Urine)

6. Intended Use

AllTest Multi-Drug Rapid Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	500 or 1000 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	150 or 300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	500 or 1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

AllTest Multi-Drug Rapid Test Cup offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.
The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

AllTest Multi-Drug Rapid Test Cup Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	d-Amphetamine	500 or 1000
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methamphetamine (MET)	d-Methamphetamine	500 or 1000

Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50

AllTest Multi-Drug Rapid Test Cup Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

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AllTest Multi-Drug Rapid Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
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Secobarbital (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	150 or 300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	500 or 1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL

AllTest Multi-Drug Rapid Test Panel offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Benzodiazepines, Secobarbital, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result,

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Methamphetamine (MET)	d-Methamphetamine	500 or 1000
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
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AllTest Multi-Drug Rapid Test Panel Rx offers any combinations of the above listed analytes. It is for in vitro diagnostic use only. It is intended for prescription use.

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The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

7. Device Description

The AllTest Multi-Drug Rapid Test Cup and AllTest Multi-Drug Rapid Test Panel are immunochromatographic assays that use a lateral flow system for the qualitative detection of target drug or drug metabolites in human urine. The products are single-use in vitro diagnostic devices. The AllTest Multi-Drug Rapid Test kit contains a Cup or a Panel device, a package insert. Each test device is sealed with a desiccant in an aluminum pouch.

8. Substantial Equivalence Information

A summary comparison of features of the AllTest Multi-Drug Rapid Tests and the predicate devices is provided in following tables.

Table 1: Features Comparison of AllTest Multi-Drug Rapid Test Cup/Panel and the Predicate Devices

Item	Device	Predicate – K182738
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator and Cut-Off Values	Amphetamine (AMP): 500 or 1000 ng/ml Benzodiazepines (BZO):300 ng/ml Cocaine (COC): 150 or 300 ng/ml 11-Nor-$\triangle^9$-Tetrahydrocannabinol-9-COOH (THC):50 ng/ml Methamphetamine (MET): 500 or 1000 ng/ml Morphine (MOP/OPI): 300 or 2000 ng/mL Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Methadone (MTD): 300 ng/ml Buprenorphine (BUP): 10 ng/ml D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Nortriptyline (TCA): 1000 ng/ml 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/ml	Same except AMP 500 MET 500 COC 150
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For prescription use and over-the-counter	Same
Configurations	Cup and Panel	Same

9. Test Principle

The AllTest Multi-Drug Rapid Test Cup/Panel tests are rapid tests for the qualitative detection of target drug or drug metabolites in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-

coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed 5 replicates per day for 5 days per device in a randomized order. The results obtained are summarized in the following tables for Amphetamine 1000, Cocaine 300, and Methamphetamine 1000. The rest data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, EDDP, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana were reported in k182738.

AMP Cup

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-

AMP Panel

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-	25+/0-

COC Cup

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-	25+/0-

COC Panel

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-

MET Cup

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	19+/6-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-

MET Panel

Concentration by LC/MS (ng/mL) / Lot Number	-100% Cut-off	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	Cut-off +25%	Cut-off +50%	Cut-off +75%	Cut-off +100 %
Lot 1	25-/0+	25-/0+	25-/0+	25-/0+	20+/5-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 2	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-	25+/0-
Lot 3	25-/0+	25-/0+	25-/0+	25-/0+	21+/4-	25+/0-	25+/0-	25+/0-	25+/0-

The following cut-off values are verified.

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 ng/mL
Cocaine (COC)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL

b. Linearity

Not applicable.

c. Stability and Traceability

The devices are stable at 2-30 °C for 24 months based on real time stability studies. All drug calibrators of the device are traceable to available commercial reference materials.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three lots of each device. Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. No differences were observed for different device format.

Acetylsalicylic Acid	5, 5-Diphenylhydantoin	19-Norethindrone
Albumin (100mg/dL)	Erythromycin	Noscapine
Amoxicillin	Estradiol	Octopamine
Ampicillin	Estrone	Papaverine
Aspartame	Ethanol (1%)	Penicillin-G
Aspirin	Fenofibrate	Perphenazine
Atropine	Fentanyl	Phenelzine
Baclofen	Fotemustine	Phenylethylamine
Benzocaine	Furosemide	Promazine
Benzoic Acid	Gemfibrozil	Promethazine
Bilirubin	Gentisic acid	Pyridoxine
Carisoprodol	Glucose	Pyrilamine
Chloramphenicol	Guaiacol glyceryl ether	Pyrogallol
Chlordiazepoxide	Hemoglobin	Quinine
(+)-Chlorpheniramine	Hydralazine	Quinolinic Acid
Chlorpromazine	Hydrocortisone	R-(-)-Apomorphine
Cholesterol	3-Hydroxytyramine	Ranitidine
Clonidine	(+/-)-Isoproterenol	Salicylic Acid
Cortisone	Ketamine	Sulindac
(-)-Cotinine	L-Ascorbic Acid	Tetracycline
Creatine Hydrate	Meprobamate	Tetrahydrozoline
Creatinine	Methylphenidate	Thiamine
Cyclodextrin	Nalidixic Acid	Thioridazine
d,l-Propranolol	Naltrexone	Tramadol
Deoxycorticosterone	(+)-Naproxen	Trifluoperazine
Dextromethorphan	Niacinamide	Tryptamine
Diclofenac	Nicotinic Acid	Uric Acid
4-Dimethyl-aminoantipyrine	Nifedipine	Zomepirac sodium salt

e. Specificity

To test specificity, drug metabolites and other structurally related compounds that are likely to cross-react in urine samples were spiked into negative urine and were tested using three lots of each device. The lowest concentration that caused a positive result for each compound are listed below for Amphetamine 1000, Cocaine 300, Methamphetamine 1000. No differences were observed for different device format. The rest data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, Morphine, Methadone, Oxycodone, Phencyclidine, EDDP, Nortriptyline and Marijuana were reported in k182738.

AMP 1000 (Cut-off=1000 ng/mL)	Result Positive at (ng/ml)	%Cross- Reactivity
d-Amphetamine	1000	100%
Methylenedioxyethylamphetamine (MDEA)	>100000	<1%
d,l-Methamphetamine	>100000	<1%
Phenylephrine	>100000	<1%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
d,l - Methylenedioxy methamphetamine	>100000	<1%
l-Amphetamine	1000	100%
Ephedrine	>100000	<1%
Pseudoephedrine	>100000	<1%
d, l-Amphetamine	1000	100%
d,l-3,4-Methylenedioxyamphetamine (MDA)	50	2000%
Phentermine	1000	100%

COC 300 (Cut-off=300 ng/mL)	Result Positive at (ng/ml)	%Cross- Reactivity
Benzoylecgonine	300	100%
Cocaine	250	120%
Cocaethylene	500	60%
Ecgonine	>100000	<0.3%
Norcocaine	>100000	<0.3%

MET 1000 (Cut-off=1000 ng/mL)	Result Positive at (ng/ml)	%Cross- Reactivity
d-Methamphetamine	1000	100%
l -Methamphetamine	25000	4%
d,l-Amphetamine	500	200%
Phentermine	>100000	<1%
d,l-Methamphetamine	500	200%
d-Amphetamine	>100000	<1%
l-Amphetamine	>100000	<1%
Ephedrine	>100000	<1%
Phenylephrine	>100000	<1%
Pseudoephedrine	>100000	<1%
3,4- Methylenedioxy methamphetamine (MDMA)	2500	40%
d,l- Methylenedioxy ethylamphetamine (MDEA)	12500	8.0%
d,l-3,4-Methylenedioxyamphetamine (MDA)	>100000	<1%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000

to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off.

2. Comparison Studies
Method comparison studies for the AllTest Multi-Drug Rapid Test Cup and AllTest Multi-Drug Rapid Test Panel were performed in-house with three laboratory assistants. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below for Amphetamine 1000, Cocaine 300, and Methamphetamine 1000. The rest data for Buprenorphine, Methylenedioxymethamphetamine, Secobarbital, Benzodiazepines, Morphine, Methadone, Oxycodone, Phencyclidine, EDDP, Nortriptyline and Marijuana were reported in k182738.

AMP Cup

AllTest Multi-Drug Test Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	13	26
	Negative	12	12	15	1	0
Viewer B	Positive	0	0	0	13	26
	Negative	12	12	16	1	0
Viewer C	Positive	0	0	1	14	26
	Negative	12	12	15	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN165	896.471	+
Viewer A	SN175	1070.815	-
Viewer B	SN044	1149.522	-
Viewer C	SN128	838.956	+

AMP Panel

AllTest Multi-Drug Test Panel		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	13	26
	Negative	12	12	16	1	0
Viewer B	Positive	0	0	1	14	26
	Negative	12	12	15	0	0

Viewer C	Positive	0	0	2	13	26
	Negative	12	12	14	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN044	1149.522	-
Viewer B	SN062	833.996	+
Viewer C	SN036	922.995	+
Viewer C	SN120	987.795	+
Viewer C	SN150	1181.731	-

COC Cup

AllTest Multi-Drug Test Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	0	9	30
	Negative	12	10	18	1	0
Viewer B	Positive	0	0	1	10	30
	Negative	12	10	17	0	0
Viewer C	Positive	0	0	1	10	30
	Negative	12	10	17	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN174	324.6	-
Viewer B	SN070	297.0	+
Viewer C	SN079	297.7	+

COC Panel

AllTest Multi-Drug Test Panel		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	8	30
	Negative	12	10	17	2	0
Viewer B	Positive	0	0	1	10	30
	Negative	12	10	17	0	0
Viewer C	Positive	0	0	0	8	30
	Negative	12	10	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN079	297.7	+
Viewer A	SN142	352.1	-
Viewer A	SN174	324.6	-
Viewer B	SN012	292.7	+
Viewer C	SN084	312.9	-
Viewer C	SN142	352.1	-

MET Cup

AllTest Multi-Drug Test Cup		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	10	29
	Negative	12	11	16	1	0
Viewer B	Positive	0	0	0	10	29
	Negative	12	11	17	1	0
Viewer C	Positive	0	0	2	10	29
	Negative	12	11	15	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN108	974.577	+
Viewer A	SN043	1194.980	-
Viewer B	SN043	1194.980	-
Viewer C	SN054	919.834	+
Viewer C	SN188	841.261	+
Viewer C	SN197	1167.315	-

MET Panel

AllTest Multi-Drug Test Panel		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	9	29
	Negative	12	11	16	2	0
Viewer B	Positive	0	0	1	10	29
	Negative	12	11	16	1	0

Viewer C	Positive	0	0	0	10	29
	Negative	12	11	17	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	Viewer Results
Viewer A	SN159	882.244	+
Viewer A	SN043	1194.980	-
Viewer A	SN186	1138.254	-
Viewer B	SN159	882.244	+
Viewer B	SN186	1138.254	-
Viewer C	SN197	1167.315	-

Lay User Study

A lay user study was performed at three intended user sites with 560 lay persons. The lay users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Results are shown below.

Results for Low Cutoff Cup

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50 % cutoff	+75 % cutoff
AMP	500	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
BAR	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BZO	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BUP	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%

COC	150	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
EDDP	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MDMA	500	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MET	500	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MOP	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MTD	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
OXY	100	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
PCP	25	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
TCA	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
THC	50	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%

Results for High Cutoff Cup

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50 % cutoff	+75 % cutoff
AMP	1000	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BAR	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BZO	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BUP	10	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
COC	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
EDDP	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MDMA	500	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MET	1000	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OPI	2000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement	100%	100%	100%	90%	90%	100%	100%

		(%)							
MTD	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OXY	100	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
PCP	25	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
TCA	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
THC	50	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%

Results for Low Cutoff Panel

Drug	**Cutoff (ng/mL)**	**Results**	**Concentration**						
			-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50 % cutoff**	**+75 % cutoff**
AMP	500	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
BAR	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BZO	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
BUP	10	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
COC	150	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
EDDP	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MDMA	500	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
MET	500	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
MOP	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MTD	300	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	95%	100%	100%
OXY	100	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
PCP	25	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
TCA	1000	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%

THC	50	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%

Results for High Cutoff Panel

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	1000	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	100%	100%	100%
BAR	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
BZO	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BUP	10	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
COC	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
EDDP	300	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%
MDMA	500	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MET	1000	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
OPI	2000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MTD	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%

OXY	100	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	95%	100%	100%
PCP	25	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
TCA	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
THC	50	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95%	90%	100%	100%

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the devices, it's concluded that the AllTest Multi-Drug Rapid Test Cup and AllTest Multi-Drug Rapid Test Panel are substantially equivalent to the predicate.