Hangzhou Alltest Biotech Co.,Ltd
% Jenny Xia, Director
LSI International Inc
504E Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K242540
Trade/Device Name: AllTest Multi-Drug Urine Test Panel; AllTest Multi-Drug Rapid Urine Test Panel
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, PTH, NGL, NFV, NFY, PTG, NGG, NGM, QAW, NFW
Dated: August 23, 2024
Received: August 26, 2024

Dear Jenny Xia:

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.

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2024.09.27 17:20:34 -04'00'

Joseph Kotarek
Branch Chief for Toxicology
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242540

Device Name

AllTest Multi-Drug Urine Test Panel;
AllTest Multi-Drug Rapid Urine Test Panel

Indications for Use *(Describe)*

AllTest Multi-Drug Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methamphetamine (MET)	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 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
Fentanyl(FYL)	1 ng/mL

AllTest Multi-Drug Urine Test Panel can be a single drug test panel or used for any combination 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 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 Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Oxazepam (BZO)	Oxazepam	300

Cocaine (COC)	Benzoylecgonine	150
Methamphetamine (MET)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300
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
Fentanyl(FYL)	Fentanyl	1

AllTest Multi-Drug Rapid Urine Test Panel can be a single drug test panel or used for any combination of the above listed analytes. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
K242540

1. **Date:** August 23, 2024
2. **Submitter:** Hangzhou AllTest Biotech Co., Ltd.
   Plant Bldg. 3, 4, 5, No. 550 Yinhai Street, Baiyang Street, Hangzhou ETDZ, Jianggan District
3. **Contact person:** Jenny Xia
   LSI International Inc.
   504 East Diamond Ave., Suite H
   Gaithersburg, MD 20877
   Telephone: 301-525-6856
   Email: jxia@lsi-consulting.org
4. **Device Name:** AllTest Multi-Drug Urine Test Panel
   AllTest Multi-Drug Rapid Urine Test Panel
5. **Classification:** Class II

Product Code **Target Drug**	**Regulation Section**	**Panel**
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NGL Buprenorphine (BUP) Fentanyl (FYL) Morphine (MOP/OPI) Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine and cocaine metabolite test system	Toxicology
PTG Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA) Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGM Phencyclidine (PCP)	Unclassified	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology

NFW Cannabinoids (THC)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Devices:

AllTest Multi-Drug Urine Test Cup (K241428)

7. Intended Use

AllTest Multi-Drug Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	150 ng/mL
Methamphetamine (MET)	500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 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
Fentanyl(FYL)	1 ng/mL

AllTest Multi-Drug Urine Test Panel can be a single drug test panel or used for any combination 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 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 Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana and Fentanyl in human urine at the cutoff concentrations of:

Drug (Identifier)	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	d-Amphetamine	500
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150
Methamphetamine (MET)	d-Methamphetamine	500
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300
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
Fentanyl (FYL)	Fentanyl	1

AllTest Multi-Drug Rapid Urine Test Panel can be a single drug test panel or used for any combination of the above listed analytes. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs 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.

8. Device Description

AllTest Multi-Drug Urine Test Panel and AllTest Multi-Drug Rapid Urine Test Panel are immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine.

The devices are a panel format. Each test device is sealed with sachets of desiccant in an aluminum pouch. The device is in a ready-to-use format and no longer requires assembly before use.

9. Substantial Equivalence Information

Similarities			
Item	**Candidate Device (K242540)**		**Predicate (K241428)**
Intended use	Qualitative detection of drugs of abuse in urine. For prescription use or over-the-counter use		Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
Target Drug and Cut Off Values	**Target Drugs**	**Cutoff (ng/mL)**	Same
	Amphetamine(AMP)	500	
	Secobarbital (BAR)	300	
	Buprenorphine (BUP)	10	
	Oxazepam (BZO)	300	
	Cocaine (COC)	150	
	Methylenedioxymethamphetamine (MDMA)	500	
	Methamphetamine (MET)	500	
	Morphine (MOP/OPI)	300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC)	50	
	Fentanyl (FYL)	1	
Differences			
Configuration	Test Panel		Test Cup

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

AllTest Multi-Drug Urine Test Panel or AllTest Multi-Drug Rapid Urine Test Panel is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When a drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test

Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.
When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

12. Performance Characteristics

A. Analytical performance

a. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cut off and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test panels. The results obtained are summarized in the following tables:

Drug	Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
AMP 500	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	21-/29+	49-/1+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	21-/29+	50-/0+	50-/0+	50-/0+	50-/0+
BUP 10	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	50+/0-	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	50+/0-	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
BZO 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
MDMA 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
MET 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+

MOP/ OPI 300	**Lot 2**	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
MTD 300	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
OXY 100	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	21-/29+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
PCP 25	**Lot 1**	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
TCA 1000	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
THC 50	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
COC 150	**Lot 1**	0-/50+	0-/50+	0-/50+	50+/0-	28+/22-	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	50+/0-	29+/21-	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	49+/1-	26+/24-	50-/0+	50-/0+	50-/0+	50-/0+
FYL 1	**Lot 1**	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	20-/30+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+

b. Linearity/assay reportable range:
Not applicable. This device is intended for qualitative use only.

c. Stability:
The device is stable at 2-30℃ for 24 months based on real time stability study.

d. Analytical specificity/Interference:
To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of the device.
Percent cross-reactivity, provided in the below table, was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100.

Drug/Cutoff	**Compound**	**Minimum concentration required to obtain a positive result**	**% Cross-Reactivity**

		(ng/mL)	
AMP 500	Hydroxyamphetamine	5000	10%
	(+/-)-Methylenedioxyamphetamine(MDA)	25	2000%
	D,L-Amphetamine	500	100%
	D-Amphetamine	500	100%
	Diethylstilbestrol	>100000	<0.5%
	L-Amphetamine	500	100%
	Phentermine	500	100%
	β-Phenylethylamine	>100000	<0.5%
	Tyramine	>100000	<0.5%
	p-Hydroxynorephedrine	>100000	<0.5%
	D,L-Norephedrine	>100000	<0.5%
	p-Hydroxyamphetamine	5000	10%
	D-Methamphetamine	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	Ephedrine hydrochloride	>100000	<0.5%
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100000	0.5%
	Phenylpropanolamine	>100000	<0.5%
	Benzphetamine	>100000	<0.5%
	L-Ephedrine	>100000	<0.5%
	L-Epinephrine	>100000	<0.5%
	D,L-Epinephrine	>100000	<0.5%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	100000	0.5%
BAR 300	Alphenal	300	100%
	Amobarbital	300	100%
	Aprobarbital	300	100%
	Butabarbital	500	60%
	Butethal	200	150%

	Cyclopentobarbital	500	60%
	Pentobarbital	200	150%
	Phenobarbital	200	150%
	Secobarbital	300	100%
	Butalbital	2000	15%
	Barbital	300	100%
BUP 10	Buprenorphine	10	100%
	Buprenorphine-3-D-Glucuronide	20	50%
	Norbuprenorphine	20	50%
	Norbuprenorphine-3-D-Glucuronide	20	50%
	Morphine	>100000	<0.01%
	Oxymorphone	>100000	<0.01%
	Hydromorphone	>100000	<0.01%
	Codeine	>100000	<0.01%
	Nalorphine	>100000	<0.01%
BZO 300	a-Hydroxyalprazolam	10000	3%
	Alprazolam	200	150%
	Bromazepam	1000	30%
	Chlordiazepoxide	300	100%
	Clobazam	200	150%
	Clonazepam	200	150%
	Clorazepate Dipotassium	300	100%
	Desalkylflurazepam	>100000	<0.3%
	Diazepam	300	100%
	Estazolam	100	300%
	Flunitrazepam	300	100%
	D,L-Lorazepam	1000	30%
	Midazolam	1000	30%
	Nitrazepam	200	150%
	Norchlordiazepoxide	200	150%
	Nordiazepam	200	150%
	Oxazepam	300	100%
	R,S-Lorazepam glucuronide	1000	30%

	Temazepam	100	300%
	Triazolam	300	100%
	Demoxepam	2000	15%
	Flurazepam	300	100%
	Delorazepam	2000	15%
	Lormetazepam	100	300%
COC 150	Benzoylecogonine	150	100%
	Cocaethylene	250	60%
	Cocaine hydrochloride	125	120%
	Ecgonine	>100000	<0.2%
	Norcocaine	>100000	<0.2%
	Ecgonine methyl ester	>100000	<0.2%
MDMA 500	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	250	200%
	(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
	(±)-MDMA	500	100%
	L-Methamphetamine	>100000	<0.5%
	d-methamphetamine	>100000	<0.5%
	d-amphetamine	>100000	<0.5%
	l-amphetamine	>100000	<0.5%
	d,l-Amphetamine	>100000	<0.5%
	d,l-Methamphetamine	>100000	<0.5%
	Phentermine	>100000	<0.5%
	Phenylephrine	>100000	<0.5%
	Ephedrine	>100000	<0.5%
	Pseudoephedrine	>100000	<0.5%
MET 500	(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	6000	8.3%
	(±)-MDMA	1000	50%
	D-Methamphetamine	500	100%
	L-Methamphetamine	10000	5%

	Fenfluramine	50000	1%
	p-Hydroxymethamphetamine	250	200%
	D,L-Methamphetamine	250	200%
	β-Phenylethylamine	>100000	<0.5%
	Mephetermine	25000	2%
	Methoxyphenamine hydrochloride	75000	0.7%
	L-Amphetamine	100000	0.5%
	D-Amphetamine	100000	0.5%
	D,L-Amphetamine	250	200%
	Chloroquine	25000	2.0%
	Ephedrine hydrochloride	>100000	<0.5%
	(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
	Trimethobenzamide	>100000	<0.5%
	l-phenylephrine	>100000	<0.5%
	(1R,2S)-(-)-Ephedrine	>100000	<0.5%
	Procaine hydrochloride	>100000	<0.5%
	Phentermine	>100000	<0.5%
	Pseudoephedrine	>100000	<0.5%
MOP/OPI 300	6-acetylmorphine	300	100%
	Codeine	250	120%
	Dihydrocodeine	5000	6%
	EthylMorphine	200	150%
	Heroin	500	60%
	Hydrocodone	1000	30%
	Hydromorphone	10000	3%
	Levorphanol tartrate	1500	20%
	Morphine	300	100%
	Nalorphine hydrochloride	300	100%
	Thebaine	20000	1.5%
	s-Monoacetylmorphine	300	100%
	Morphine-3-β-d-glucuronide	1000	30%
	6-Monoacetylmorphine (6-MAM)	300	100%

	Codeine-6-β-D-glucuronide	25000	1.2%
	Morphine-6-β-D-glucuronide	1000	30%
	6-Acetylcodeine	25000	1.2%
	Normorphine	50000	0.6%
	Oxycodone	>100000	<0.3%
	Oxymorphone	>100000	<0.3%
	Norcodeine	25000	1.2%
	Procaine hydrochloride	>100000	<0.3%
	Norpropoxyphene	>100000	<0.3%
MTD 300	(±)-Methadone	300	100%
	EDDP	>100000	<0.3%
	EMDP	>100000	<0.3%
	LAAM	>100000	<0.3%
	Alpha Methadol	>100000	<0.3%
	Doxylamine	>100000	<0.3%
	Disopyramide	6000	5.0%
	Esomeprazole	10000	3.0%
	Pheniramine	100000	0.3%
OXY 100	Ethyl Oxycodone	100	100%
	Hydrocodone	50000	0.2%
	Hydromorphone	25000	0.4%
	Levorphanol tartrate	50000	0.2%
	Naloxone hydrochloride	50000	0.2%
	Naltrexone hydrochloride	>100000	<0.1%
	Oxycodone	100	100%
	Oxymorphone	100	100%
	Oxymorphone-3β-D-glucuronide	>100000	<0.1%
	Noroxycodone	1000	10%
	Noroxymorphone	25000	0.4%
	Dihydrocodeine	12500	0.8%
	Codeine	100000	0.1%
	Morphine	>100000	<0.1%
	Acetylmorphine	>100000	<0.1%
	Buprenorphine	>100000	<0.1%

	Ethylmorphine	>100000	<0.1%
	Thebaine	>100000	<0.1%
	6-acetylmorphine	>100000	<0.1%
PCP 25	PCP (Phencyclidine)	25	100%
	4-Hydroxyphencyclidine	15	167%
	Pheniramine	50000	0.05%
TCA 1000	Amitriptyline	1500	66.7%
	Chlorpheniramine	>100000	<1%
	Clomipramine	1000	100%
	Cyclobenzaprine Hydrochloride	>100000	<1%
	Desipramine	300	333.3%
	Doxepine	10000	10%
	Duloxetine	>100000	<1%
	Imipramine	500	200%
	Norclomipramine	250	400%
	Nordoxepine	>100000	<1%
	Nortriptyline hydrochloride	1000	100%
	Promazine	500	200%
	Trimipramine	1500	66.7%
	Maprotiline	>100000	<1%
	Promethazine hydrochloride	50000	2%
THC 50	11-nor-Δ^8-THC-9-COOH	20000	0.25%
	(-)-11-nor-9-carboxy-Δ^9-THC	50	100%
	(±)-11-nor-9-Carboxy-Δ^9-THC	50	100%
	11-nor-Δ^9-THC -carboxy glucuronide	50	100%
	11-hydroxy-Δ^9-Tetrahydrocannabinol	5000	1.0%
	Δ^8- Tetrahydrocannabinol	100000	0.05%
	Δ^9- Tetrahydrocannabinol	100000	0.05%
	Cannabinol	>100000	<0.05%
	Cannabidiol	>100000	<0.05%
FYL 1	Fentanyl	1	100%
	Acetyl fentanyl	1	100%

	Acrylfentanyl	1	100%
	ω-1-Hydroxyfentanyl	20000	0.005%
	Isobutyryl fentanyl	1	100%
	Ocfentanil	2.5	40%
	Butyryl fentanyl	2.5	40%
	Furanyl fentanyl	5	20%
	Valeryl fentanyl	10	10%
	(±) β-hydroxythiofentanyl	2	50%
	4-Fluoro-isobutyrylfentanyl	50	2%
	Para-fluorobutyryl fentanyl	4	25%
	Para-fluoro fentanyl	3	33.3%
	(±)-3-cis-methyl fentanyl	50	2%
	Carfentanil	2	50%
	Sufentanil	10	10%
	Alfentanil	5000	0.02%
	Despropionyl fentanyl (4-ANPP)	2500	0.04%
	Cyclopropylfentanyl	3	33.3%
	Remifentanil	>100000	<0.001%
	Norfentanyl	>100000	<0.001%
	Acetyl norfentanyl	>100000	<0.001%
	Norcarfentanil	>100000	<0.001%
	6-Acetyl morphine	>100000	<0.001%
	Amphetamine	>100000	<0.001%
	Buprenorphine	>100000	<0.001%
	Buprenorphineglucuronide	>100000	<0.001%
	Codeine	>100000	<0.001%
	Dextromethorphan	>100000	<0.001%
	Dihydrocodeine	>100000	<0.001%
	EDDP	>100000	<0.001%
	EMDP	>100000	<0.001%
	Fluoxetine	>100000	<0.001%
	Heroin	>100000	<0.001%
	Hydrocodone	>100000	<0.001%
	Hydromorphone	>100000	<0.001%

	Ketamine	>100000	<0.001%
	Levorphanol	>100000	<0.001%
	Meperidine	>100000	<0.001%
	Methadone	>100000	<0.001%
	Morphine	>100000	<0.001%
	Morphine-3-glucuronide	>100000	<0.001%
	Naloxone	>100000	<0.001%
	Naltrexone	>100000	<0.001%
	Norbuprenorphine	>100000	<0.001%
	Norcodeine	>100000	<0.001%
	Norketamine	>100000	<0.001%
	Normeperidine	>100000	<0.001%
	Normorphine	>100000	<0.001%
	Noroxycodone	>100000	<0.001%
	Oxycodone	>100000	<0.001%
	Oxymorphone	>100000	<0.001%
	Pentazocine (Talwin)	>100000	<0.001%
	Pipamperone	>100000	<0.001%
	Risperidone	>100000	<0.001%
	Tapentadol	>100000	<0.001%
	Thioridazine	>100000	<0.001%
	Tilidine	>100000	<0.001%
	Tramadol	>100000	<0.001%
	Tramadol-O-Desmethyl	>100000	<0.001%
	Tramadol-N-Desmethyl	>100000	<0.001%
	Isotonitaze	>100000	<0.001%

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff.

Compounds that show no interference at a concentration of 100µg/mL are summarized in the following table.

3-Hydroxytyramine	Digoxin	Nitroglycerin
Acetaminophen	Diphenhydramine HCl	Nordoxepin

Acetone(1000mg/dL)	Disopyramide(except MTD test)	Norethindrone
Acetophenetidin	DL-Tryptophan	Norfentanyl
Acetylsalicylic acid	DL-Tyrosine	Noscapine
Acyclovir	Dopamine HCl	O-Hydroxyhippuric acid
Albumin(100mg/dL)	Doxepin(except TCA test)	Octopamine
Albuterol sulfate(Proair HFA)	Doxylamine	Olanzapine
Alpha Methadol	Duloxetine	Omeprazole
Aminophylline	Ecgonine methyl ester	Oxalic acid (100 mg/dL)
Aminopyrine	EMDP	Oxolinic acid
Amoxicillin	Ephedrine	Oxymetazoline
Ampicillin	Erythromycin	Paliperidone
Apomorphine	Esomeprazole Magnesium(except MTD test)	Papaverine
Aripiprazole	Ethanol(1%)	Penicillin-G
Ascorbic acid	Fenoprofen	PenicillinV Potassium
Aspartame	Fluoxetine Hydrochloride	Perphenazine
Aspirin	Fluphenazine	Phenacetin
Atomoxetine	Furosemide	Phenelzine
Atorvastatin Calcium	Gabapentin	Phenethylamine
Atropine	Galactose (10mg/dL)	Phenylpropanolamine
Azithromycin	Gamma Globulin (500mg/dL)	Prednisone
Benzilic acid	Gatifloxacin	Pregablin
Benzocaine	Gentisic acid	Procaine
Benzoic acid	Glucose (3000mg/dL)	Promethazine(except TCA test)
Benzphetamine	Hemoglobin	Propoxyphene
Bilirubin	Hydralazine	Propranolol
Boric Acid (1%)	Hydrochlorothiazide	Pseudoephedrine
Bupropion	Hydrocortisone	Quetiapine
Caffeine	Hydroxytyramine	Quinine
Cannabidiol	Ibuprofen	Ranitidine
Captopril	Isoproterenol	Riboflavin (10mg/dL)
Carbamazepine	Isoxsuprine	Rifampicin
Carfentanil(except FYL test)	Ketamine	Risperidone
Cefradine	Ketoprofen	Salicylic acid
Cephalexin	L-Ephedrine	Serotonin (5-Hydroxytyramine)
Chloralhydrate	L-Epinephrine	Sertraline
Chloramphenicol	L-phenylephrine	Sildenafil Citrate
Chloroquine(except MET test)	LAAM HCl	Simvastatin
Chlorothiazide	Labetalol	Sulfamethazine
Chlorpheniramine	Levofloxacin Hydrochloride	Sulindac

Chlorpromazine	Levonorgestrel	Telmisartan
Cholesterol	Levothyroxine Sodium	Tetrahydrocortisone 3-(β-Dglucuronide)
Ciprofloxacin Hydrochloride	Lidocaine Hydrochloride	Tetrahydrocortisone, 3-acetate
Citalopram	Lisinopril	Tetrahydrozoline
Clarithromycin	Loperamide	Theophylline
Clonidine	Loratadine	Thiamine
Clozapine	Magnesium	Thioridazine
Conjugated Estrogens	Maprotiline	Tramadol Hydrochloride
Cortisone	Meperidine	Triamterene
Cotinine	Meprobamate	Trifluoperazine
Creatinine	Methapyrilene	Trimethobenzamide
Cyclobenzaprine	Methaqualone	Trimethoprim
D-Pseudoephedrine	Methoxyphenamine (except AMP/MET test)	Tyramine
D,L-Epinephrine	Metoprolol Tartrate	Urea (2000mg/dL)
D,L-Isoproterenol	Metronidazole (300ug/ml)	Uric acid
D,L-Octopamine	Mifepristone	Valproic acid (250ug/ml)
D,L-Propranolol	N-Acetylprocainamide	Venlafaxine HCl
D,L-Tryptophan	NaCl (4000mg/dL)	Verapamil
D,L-Tyrosine	Nalidixic acid	Vitamin B2
Delorazepam(except BZO test)	Naloxone hydrochloride(except OXY test)	Vitamin C
Deoxycorticosterone	Naltrexone hydrochloride	Zaleplon
Desloratadine	Naproxen	Zomepirac
Dextromethorphan	Niacinamide	β-Estradiol
Diclofenac sodium	Nicotine	
Diflunisal	Nifedipine	

Interference by pH and specific gravity were also evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding cutoff. The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

B. Method comparison study

The method comparison studies for the device were performed in-house with three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The results are presented in the table below:

Drug test	Test Result		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
AMP	Operator A	+	0	0	1	10	30
		-	12	13	14	0	0
	Operator B	+	0	0	1	9	30
		-	12	13	14	1	0
	Operator C	+	0	0	1	9	30
		-	12	13	14	1	0
BAR	Operator A	+	0	0	0	14	25
		-	12	14	14	1	0
	Operator B	+	0	0	1	15	25
		-	12	14	13	0	0
	Operator C	+	0	0	1	14	25
		-	12	14	13	1	0
BUP	Operator A	+	0	0	1	10	29
		-	12	17	10	1	0
	Operator B	+	0	0	0	10	29
		-	12	17	11	1	0
	Operator C	+	0	0	1	11	29
		-	12	17	10	0	0
BZO	Operator A	+	0	0	0	11	28
		-	12	13	15	1	0
	Operator B	+	0	0	1	11	28
		-	12	13	14	1	0
	Operator C	+	0	0	1	12	28
		-	12	13	14	0	0
COC	Operator A	+	0	0	1	11	28
		-	12	18	9	1	0
	Operator B	+	0	0	1	11	28
		-	12	18	9	1	0
	Operator C	+	0	0	0	12	28
		-	12	18	10	0	0
MDMA	Operator A	+	0	0	1	13	27
		-	12	14	13	0	0
	Operator B	+	0	0	1	12	27
		-	12	14	13	1	0
	Operator C	+	0	0	0	12	27
		-	12	14	14	1	0

MET	Operator A	+	0	0	0	10	29
		-	12	16	12	1	0
	Operator B	+	0	0	1	11	29
		-	12	16	11	0	0
	Operator C	+	0	0	1	10	29
		-	12	16	11	1	0
MOP/OPI	Operator A	+	0	0	0	13	26
		-	12	16	12	1	0
	Operator B	+	0	0	1	13	26
		-	12	16	11	1	0
	Operator C	+	0	0	1	14	26
		-	12	16	11	0	0
MTD	Operator A	+	0	0	1	10	29
		-	12	16	11	1	0
	Operator B	+	0	0	1	11	29
		-	12	16	11	0	0
	Operator C	+	0	0	1	10	29
		-	12	16	11	1	0
OXY	Operator A	+	0	0	0	12	28
		-	12	16	12	0	0
	Operator B	+	0	0	1	11	28
		-	12	16	11	1	0
	Operator C	+	0	0	0	11	28
		-	12	16	12	1	0
PCP	Operator A	+	0	0	1	12	27
		-	12	16	11	1	0
	Operator B	+	0	0	1	12	27
		-	12	16	11	1	0
	Operator C	+	0	0	0	12	27
		-	12	16	12	1	0
TCA	Operator A	+	0	0	1	9	30
		-	12	15	12	1	0
	Operator B	+	0	0	0	9	30
		-	12	15	13	1	0
	Operator C	+	0	0	1	10	30
		-	12	15	12	0	0
THC	Operator A	+	0	0	1	10	30
		-	12	17	10	0	0
	Operator B	+	0	0	1	9	30
		-	12	17	10	1	0
	Operator C	+	0	0	0	10	30
		-	12	17	11	0	0

FYL	Operator A	+	0	0	2	22	16
		-	12	13	13	2	0
	Operator B	+	0	0	3	22	16
		-	12	13	12	2	0
	Operator C	+	0	0	2	22	16
		-	12	13	13	2	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Accurate Result
AMP	A	N0957	494.481	+
	B	N0949	491.559	+
	B	N0966	619.861	-
	C	N0949	491.559	+
	C	N0966	619.861	-
BAR	A	N0756	304.564	-
	B	N0733	294.112	+
	C	N0728	271.093	+
	C	N0756	304.564	-
BUP	A	N1328	11.971	-
	A	N1364	9.635	+
	B	N1331	10.385	-
	C	N1353	9.149	+
BZO	A	N0840	306.319	-
	B	N0825	297.539	+
	B	N0840	306.319	-
	C	N0818	261.170	+
COC	A	N0538	122.809	+
	A	N0557	151.609	-
	B	N0538	122.809	+
	B	N0557	151.609	-
MDMA	A	N0219	498.645	+
	B	N0219	498.645	+
	B	N0220	503.780	-
	C	N0220	503.780	-
MET	A	N1032	514.414	-
	B	N1066	482.955	+
	C	N1032	514.414	-
	C	N1066	482.955	+
MOP/OPI	A	N0129	337.839	-
	B	N0108	289.278	+
	B	N0129	337.839	-
	C	N0108	289.278	+

MTD	A	N0608	299.063	+
	A	N0615	300.546	-
	B	N0618	295.461	+
	C	N0608	299.063	+
	C	N0630	306.162	-
OXY	B	N0314	100.815	-
	B	N0356	98.859	+
	C	N0309	104.534	-
PCP	A	N0426	23.006	+
	A	N0459	25.355	-
	B	N0441	25.891	-
	B	N0456	22.017	+
	C	N0459	25.355	-
TCA	A	N1106	981.923	+
	A	N1146	1025.476	-
	B	N1123	1038.965	-
	C	N1140	981.903	+
THC	A	N1227	49.942	+
	B	N1227	49.942	+
	B	N1236	50.876	-
FYL	A	N1402	0.917	+
	A	N1425	1.024	-
	A	N1439	1.015	-
	A	N1465	0.920	+
	B	N1402	0.917	+
	B	N1420	0.872	+
	B	N1422	1.079	-
	B	N1442	0.906	+
	B	N1447	1.013	-
	C	N1439	1.015	-
	C	N1442	0.906	+
	C	N1447	1.013	-
	C	N1465	0.920	+

C. Lay person study

A lay user study was performed at three intended user sites with 140 lay persons. 48 males and 92 females tested AllTest Multi-Drug Urine Test Panel. They had diverse educational and professional backgrounds and their ages ranged from 21 to > 50. Urine samples were prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC-MS/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. The results are summarized below.

Result of AllTest Multi-Drug Urine Test 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	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
BAR	300	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	100%	100%	100%
BZO	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%	95.0%	95.0%	100%	100%
BUP	10	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%	90.0%	100%	100%	100%
COC	150	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%	90.0%	100%	100%	100%
MDMA	500	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	100%	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%	90.0%	90.0%	100%	100%
MOP	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%	90.0%	95.0%	100%	100%
MTD	300	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	100%	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%	95.0%	95.0%	100%	100%
PCP	25	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	100%	100%	100%
TCA	1000	Negative	20	20	20	19	0	0	0
		Positive	0	0	0	1	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	100%	100%	100%
THC	50	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%	90.0%	95.0%	100%	100%
FYL	1	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%	90.0%	100.0%	100%	100%

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

Clinical Studies:
Not applicable.

13. Conclusion

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