February 27, 2025

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

Re: K244043
Trade/Device Name: AllTest Multi-Drug Rapid Test Cup ; AllTest Multi-Drug Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: NFT, PTH, NGL, NFV, NFY, PTG, NGG, QBF, NGM, QAW, NFW, NGI
Dated: December 28, 2024
Received: December 30, 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.

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.

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: 2025.02.27 10:58:43 -05'00'

Joseph Kotarek, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K244043

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

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, Marijuana, Tramadol, Propoxyphene, Fentanyl and 6-monoacetylmorphine 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
Tramadol (TRA)	100 ng/mL
Propoxyphene (PPX)	300 ng/mL
Fentanyl(FYL)	1 ng/mL
6-monoacetylmorphine (6-MAM)	10 ng/mL

AllTest Multi-Drug Rapid Test Cup can be a single drug test cup 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 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, Marijuana, Tramadol, Propoxyphene Fentanyl and 6-monoacetylmorphine 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)	1-nor-Δ9-THC-9 COOH	50
Tramadol (TRA)	Tramadol	100
Propoxyphene (PPX)	Propoxyphene	300
Fentanyl(FYL)	Fentanyl	1
6-monoacetylmorphine (6-MAM)	6-monoacetylmorphine	10

AllTest Multi-Drug Test Cup can be a single drug test cup 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.

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510(k) SUMMARY
K244043

1. **Date:** December 28, 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 Rapid Test Cup
   AllTest Multi-Drug Test Cup
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) 6-Monoacetylmorphine(6-MAM) Tramadol (TML)	862.3650, Opiate Test System	Toxicology
NGI Morphine (MOP/OPI)	862.3640, Morphine 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 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA)	862.3610, Methamphetamine Test System	Toxicology

Methamphetamine (MET)		
QBF Propoxyphene(PPX)	862.3700 Propoxyphene 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 Rapid Test Cup (K233019)

7. 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, Marijuana, Tramadol , Propoxyphene , Fentanyl and 6-monoacetylmorphine in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off (ng/mL)**
Amphetamine (AMP)	500 or 1000
Buprenorphine (BUP)	10
Secobarbital (BAR)	300
Benzodiazepines (BZO)	300
Cocaine (COC)	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Methamphetamine (MET)	500 or 1000
Methylenedioxymethamphetamine (MDMA)	500
Morphine (MOP/OPI)	300 or 2000
Methadone (MTD)	300
Oxycodone (OXY)	100
Phencyclidine (PCP)	25
Nortriptyline (TCA)	1000
Marijuana (THC)	50
Tramadol (TRA)	100
Propoxyphene (PPX)	300
Fentanyl (FYL)	1
6-monoacetylmorphine (6-MAM)	10

AllTest Multi-Drug Rapid Test Cup can be a single drug test cup or used for 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 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 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, Marijuana, Tramadol, Propoxyphene Fentanyl and 6-monoacetylmorphine 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
Tramadol (TRA)	Tramadol	100
Propoxyphene (PPX)	Propoxyphene	300
Fentanyl (FYL)	Fentanyl	1
6-monoacetylmorphine (6-MAM)	6-monoacetylmorphine	10

AllTest Multi-Drug Test Cup can be a single drug test cup 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 Rapid Test Cup and AllTest Multi-Drug Test Cup 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 cup 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	Device		Predicate (K233019)
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 except that no FYL TRA 6-MAAM PPX
	Amphetamine(AMP)	1000 or 500	
	Secobarbital (BAR)	300	
	Buprenorphine (BUP)	10	
	Oxazepam (BZO)	300	
	Cocaine (COC)	150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methylenedioxymethamphetamine (MDMA)	500	
	Methamphetamine (MET)	1000 or 500	
	Morphine (MOP300/OPI2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene(PPX)	300	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC)	50	
	6-Monoacetylmorphine(6-MAM)	10	
	Fentanyl (FYL)	1	
	Tramadol (TRA)	100	
Differences			
Configurations	Test cup		Test cup & Test Dip Card

10. Standard/Guidance Document Reference (if applicable)

None referenced.

11. Test Principle

AllTest Multi-Drug Rapid Test Cup or AllTest Multi-Drug Test Cup 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 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. Other samples were prepared by spiked target drug 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 cups. The results obtained are summarized in the following table for Tramadol (TRA), Propoxyphene (PPX), Fentanyl(FYL) and 6-monoacetylmorphine (6-MAM). The rest data were reported in the cleared AllTest submission of k233019.

TRA

Concentration (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	193	175.0	152.5	129.1	101.5	74.3	49.2	25.6	0

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+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+

PPX

Concentration (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	613.3	528.7	435.4	371.3	304.6	229.7	146.9	79.9	0
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+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	20-/30+	50-/0+	50-/0+	50-/0+	50-/0+

FYL

Concentration (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	2.05	1.79	1.53	1.21	0.96	0.71	0.48	0.26	0
Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+

6-MAM

Concentration (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	20.6	17.0	15.3	12.2	9.8	7.0	5.3	2.6	0
Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	48-/2+	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+	23-/27+	49-/1+	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. The results obtained are summarized in the following table for Tramadol (TRA),

Propoxyphene (PPX), Fentanyl(FYL) and 6-monoacetylmorphine (6-MAM). The rest data were reported in the cleared AllTest submission of k233019.
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. If no cross-reactivity was observed, the highest concentration tested is shown.

Drug/Cutoff	**Compound**	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
TRA 100	Tramadol	100	100%
	N-Desmethyl-cis-tramadol	200	50%
	O-Desmethyl-cis-tramadol	1000	10%
	Venlafaxine	100000	0.1%
	(±)-O-Desmethylvenlafaxine	100000	0.1%
PPX 300	(+)-Propoxyphene	300	100%
	(+)-Norpropoxyphene	500	60%
6-MAM 10	6-Monoacetylmorphine	10	100%
	Hydrocodone	>100000	<0.01%
	Hydromorphone	>100000	<0.01%
	Morphine	>100000	<0.01%
	Oxymorphone	>100000	<0.01%
	Procaine	>100000	<0.01%
	Thebaine	>100000	<0.01%
	Diacetylmorphine (heroin)	300	3.3%
	Acetylcodeine	>100000	<0.01%
	Buprenorphine	>100000	<0.01%
	Dihydrocodeine	>100000	<0.01%
	Nalorphine	>100000	<0.01%
	Mitragynine (kratom)	>100000	<0.01%
	Norbuprenorphine	>100000	<0.01%
	s-Monoacetylmorphine	10	100%
	Codeine	>100000	<0.01%
	Ethylmorphine	>100000	<0.01%
	Levorphanol tartrate	>100000	<0.01%

	Morphine-3-β-D-glucuronide	>100000	<0.01%
	Norcodeine	>100000	<0.01%
	Normorphine	>100000	<0.01%
	Oxycodone	>100000	<0.01%
	Dextromethorphan	>100000	<0.01%
	Imipramine hydrochloride	>100000	<0.01%
	Levacetylmethadol (LAAM)	>100000	<0.01%
	Meperidine	>100000	<0.01%
	(±)-Methadone	>100000	<0.01%
	Naloxone hydrochloride	>100000	<0.01%
	Naltrexone hydrochloride	>100000	<0.01%
	Naproxen	>100000	<0.01%
	Noroxycodone HCL	>100000	<0.01%
	Noroxymorphone HCL	>100000	<0.01%
	(+)-Norpropoxyphene maleate	>100000	<0.01%
	Oxymorphone-3β-D-glucuronide	>100000	<0.01%
	Tapentadol HCl	>100000	<0.01%
	Tramadol hydrochloride	>100000	<0.01%
	Chlordiazepoxide	>100000	<0.01%
	Clobazam	>100000	<0.01%
	D-Amphetamine	>100000	<0.01%
	(±)-Amphetamine	>100000	<0.01%
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%
	Cyclopropylfentanyl	3	33.3%
	Despropionyl fentanyl (4-ANPP)	2500	0.04%
	Isotonitaze	>100000	<0.001%
	AH-7921 HCL	>100000	<0.001%
	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%

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 or specified concentrations are summarized in the following table.

Acetaminophen	D-Pseudoephedrine	Norfentanyl
Acetone (1000mg/dL)	Duloxetine	Noscapine
Acetophenetidin	4-Dimethyl-aminoantipyrine	(+)-Naproxen
Acetylsalicylic Acid	5, 5-Diphenylhydantoin	19-Norethindrone
Acyclovir	Ecgonine methyl ester	Octopamine
Albumin (100mg/dL)	EMDP	O-Hydroxyhippuric acid
Albuterol sulfate (Proair HFA)	Ephedrine	Olanzapine
Alpha Methadol	Erythromycin	Omeprazole
Aminophylline	Esomeprazole Magnesium (except MTD test)	Oxalic acid (100 mg/dL)
Aminopyrine	Estradiol	Oxolinic acid
Amoxicillin	Estrone	Oxymetazoline
Ampicillin	Ethanol (1%)	Paliperidone
Aripiprazole	Fenofibrate	Papaverine
Aspartame	Fenoprofen	Penicillin-G
Aspirin	Fentanyl(except FYL test)	PenicillinV Potassium
Atomoxetine	Fluoxetine Hydrochloride	Perphenazine
Atorvastatin Calcium	Fluphenazine	Phenacetin

Atropine	Fotemustine	Phenelzine
Azithromycin	Furosemide	Phenethylamine
Baclofen	Gabapentin	Phenylethylamine
Benzilic acid	Galactose(10mg/dL)	Phenylpropanolamine
Benzocaine	Gamma Globulin(500mg/dL)	Prednisone
Benzoic Acid	Gatifloxacin	Pregablin
Benzphetamine	Gemfibrozil	Procaine
Bilirubin	Gentisic acid	Promazine
Boric Acid (1%)	Glucose(3000mg/dL)	Promethazine
Bupropion	Guaiacol glyceryl ether	Propoxyphene (except PPX test)
Caffeine	Hemoglobin	Propranolol
Cannabidiol	Hydralazine	Pseudoephedrine
Captopril	Hydrochlorothiazide	Pyridoxine
Carbamazepine	Hydrocortisone	Pyrilamine
Carfentanil (except FYL test)	3-Hydroxytyramine	Pyrogallol
Carisoprodol	Ibuprofen	Quetiapine
Cefradine	Isoxsuprine	Quinine
Cephalexin	(+/-)-Isoproterenol	Quinolinic Acid
Chloralhydrate	Ketamine	R-(-)-Apomorphine
Chloramphenicol	Ketoprofen	Ranitidine
Chlordiazepoxide (except BZO test)	LAAM HCl	Riboflavin (10mg/dL)
Chloroquine (except MET test)	Labetalol	Rifampicin
Chlorothiazide	L-Ascorbic Acid	Risperidone
Chlorpromazine	L-Ephedrine	Salicylic Acid
Cholesterol	L-Epinephrine	Serotonin(5- Hydroxytyramine)
Ciprofloxacin Hydrochloride	Levofloxacin Hydrochloride	Sertraline
Citalopram	Levonorgestrel	Sildenafil Citrate
Clarithromycin	Levothyroxine Sodium	Simvastatin
Clonidine	Lidocaine Hydrochloride	Sulfamethazine
Clozapine	Lisinopril	Sulindac
Conjugated Estrogens	Loperamide	Telmisartan
Cortisone	Loratadine	Tetracycline
Creatine Hydrate	L-phenylephrine	Tetrahydrocortisone 3-(β-Dglucuronide)
Creatinine	Magnesium	Tetrahydrocortisone, 3-acetate
Cyclobenzaprine	Maprotiline	Tetrahydrozoline
Cyclodextrin	Meperidine	Theophylline
(-)-Cotinine	Meprobamate	Thiamine
(+)-Chlorpheniramine	Methapyrilene	Thioridazine
D,L-Epinephrine	Methaqualone	Tramadol (except TRA test)
D,L-Octopamine	Methoxyphenamine (except AMP/MET test)	Triamterene
d,l-Propranolol	Methylphenidate	Trifluoperazine
D,L-Tryptophan	Metoprolol Tartrate	Trimethobenzamide
D,L-Tyrosine	Metronidazole (300ug/ml)	Trimethoprim
Delorazepam (except BZO test)	Mifepristone	Tryptamine
Deoxycorticosterone	N-Acetylprocainamide	Tyramine
Desloratadine	NaCl(4000mg/dL)	Urea (2000mg/dL)
Dextromethorphan	Nalidixic Acid	Uric Acid
Diclofenac	Naloxone hydrochloride (except OXY test)	Valproic acid (250ug/ml)

Diflunisal	Naltrexone	Venlafaxine HCl (except TRA test)
Digoxin	Niacinamide	Verapamil
Diphenhydramine HCl	Nicotine	Vitamin B2
Disopyramide (except MTD test)	Nicotinic Acid	Vitamin C
Dopamine HCl	Nifedipine	Zaleplon
Doxepin	Nitroglycerin	Zomepirac sodium salt
Doxylamine	Nordoxepin	

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 for Tramadol (TRA), Propoxyphene (PPX), Fentanyl(FYL) and 6-monoacetylmorphine (6-MAM). The rest data were reported in the cleared AllTest submission of k233019.

Drug test	Test Cup 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%)
TRA	Operator A	+	0	0	1	11	29
		-	12	14	13	0	0
	Operator B	+	0	0	0	10	29
		-	12	14	14	1	0
	Operator C	+	0	0	1	10	29
		-	12	14	13	1	0
PPX	Operator A	+	0	0	1	10	30
		-	12	13	14	0	0
	Operator B	+	0	0	1	10	30
		-	12	13	14	0	0
	Operator C	+	0	0	0	9	30
		-	12	13	15	1	0
6-MAM	Operator A	+	0	0	1	14	26
		-	12	11	16	0	0
	Operator B	+	0	0	1	13	26
		-	12	11	16	1	0

	Operator C	+	0	0	2	13	26
		-	12	11	15	1	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
TRA	A, C	S2148	91.6	+
	B, C	S2157	103.0	-
PPX	A	S2052	286.3	+
	B	S2017	280.6	+
	C	S2018	319.8	-
6-MAM	A, C	S2249	9.5	+
	B, C	S2236	9.6	+
	B, C	S2228	10.2	-
FYL	A, C	S1425	1.02	-
	A	S1420	0.87	+
	A, B	S1447	1.01	-
	A, B	S1442	0.91	+
	B, C	S1402	0.92	+
	B	S1422	1.08	-
	B	S1465	0.92	+
	C	S1453	0.82	+
	C	S1439	1.02	-

C. Lay person study

A lay user study was performed at three intended user sites with 280 lay persons. 121 male and 159 female tested AllTest Multi-Drug Rapid Test Cup. They had diverse educational and professional backgrounds and their age range from 20 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 Rapid Test Cup: Configuration 1

Drug	Cutoff	Results	Concentration

	(ng/mL)		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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%	95.0%	95.0%	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%	95.0%	95.0%	100%	100%
BZO	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%	95.0%	90.0%	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%	95.0%	90.0%	100%	100%
COC	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%
EDDP	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%
MDMA	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%	95.0%	90.0%	100%	100%
MET	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%	90.0%	95.0%	100%	100%
MOP	2000	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	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%
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%	95.0%	90.0%	100%	100%
PCP	25	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%
TCA	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%	95.0%	95.0%	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%
TRA	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%	90.0%	95.0%	100%	100%
PPX	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%	95.0%	90.0%	100%	100%
FYL	1	Negative	20	20	20	17	0	0	0
		Positive	0	0	0	3	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	85.0%	100.0%	100%	100%
6-MAM	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%	90.0%	90.0%	100%	100%

Result of AllTest Multi-Drug Rapid Test Cup: Configuration 2

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	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%
BAR	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%	95.0%	90.0%	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	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%
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%	90.0%	95.0%	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%	95.0%	90.0%	100%	100%
MDMA	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%	95.0%	90.0%	100%	100%
MET	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%
MOP	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%
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%	90.0%	95.0%	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	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%
TCA	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%	95.0%	95.0%	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%
TRA	100	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%
PPX	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%
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%
6-MAM	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%	90.0%	90.0%	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's concluded that AllTest Multi-Drug Rapid Test Cup and AllTest Multi-Drug Test Cup are substantially equivalent to the predicate device.