August 7, 2019

Healstone Biotech Inc
% Joe Shia, Director
LSI International Inc.
504 East Diamond Ave. Suite I
Gaithersburg, MD 20877

Re: K191841
Trade/Device Name: Accurate Multi Panel Drug Urine Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NGL, PTH, NFV, NFY, PTG, QBF, NGG, QAW, NGM, NFW
Dated: July 5, 2019
Received: July 9, 2019

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Kellie B. Kelm, Ph.D.
Acting Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k191841

Device Name
Accurate Multi Panel Drug Urine Test Cup

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

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

Accurate Multi Panel Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, 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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510(k) SUMMARY

K191841

1 Date August 7, 2019

2 Submitter
Healstone Biotech Inc.
650-655 W Kent N.
Vancouver, BC V6P6T7
Canada

3 Contact Person
Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4 Device Name Accurate® Multi Panel Drug Urine Test Cup

5 Classification Class II

Product Code Target Drug	Regulation Section	Panel
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
NGL Buprenorphine (BUP)	862.3650, Opiate Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine Test System	Toxicology
PTG 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	862.3620, Methadone Test System	Toxicology
NGG Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA)	862.3610, Methamphetamine Test System	Toxicology
NGL	862.3650, Opiate Test System	Toxicology

Morphine (MOP/OPI)		
PTG Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGL Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
NGM Phencyclidine (PCP)	Unclassified, Enzyme Immunoassay Phencyclidine	Toxicology
QBF Propoxyphene (PPX)	862.3700 Propoxyphene test system.	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Marijuana (THC 50)	862.3870, Cannabinoids Test System	Toxicology

6 Predicate Device: K182701 Wondfo T-Cup® Multi-Drug Urine Test Cup

7. Intended Use

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

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL
Buprenorphine (BUP)	10ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	300 ng/mL or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1,000 ng/mL
Marijuana (THC 50)	50 ng/mL

Accurate Multi Panel Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, 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.

8. Device Description

Accurate® Multi Panel Drug Urine Test Cup are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine. Each Accurate® Multi Panel Drug Urine Test Cup device consists of a test cup and a package insert. Each test cup is sealed with desiccant in an aluminum pouch.

9. Substantial Equivalence Information

Item	**Proposed Device**		**Predicate (K182701)**
Indication(s) for use	For the qualitative determination of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in human urine.		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 Drug**	**Cutoff (ng/mL)**	Same
	Amphetamine (AMP)	1000	
	Buprenorphine (BUP)	10	
	Secobarbital (BAR)	300	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methamphetamine (MET)	1000	

	Methylenedioxymethamphetamine (MDMA)	500	
	Morphine (MOP 300/OPI 2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene (PPX)	300	
	Nortriptyline (TCA)	1000	
	Marijuana (THC 50)	50	
Configurations	Test cup		Same
Intended Use	For over-the-counter use		Same

10. Test Principle

Accurate® Multi Panel Drug Urine Test Cup is a rapid test for the qualitative detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana in urine samples. They are lateral flow chromatographic immunoassay. When urine sample is added to the cup device, urine is absorbed into the test strip and migrates upwards by capillary action. If the concentration of target drug presented in the urine sample is below the cutoff level, the target drug will not saturate the binding sites of its specific monoclonal antibody-coated particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored band will be formed on the test line region. If the concentration of target is beyond the cutoff level, the target drug will saturate the binding sites of its specific monoclonal antibody-particles, thus the antibody-coated particles will not be captured by immobilized drug-conjugate hence no colored band will be formed on the test line region.

A band should be formed on the control line region regardless of the presence of target drug or metabolite in the sample to indicate that the tests have been performed properly.

11. 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, +25%cut off, +50%cut off, +75%cut off and +100%cut off. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following table.

Accurate® Multi Panel Drug Urine Test Cup BUP

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	19.1	16.1	15.2	12.9	9.4	7.1	5.4	2.4	0

Lot Number									
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	48-/2+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	2-/48+	20-/30+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup PCP

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	50.3	43.1	36.2	30.4	25.0	17.9	12.2	6.4	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	48-/2+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	21-/29+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup THC

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	100.8	88.6	72.9	65.8	50.2	39.5	25.2	12.6	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	47-/3+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	28-/22+	48-/2+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	3-/47+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup OXY

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	200.3	170.6	150.1	118.5	98.4	77.9	52.5	28.3	0
Lot I	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	22-/28+	47-/3+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	2-/48+	21-/29+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup BAR

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	645.0	510.9	437.8	394.7	270.1	235.5	161.8	77.9	0

Lot Number									
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	19-/31+	47-/3+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup BZO

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	580.3	530.3	488.3	386.6	307.9	247.0	142.3	71.8	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	21-/29+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	2-/48+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup EDDP

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	571.3	498.7	430.7	358.5	300.7	222.8	142.4	79.5	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	20-/30+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	20-/30+	50-/0+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup MTD

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	588.6	514.8	471.0	393.1	314.6	223.5	140.9	74.6	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup MOP

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	591.7	504.6	470.3	384.0	289.0	244.9	163.6	74.0	0

Lot Number									
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup PPX

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	626.7	534.8	433.6	364.2	308.6	225.3	159.1	79.4	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	48-/2+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup MDMA

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1208.1	863.1	711.1	592.8	516.6	375.2	259.9	124.1	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	19-/31+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup TCA

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	2024.2	1727.6	1459.5	1276.1	1091.2	718.8	505.0	257.5	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	21-/29+	48-/2+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	2-/48+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup OPI

Concentration by LC/MS	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off

(ng/mL) Lot Number	4166.3	3535.6	3077.2	2407.8	2008.3	1611.8	1041.0	509.5	0
Lot I	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	48-/2+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup COC

Concentration by LC/MS (ng/mL) Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	619.3	533.4	432.2	360.6	303.1	226.4	157.7	73	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	20-/30+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup AMP

Concentration by LC/MS (ng/mL) Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	2015.9	1749.1	1496.0	1202.3	1091.8	789.2	532.7	270.3	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	2-/48+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

Accurate® Multi Panel Drug Urine Test Cup MET

Concentration by LC/MS (ng/mL) Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1906.8	1629.3	1459.1	1229.8	949.7	733.1	491.1	236.2	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	20-/30+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	1-/49+	19-/31+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	19-/31+	49-/1+	50-/0+	50-/0+	50-/0+

The following cutoff values are verified:

Target Drug	**Cut-off level**

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

b. Linearity

Not applicable

c. Stability

The devices are stable at 4-30℃ for 24 months based on real-time stability studies.

d. Interference

Potential interfering substances were added to drug-free urine sample and samples with target drugs of -50% cutoff and +50% cutoff level.

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

(±)-4-Methylephedrine	Ecgonine methylester	Oxalic acid
Acetaminophen	β-Estradiol	Oxolinic acid
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetylprocainamide	Fenoprofen	Papaverine
Acetylsalicylic acid	Furosemide	Penicillin G
Albumin (100 mg/dL)	Gentisic acid	Perphenazine
Aminopyrine	Hemoglobin	Phenelzine
Amoxicillin	Hydralazine	Prednisone
Ampicillin	Hydrochlorothiazide	(±)-Propranolol
Apomorphine	Hydrocortisone	Pseudoephedrine

Ascorbic acid	O-Hydroxyhippuric acid	Quinine
Aspartame	3-Hydroxytyramine	Ranitidine
Atropine	Ibuprofen	Salicylic acid
Benzilic acid	Isoproterenol	Serotonin (5-Hydroxytyramine)
Benzoic acid	Isoxsuprine	Sulfamethazine
Bilirubin	Ketamine	Sulindac
Chloral hydrate	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chloramphenicol	Labetalol	Tetrahydrocortisone 3-acetate
Chlorothiazide	Loperamide	Tetrahydrozoline
Chlorpromazine	Meperidine	Thiamine
Cholesterol	Meprobamate	Thioridazine
Clonidine	Methoxyphenamine	Triamterene
Cortisone	Nalidixic acid	Trifluoperazine
(-)-Cotinine	Naproxen	Trimethoprim
Creatinine	Niacinamide	DL-Tryptophan
Deoxycorticosterone	Nifedipine	DL-Tyrosine
Dextromethorphan	Norethindrone	Uric acid
Diclofenac	Noscapine	Verapamil
Diflunisal	(±)-Octopamine	Zomepirac
Digoxin		

e. Specificity

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 each device.

Compounds that produced positive results are listed below.

BUP (Buprenorphine, Cutoff=10 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Buprenorphine	10	100%
Buprenorphine -3-D-Glucuronide	160	6%
Norbuprenorphine	10	100%
Norbuprenorphine-3-D-Glucuronide	200	5%
Morphine	100000 (negative)	Not detected
Oxymorphone	100000 (negative)	Not detected
Hydromorphone	100000 (negative)	Not detected

PCP (Phencyclidine) (Phencyclidine, Cutoff=25 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Phencyclidine	25	100%
4-Hydroxy Phencyclidine	12500	0.2%

THC (11-nor-Δ9-THC-9-COOH, Cutoff=50 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
11-nor-Δ8-THC -9-COOH	30	167%
(-)-11-nor-9-carboxy-Δ 9-THC	50	100%
(±)-11-nor-9-Carboxy-Δ9-THC	50	100%
11-nor-Δ9-THC -carboxy glucuronide	100	50%
11-hydroxy-Δ9-Tetrahydrocannabinol	5,000	1%
Δ8- Tetrahydrocannabinol	1,300	4%
Δ9- Tetrahydrocannabinol	5,000	1%
Cannabinol	20,000	0.25%
Cannabidiol	100000(negative)	Not Detected

OXY (Oxycodone, Cutoff=100 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Ethyl Oxycodone	75,000	0.1%
Hydrocodone	5,000	2%
Hydromorphone	25,000	0.4%
Levorphanol	10,000	1%
Oxycodone	100	100%
Oxymorphone	200	50%
Dihydrocodeine	100000(negative)	Not Detected
Codeine	100000(negative)	Not Detected
Morphine	100000(negative)	Not Detected
Acetylmorphine	100000(negative)	Not Detected
Buprenorphine	100000(negative)	Not Detected
Ethylmorphine	100000(negative)	Not Detected
Thebaine	100000(negative)	Not Detected

BAR (Secobarbital, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Alphenal	150	200%
Amobarbital	300	100%

Aprobarbital	250	120%
Butabarbital	2,500	12%
Butethal	100	300%
Butalbital	2,500	12%
Cyclopentobarbital	600	50%
Pentobarbital	250	120%
Phenobarbital	250	120%
Secobarbital	300	100%

BZO (Oxazepam, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Alprazolam	200	150%
a-Hydroxyalprazolam	1,260	24%
Bromazepam	1,560	19%
Chlordiazepoxide	1,560	19%
Clobazam	100	300%
Clonazepam	2,500	12%
Clorazepate dipotassium	200	150%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
Midazolam	12,500	2.4%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
Temazepam	100	300%
Triazolam	2,500	12%
Demoxepam	2,000	15%
Flurazepam	500	60%
D,L-Lorazepam	1,560	20%
Oxazepam	300	100%
RS-Lorazepam glucuronide	160	188%
Delorazepam	100000 (negative)	Not detected

EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Cutoff = 300 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine	300	100%
Methadone	>100000	Not detected
EMDP	>100000	Not detected

Doxylamine	>100000	Not detected
Disopyramide	>100000	Not detected
LAAM (Levo-alpha-acetylmethadol)	>100000	Not detected
Alpha Methadol	>100000	Not detected

MTD (Methadone, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Methadone	300	100%
Doxylamine	>100000	Not detected
EDDP	>100000	Not detected
EMDP	>100000	Not detected
LAAM	>100000	Not detected
Alpha Methadol	>100000	Not detected

MOP 300 (Morphine, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Morphine	300	100%
Normorphine	300	100%
s-Monoacetylmorphine	300	100%
Codeine	300	100%
Ethyl Morphine	100	300%
Heroin	600	50%
Hydrocodone	10000	3%
Hydromorphone	500	60%
Morphinie-3-β-d-glucuronide	1000	30%
Thebaine	6,240	4.8%
Levorphanol	10000	3%
6-Monoacetylmorphine (6-MAM)	150	200%
6-acetylmorphine	400	75%
Dihydrocodeine	1000	30%
Normorphine	>100000	Not detected
Oxycodone	>100000	Not detected
Oxymorphone	>100000	Not detected
Norcodeine	>100000	Not detected
Procaine	>100000	Not detected

PPX (Propoxyphene, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
d-Propoxyphene	300	100%

d-Norpropoxyphene	300	100%

MDMA (3,4-Methylenedioxymethamphetamine HCl, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
3,4-Methylenedioxyamphetamine HCl (MDA)	3000	17%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
l-Methamphetamine	50000	1%
d-methamphetamine	100000(Negative)	Not detected
d-amphetamine	100000(Negative)	Not detected
l-amphetamine	100000(Negative)	Not detected

TCA 1000 (Nortriptyline, Cutoff=1000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Chlorpheniramine maleate	50000	2%
Nortriptyline	1000	100%
Nordoxepine	1000	100%
Trimipramine	10000	10%
Amitriptyline	1500	66.7%
Promazine	50000	2%
Desipramine	1000	100%
Imipramine	1000	100%
Clomipramine	10000	10%
Doxepin	2000	50%
Maprotiline	100000(Negative)	Not detected
Promethazine	100000(Negative)	Not detected
Cyclobenzaprine	5000	20%
Norclomipramine	12500	8%
Duloxetine	10000	10%

COC (Benzoylecgonine, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Benzoylecgonine	300	100%
Cocaine	300	100%
Cocaethylene	300	100%
Ecgonine	300	100%
Ecgonine methyl ester	100000 (negative)	Not detected
Norcocaine	100000 (negative)	Not detected

AMP (d-Amphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(+/-)-4-Hydroxyamphetamine	8000	12.5%
Methylenedioxyamphetamine(MDA)	400	250%
D,L-Amphetamine	1,000	100%
D-Amphetamine	1,000	100%
Diethylstilbestrol	5,000	20%
L-Amphetamine	50,000	2%
Phentermine	8,000	12.5%
β-Phenylethylamine	100000	1%
p-Hydroxynorephedrine	100000	1%
p-Hydroxyamphetamine	100,000	1%
d/l-Norephedrine	100,000	1%
d-Methamphetamine	50,000	2%
l-Methamphetamine	1,000	100%
Ephedrine	100000 (negative)	Not detected
Methylenedioxymethamphetamine (MDMA)	100000 (negative)	Not detected
Phenylpropanolamine	100000 (negative)	Not detected
Benzphetamine	100000 (negative)	Not detected
l-Ephedrine	100000 (negative)	Not detected
l-Epinephrine	100000 (negative)	Not detected
d/l-Epinephrine	100000 (negative)	Not detected

MET (D(+)-Methamphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000	5%
(±)-MDMA	2,500	40%
d-Methamphetamine	1,000	100%
l-Methamphetamine	25,000	4%
d/l-Methamphetamine	1,000	100%
p-Hydroxymethamphetamine	10,000	10%
L-Amphetamine	75000	1.3%
β-Phenylethylamine	50000	2%
Mephetermine	50000	2%
Fenfluramine	50000	2%
D-Amphetamine	100000(negative)	Not Detected
Chloroquine	100000(negative)	Not Detected

(+/-)3,4-Methylenedioxyamphetamine (MDA)	100000(negative)	Not Detected
Trimethobenzamide	100000(negative)	Not Detected
d,l-Amphetamine	100000(negative)	Not Detected
(1R,2S)-(-)-Ephedrine	100000(negative)	Not Detected
l-phenylephrine	100000(negative)	Not Detected

OPI (Morphine, Cutoff=2000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Morphine	2000	100%
Codeine	1000	200%
Ethyl Morphine	2500	80%
Hydrocodone	5000	40%
Hydromorphone	25000	8%
Levorphanol	10000	20%
6-Monoacetylmorphine（6-MAM）	1500	133%
Morphine 3-β-D-glucuronide	2000	100%
Norcodeine	4000	50%
Normorphine	5000	40%
Oxymorphone	75000	3%
Thebaine	13000	15%
Heroin	5000	40%
s-Monoacetylmorphine	2000	100%
Dihydrocodeine	1500	133%
Nalorphine	5000	40%
6-acetylmorphine	2,500	80%
Procaine	100000(negative)	Not Detected
Oxycodone	100000(negative)	Not Detected

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity, urine samples with specific gravity from 1.000 to 1.035 were spiked with target drugs at +50% cutoff and -50% cutoff levels. Three operators tested samples using test devices from three different lots. The results were all positive for samples at +50% cutoff and all negative for samples at -50% cutoff, indicating that urine specific gravity between 1.000 and 1.035 has no effect on the accuracy and precision of the test device.

To investigate the effect of urine pH, urine samples with pH value from 4 to 9 were spiked with target drugs at +50% cutoff and -50% cutoff levels. Three operators tested samples using test devices from three different lots. The results were all positive for samples at +50% cutoff and all negative for samples at -50% cutoff, indicating that urine pH value between 4.0 and 9.0 has no effect on the accuracy and precision of the test device.

2. Comparison Studies

The method comparison studies for Accurate® Multi Panel Drug Urine Test cup were performed in-house with three operators.

Operators ran 80 (40 negative and 40 positive) unaltered urine samples. The samples were blind labeled and compared to LC/MS or GC/MS results. The results are presented in the table below:

For Accurate® Multi Panel Drug Urine Test Cup:

BUP

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	14	23
	Negative	10	16	13	3	0
Viewer B	Positive	0	0	3	14	23
	Negative	10	16	11	3	0
Viewer C	Positive	0	0	1	14	23
	Negative	10	16	13	3	0

Discordant Results for BUP:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-BUP-A75	10.2	-
Viewer A	MCP-BUP-A42	10.9	-
Viewer A	MCP-BUP-A61	11.2	-
Viewer B	MCP-BUP-A58	10.3	-
Viewer B	MCP-BUP-A42	10.9	-
Viewer B	MCP-BUP-A06	12.3	-
Viewer C	MCP-BUP-A58	10.3	-
Viewer C	MCP-BUP-A70	11.3	-
Viewer C	MCP-BUP-A11	12.9	-
Viewer A	MCP-BUP-A79	9.0	+
Viewer B	MCP-BUP-A01	8.4	+
Viewer B	MCP-BUP-A79	9.0	+
Viewer B	MCP-BUP-A54	9.5	+
Viewer C	MCP-BUP-A54	9.5	+

BAR

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS	Near Cutoff Positive by LC/MS	High Positive by LC/MS (greater than +50%)

				(Between -50% and the Cutoff)	(Between the cutoff and +50%)	
Viewer A	Positive	0	0	3	14	23
	Negative	10	16	11	3	0
Viewer B	Positive	0	0	2	14	23
	Negative	10	16	12	3	0
Viewer C	Positive	0	0	2	14	23
	Negative	10	16	12	3	0

Discordant Results for BAR:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-BAR-A64	271.6	+
Viewer A	MCP-BAR-A02	285.9	+
Viewer A	MCP-BAR-A41	295.6	+
Viewer B	MCP-BAR-A23	246.0	+
Viewer B	MCP-BAR-A02	285.9	+
Viewer C	MCP-BAR-A02	285.9	+
Viewer C	MCP-BAR-A41	295.6	+
Viewer A	MCP-BAR-A14	301.7	-
Viewer A	MCP-BAR-A03	317.8	-
Viewer A	MCP-BAR-A52	332.9	-
Viewer B	MCP-BAR-A47	311.9	-
Viewer B	MCP-BAR-A78	327.1	-
Viewer B	MCP-BAR-A27	347.5	-
Viewer C	MCP-BAR-A14	301.7	-
Viewer C	MCP-BAR-A47	311.9	-
Viewer C	MCP-BAR-A20	347.5	-

BZO

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	14	23
	Negative	10	16	13	3	0
Viewer B	Positive	0	0	3	13	23
	Negative	10	16	11	4	0
Viewer C	Positive	0	0	2	14	23

	Negative	10	16	12	3	0

Discordant Results for BZO:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-BZO-A37	274.5	+
Viewer B	MCP-BZO-A51	227.5	+
Viewer B	MCP-BZO-A42	264.1	+
Viewer B	MCP-BZO-A18	288.6	+
Viewer C	MCP-BZO-A75	235.0	+
Viewer C	MCP-BZO-A37	274.5	+
Viewer A	MCP-BZO-A76	304.6	-
Viewer A	MCP-BZO-A56	350.5	-
Viewer A	MCP-BZO-A73	358.2	-
Viewer B	MCP-BZO-A76	304.6	-
Viewer B	MCP-BZO-A03	311.2	-
Viewer B	MCP-BZO-A63	335.5	-
Viewer B	MCP-BZO-A73	358.2	-
Viewer C	MCP-BZO-A27	309.5	-
Viewer C	MCP-BZO-A08	332.0	-
Viewer C	MCP-BZO-A56	350.5	-

EDDP

Accurate®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	14	23
	Negative	10	16	13	3	0
Viewer B	Positive	0	0	1	14	23
	Negative	10	16	13	3	0
Viewer C	Positive	0	0	1	15	23
	Negative	10	16	13	2	0

Discordant Results for EDDP:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-EDDP-A07	254.8	+
Viewer B	MCP-EDDP-A07	254.8	+
Viewer C	MCP-EDDP-A21	245.1	+
Viewer A	MCP-EDDP-A12	303.7	-
Viewer A	MCP-EDDP-A34	306.8	-
Viewer A	MCP-EDDP-A20	316.7	-

Viewer B	MCP-EDDP-A38	302.4	-
Viewer B	MCP-EDDP-A46	310.5	-
Viewer B	MCP-EDDP-A14	319.9	-
Viewer C	MCP-EDDP-A12	303.7	-
Viewer C	MCP-EDDP-A20	316.7	-

MDMA

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	23
	Negative	10	16	13	4	0
Viewer B	Positive	0	0	2	14	23
	Negative	10	16	12	3	0
Viewer C	Positive	0	0	1	14	23
	Negative	10	16	13	3	0

Discordant Results for MDMA:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-MDMA-A10	451.4	+
Viewer B	MCP-MDMA-A48	379.2	+
Viewer B	MCP-MDMA-A26	476.0	+
Viewer C	MCP-MDMA-A10	451.4	+
Viewer A	MCP-MDMA-A21	525.2	-
Viewer A	MCP-MDMA-A04	538.5	-
Viewer A	MCP-MDMA-A07	562.6	-
Viewer A	MCP-MDMA-A38	542.7	-
Viewer B	MCP-MDMA-A78	532.6	-
Viewer B	MCP-MDMA-A38	542.7	-
Viewer B	MCP-MDMA-A24	591.1	-
Viewer C	MCP-MDMA-A39	528.9	-
Viewer C	MCP-MDMA-A56	551.9	-
Viewer C	MCP-MDMA-A24	591.1	-

MOP 300

Accurate ®		Drug-Free	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	15	23
	Negative	10	16	12	2	0
Viewer B	Positive	0	0	3	15	23
	Negative	10	16	11	2	0
Viewer C	Positive	0	0	2	15	23
	Negative	10	16	12	2	0

Discordant Results for MOP 300:

Viewer	Sample Number	GC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-MOP-A152	277.0	+
Viewer A	MCP-MOP-A141	283.1	+
Viewer B	MCP-MOP-A135	240.9	+
Viewer B	MCP-MOP-A098	272.3	+
Viewer B	MCP-MOP-A147	290.0	+
Viewer C	MCP-MOP-A098	272.3	+
Viewer C	MCP-MOP-A141	283.1	+
Viewer A	MCP-MOP-A151	305.6	-
Viewer A	MCP-MOP-A114	372.5	-
Viewer B	MCP-MOP-A081	300.4	-
Viewer B	MCP-MOP-A151	305.6	-
Viewer C	MCP-MOP-A081	300.4	-
Viewer C	MCP-MOP-A157	331.8	-

MTD

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	23
	Negative	10	16	13	4	0
Viewer B	Positive	0	0	2	14	23
	Negative	10	16	12	3	0
Viewer C	Positive	0	0	1	13	23
	Negative	10	16	13	4	0

Discordant Results for MTD:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-MTD-A71	290.9	+
Viewer B	MCP-MTD-A25	262.4	+
Viewer B	MCP-MTD-A36	272.2	+
Viewer C	MCP-MTD-A71	290.9	+
Viewer A	MCP-MTD-A52	309.6	-
Viewer A	MCP-MTD-A80	316.6	-
Viewer A	MCP-MTD-A10	326.3	-
Viewer A	MCP-MTD-A43	363.5	-
Viewer B	MCP-MTD-A52	309.6	-
Viewer B	MCP-MTD-A10	326.3	-
Viewer B	MCP-MTD-A42	319.1	-
Viewer C	MCP-MTD-A45	300.5	-
Viewer C	MCP-MTD-A52	309.6	-
Viewer C	MCP-MTD-A42	319.1	-
Viewer C	MCP-MTD-A76	327.8	-

OXY

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	12	23
	Negative	10	16	13	5	0
Viewer B	Positive	0	0	1	14	23
	Negative	10	16	13	3	0
Viewer C	Positive	0	0	1	13	23
	Negative	10	16	13	4	0

Discordant Results for OXY:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-OXY-A54	77.1	+
Viewer B	MCP-OXY-A33	92.3	+
Viewer C	MCP-OXY-A33	92.3	+
Viewer A	MCP-OXY-A76	102.8	-
Viewer A	MCP-OXY-A31	105.3	-
Viewer A	MCP-OXY-A14	105.5	-
Viewer A	MCP-OXY-A38	109.7	-

Viewer A	MCP-OXY-A52	115.5	-
Viewer B	MCP-OXY-A15	103.7	-
Viewer B	MCP-OXY-A34	109.4	-
Viewer B	MCP-OXY-A27	120.5	-
Viewer C	MCP-OXY-A60	100.5	-
Viewer C	MCP-OXY-A15	103.7	-
Viewer C	MCP-OXY-A65	105.8	-
Viewer C	MCP-OXY-A34	109.4	-

PCP

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	12	23
	Negative	10	16	13	5	0
Viewer B	Positive	0	0	0	13	23
	Negative	10	16	14	4	0
Viewer C	Positive	0	0	1	11	23
	Negative	10	16	13	6	0

Discordant Results for PCP:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-PCP-A38	23.6	+
Viewer C	MCP-PCP-A65	23.1	+
Viewer A	MCP-PCP-A04	25.5	-
Viewer A	MCP-PCP-A73	25.5	-
Viewer A	MCP-PCP-A20	26.6	-
Viewer A	MCP-PCP-A22	27.3	-
Viewer A	MCP-PCP-A55	28.3	-
Viewer B	MCP-PCP-A04	25.5	-
Viewer B	MCP-PCP-A59	25.9	-
Viewer B	MCP-PCP-A22	27.3	-
Viewer B	MCP-PCP-A46	27.6	-
Viewer C	MCP-PCP-A53	25.1	-
Viewer C	MCP-PCP-A73	25.5	-
Viewer C	MCP-PCP-A59	25.9	-
Viewer C	MCP-PCP-A20	26.6	-
Viewer C	MCP-PCP-A29	26.8	-

Viewer C	MCP-PCP-A08	27.4	-

PPX

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	14	23
	Negative	10	16	13	3	0
Viewer B	Positive	0	0	1	15	23
	Negative	10	16	13	2	0
Viewer C	Positive	0	0	1	15	23
	Negative	10	16	13	2	0

Discordant Results for PPX 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-PPX-A78	255.3	+
Viewer B	MCP-PPX-A20	295.8	+
Viewer C	MCP-PPX-A20	295.8	+
Viewer A	MCP-PPX-A38	314.2	-
Viewer A	MCP-PPX-A46	327.2	-
Viewer A	MCP-PPX-A22	349.3	-
Viewer B	MCP-PPX-A38	314.2	-
Viewer B	MCP-PPX-A42	339.5	-
Viewer C	MCP-PPX-A12	307.1	-
Viewer C	MCP-PPX-A38	314.2	-

TCA

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	2	14	23
	Negative	10	16	12	3	0
Viewer B	Positive	0	0	2	14	23
	Negative	10	16	12	3	0

Viewer C	Positive	0	0	3	15	23
	Negative	10	16	11	2	0

Discordant Results for TCA:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-TCA-A45	806.6	+
Viewer A	MCP-TCA-A66	983.7	+
Viewer B	MCP-TCA-A09	925.4	+
Viewer B	MCP-TCA-A21	955.8	+
Viewer C	MCP-TCA-A57	780.7	+
Viewer C	MCP-TCA-A09	925.4	+
Viewer C	MCP-TCA-A66	983.7	+
Viewer A	MCP-TCA-A06	1070.1	-
Viewer A	MCP-TCA-A05	1111.1	-
Viewer A	MCP-TCA-A77	1239.5	-
Viewer B	MCP-TCA-A33	1045.4	-
Viewer B	MCP-TCA-A06	1070.1	-
Viewer B	MCP-TCA-A05	1111.1	-
Viewer C	MCP-TCA-A06	1070.1	-
Viewer C	MCP-TCA-A05	1111.1	-

THC

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	15	23
	Negative	10	16	13	2	0
Viewer B	Positive	0	0	1	14	23
	Negative	10	16	13	3	0
Viewer C	Positive	0	0	2	15	23
	Negative	10	16	12	2	0

Discordant Results for THC:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-THC-A80	39.1	+
Viewer B	MCP-THC-A55	48.2	+
Viewer C	MCP-THC-A48	40.2	+
Viewer C	MCP-THC-A55	48.2	+

Viewer A	MCP-THC-A59	50.5	-
Viewer A	MCP-THC-A66	54.1	-
Viewer B	MCP-THC-A53	52.2	-
Viewer B	MCP-THC-A66	54.1	-
Viewer B	MCP-THC-A60	60.1	-
Viewer C	MCP-THC-A53	52.2	-
Viewer C	MCP-THC-A79	57.5	-

AMP

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	3	15	23
	Negative	10	16	11	2	0
Viewer B	Positive	0	0	4	14	23
	Negative	10	16	10	3	0
Viewer C	Positive	0	0	2	14	23
	Negative	10	16	12	3	0

Discordant Results for AMP:

Viewer	Sample Number	LC/MS Result (ng/mL)	Accurate Result
Viewer A	MCP-AMP-A60	906.4	+
Viewer A	MCP-AMP-A14	971.9	+
Viewer A	MCP-AMP-A50	988.0	+
Viewer B	MCP-AMP-A47	789.6	+
Viewer B	MCP-AMP-A24	951.4	+
Viewer B	MCP-AMP-A31	966.9	+
Viewer B	MCP-AMP-A50	988.0	+
Viewer C	MCP-AMP-A10	923.2	+
Viewer C	MCP-AMP-A26	965.0	+
Viewer A	MCP-AMP-A56	1013.8	-
Viewer A	MCP-AMP-A78	1180.9	-
Viewer B	MCP-AMP-A49	1053.4	-
Viewer B	MCP-AMP-A48	1201.4	-
Viewer B	MCP-AMP-A13	1255.2	-
Viewer C	MCP-AMP-A49	1053.4	-
Viewer C	MCP-AMP-A05	1166.2	-
Viewer C	MCP-AMP-A80	1235.3	-

COC

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	14	23
	Negative	10	16	13	3	0
Viewer B	Positive	0	0	1	13	23
	Negative	10	16	13	4	0
Viewer C	Positive	0	0	1	14	23
	Negative	10	16	13	3	0

Discordant Results for COC:

Viewer	Sample Number	LC/MS Result	Accurate Result
Viewer A	MCP-COC-A75	267.4	+
Viewer B	MCP-COC-A14	267.8	+
Viewer C	MCP-COC-A38	291.6	+
Viewer A	MCP-COC-A15	309.0	-
Viewer A	MCP-COC-A73	322.7	-
Viewer A	MCP-COC-A25	337.0	-
Viewer B	MCP-COC-A50	302.3	-
Viewer B	MCP-COC-A15	309.0	-
Viewer B	MCP-COC-A73	322.7	-
Viewer B	MCP-COC-A11	344.4	-
Viewer C	MCP-COC-A50	302.3	-
Viewer C	MCP-COC-A54	317.8	-
Viewer C	MCP-COC-A76	334.4	-

MET

Accurate ®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	23
	Negative	10	16	14	4	0
Viewer B	Positive	0	0	1	14	23
	Negative	10	16	13	3	0

Viewer C	Positive	0	0	1	13	23
	Negative	10	16	13	4	0

Discordant Results for MET:

Viewer	Sample Number	LC/MS Result	Accurate Result
Viewer B	MCP-MET-A27	846.8	+
Viewer C	MCP-MET-A71	732.5	+
Viewer A	MCP-MET-A50	1034.1	-
Viewer A	MCP-MET-A39	1059.0	-
Viewer A	MCP-MET-A36	1225.0	-
Viewer A	MCP-MET-A09	1288.3	-
Viewer B	MCP-MET-A39	1059.0	-
Viewer B	MCP-MET-A14	1122.5	-
Viewer B	MCP-MET-A01	1246.5	-
Viewer C	MCP-MET-A50	1034.1	-
Viewer C	MCP-MET-A23	1081.3	-
Viewer C	MCP-MET-A36	1225.0	-
Viewer C	MCP-MET-A38	1267.0	-

OPI 2000

Wondfo Q-Cup		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the 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	23
	Negative	10	16	13	4	0
Viewer B	Positive	0	0	1	14	23
	Negative	10	16	13	3	0
Viewer C	Positive	0	0	1	12	23
	Negative	10	16	13	5	0

Discordant Results for OPI 2000:

Viewer	Sample Number	LC/MS Result	Accurate Result
Viewer A	MCP-MOP-A24	1423.7	+
Viewer B	MCP-MOP-A10	1955.2	+
Viewer C	MCP-MOP-A10	1955.2	+
Viewer A	MCP-MOP-A09	2018.7	-
Viewer A	MCP-MOP-A07	2028.1	-
Viewer A	MCP-MOP-A36	2153.3	-
Viewer A	MCP-MOP-A40	2368.2	-

Viewer B	MCP-MOP-A50	2024.3	-
Viewer B	MCP-MOP-A07	2028.1	-
Viewer B	MCP-MOP-A36	2153.3	-
Viewer C	MCP-MOP-A09	2018.7	-
Viewer C	MCP-MOP-A50	2024.3	-
Viewer C	MCP-MOP-A14	2050.8	-
Viewer C	MCP-MOP-A46	2064.1	-
Viewer C	MCP-MOP-A43	2398.2	-

Lay-user study:

184 males and 126 females tested Accurate® Multi Panel Drug Urine Test Cup Configuration 1 (including MOP 300); 178 male and 132 females tested Accurate® Multi Panel Drug Urine Test Cup Configuration 2 (including MOP 2000 (OPI). They had diverse educational and professional backgrounds and fluent in English and their age range from 20 to over 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. 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.

Lay-User Study Results for Accurate® Multi Panel Drug Urine Test Cup Configuration 1 (MOP 300):

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
Methamphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Cocaine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Marijuana	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%

	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	17	3	85%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Morphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	20	0	100%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Oxazepam	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Amphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Oxycodone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Methadone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
MDMA	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%

	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Secobarbital	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Buprenorphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Phencyclidine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	17	3	85%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Propoxyphene	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Tricyclic Antidepressants	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
EDDP	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%

	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%

Lay-User Study Results for Accurate® Multi Panel Drug Urine Test Cup Configuration 2 (MOP 2000 (OPI)):

Drugs	% of Cutoff	Number of samples	Lay person results		The percentage agreement (%)
			No. of Positive	No. of Negative	
Methamphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Cocaine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Marijuana	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Morphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Oxazepam	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%

	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Amphetamine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Oxycodone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Methadone	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
MDMA	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Secobarbital	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Buprenorphine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	3	17	85%

	+25% Cutoff	20	18	2	90%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Phencyclidine	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	17	3	85%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Propoxyphene	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
Tricyclic Antidepressants	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	1	19	95%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	100%
EDDP	-100%Cutoff	20	0	20	100%
	-75%Cutoff	20	0	20	100%
	-50% Cutoff	20	0	170	100%
	-25% Cutoff	20	2	18	90%
	+25% Cutoff	20	19	1	95%
	+50% Cutoff	20	40	0	100%
	+75% Cutoff	20	20	0	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.

12. 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 Accurate® Multi Panel Drug Urine Test Cup are substantially equivalent to the predicate devices.