



August 30, 2022

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

Re: K221871

Trade/Device Name: Healstone Accurate™ Drug of Abuse Urine Test Cup, Healstone Accurate™  
Drug of Abuse Urine Test Cup Rx

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, NFW, NGM

Dated: June 26, 2022

Received: June 28, 2022

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Paula Caposino, Ph.D.  
Acting Deputy Director  
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**

510(k) Number (if known)

K221871

Device Name

Healstone Accurate™ Drug of Abuse Urine Test Cup

Indications for Use (Describe)

The Healstone Accurate™ Drug of Abuse Urine Test Cup is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs. This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	3,4-methylenedioxy-methamphetamine	500
OPI/MOP	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50

This drug test cup may contain any combination of the drug tests listed in the table above.

This drug tests cup provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test.

For in vitro diagnostic use only.

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

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

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

**Indications for Use**

510(k) Number (if known)

K221871

Device Name

Healstone Accurate™ Drug of Abuse Urine Test Cup Rx

Indications for Use (Describe)

The Healstone Accurate™ Drug of Abuse Urine Test Cup Rx is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs. This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	3,4-methylenedioxy-methamphetamine	500
OPI/MOP	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50

This drug test cup may contain any combination of the drug tests listed in the table above.

This drug tests cup provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test.

It is intended for prescription use. For in vitro diagnostic use only.

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

K221871

- 1 Date August 30, 2022
- 2 Submitter Healstone Biotech Inc.  
655 W Kent Ave N #650  
Vancouver, BC V6P 6T7, Canada
- 3 Contact Person Joe Shia  
LSI International Inc.  
504 East Diamond Ave., Suite I  
Gaithersburg, MD 20877  
Telephone: 240-505-7880  
Fax: 301-916-6213  
Email: shiajl@yahoo.com
- 4 Device Name Healstone Accurate™ Drug of Abuse Urine Test Cup  
Healstone Accurate™ Drug of Abuse Urine Test Cup Rx
- 5 Classification Class II

Product Code Target Drug	Regulation Section	Cup
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 Methylenedioxy metha mphetamine (MDMA)	862.3610, Methamphetamine Test System	Toxicology

NGL Morphine (MOP/OPI)	862.3650, Opiate Test System	Toxicology
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 Cannabinoids (THC 50)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Device K191841

Healstone Accurate™ Multi Panel Drug Urine Test Cup

7. Intended Use

The Healstone Accurate™ Drug of Abuse Urine Test Cup is a rapid qualitative immunoassay. The device provides preliminary results for the detection of potential abuse of one or more drugs. This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	3,4-methylenedioxy-methamphetamine	500
OPI / MOP	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50

This drug test cup may contain any combination of the drug tests listed in the table above.

This drug tests cup provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test.

For in vitro diagnostic use only.

The Healstone Accurate™ Drug of Abuse Urine Test Cup Rx is a rapid qualitative immunoassay.



The device provides preliminary results for the detection of potential abuse of one or more drugs. This is not a screening device to monitor prescription medication.

CODE	SUBSTANCE	CUT-OFF (ng/mL)
AMP	Amphetamine	1000 or 500
BUP	Buprenorphine	10
BAR	Secobarbital	300
BZO	Oxazepam	300
COC	Cocaine	300 or 150
EDDP	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine	300
MET/mAMP	Methamphetamine	1000 or 500
MDMA	3,4-methylenedioxy-methamphetamine	500
OPI/MOP	Morphine	2000 or 300
MTD	Methadone	300
OXY	Oxycodone	100
PCP	Phencyclidine	25
PPX	Propoxyphene	300
TCA	Nortriptyline	1000
THC	Marijuana	50

This drug test cup may contain any combination of the drug tests listed in the table above.

This drug tests cup provides only a preliminary result. An alternative laboratory test must be used to confirm the results provided by this drug test. Gas chromatography/mass spectrometry (GC/MS) is the preferred method confirmation test. It is intended for prescription use. For in vitro diagnostic use only.

#### 8. Device Description

The Healstone Accurate™ Drug of Abuse Urine Test Cup and Healstone Accurate™ Drug of Abuse Urine Test Cup Rx are rapid, single-use in vitro diagnostic devices. Each test kit contains a test device in one pouch. One pouch contains a test Accurate™ Cup and two desiccants, and a package insert. The Healstone Accurate™ Drug of Abuse Urine Test Cup is intended for over-the-counter use and the Healstone Accurate™ Drug of Abuse Urine Test Cup Rx is intended for prescription use.

#### 9. Substantial Equivalence Information

Item	Proposed Device	Predicate (K191841)
<b>Indication(s) for use</b>	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 Cannabinoids in human urine.	Same
<b>Methodology</b>	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction	Same

<b>Type of Test</b>	Qualitative	Same	
<b>Specimen Type</b>	Human urine	Same	
<b>Target Drug and Cut Off Values</b>	<b>Target Drug</b>	<b>Cutoff (ng/mL)</b>	Same except that AMP and MET have no 500 cutoff, and COC has no 150 cutoff.
	Amphetamine (AMP)	1000 or 500	
	Buprenorphine (BUP)	10	
	Secobarbital (BAR)	300	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methamphetamine (MET)	1000 or 500	
	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		
Cannabinoids (THC 50)	50		
<b>Configurations</b>	Test Cup	Cup	
<b>Intended Use</b>	Prescription Use and over-the-counter use	For over-the-counter use	

#### 10. Test Principle

Healstone Accurate™ Drug of Abuse Urine Test Cup and Healstone Accurate™ Drug of Abuse Urine Test Cup Rx are rapid tests 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 Cannabinoids 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, cutoff, +25% cut off, +50% cut off, +75% cut off and +100% cut off.

Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking target drug in drug-free urine samples. Each drug concentration was confirmed by LC/MS or GC/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 tables:

**Accurate™ Drug of Abuse Urine Test Cup BUP 10**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	2.4	5.1	7.5	10.2	12.3	14.8	17.6	19.6
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	47-/3+	27-/23+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup PCP 25**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	5.8	11.9	18.7	25.2	32.0	38.7	43.1	50.8
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	22-/28+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup THC 50**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	12.4	26.9	39.3	53.5	64.5	77.7	89.6	102.4
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	22-/28+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup OXY 100**

Concentration	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%

(ng/mL)	cut off	cut off	cut off	cutoff		cut off	cut off	cut off	cut off
Lot Number	0	26.8	49.2	81.1	101.5	131.6	153.4	174.1	192.0
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	27-/23+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup BAR 300**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	78.2	145.0	230.9	316.6	382.5	455.2	533.0	587.7
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	21-/29+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup BZO 300**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	76.6	148.6	222.9	300.0	374.3	455.7	516.0	598.6
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup EDDP 300**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	72.4	149.2	233.2	312.4	385.2	451.2	522.0	599.0
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup MTD 300**

Concentration (ng/mL)	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot Number	0	73.7	156.5	229.9	314.4	365.1	456.9	521.2	590.2
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-

Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup MOP 300**

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	69.1	148.2	228.7	302.0	382.1	445.0	509.1	583.2
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup PPX 300**

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	73.0	160.0	236.0	320.7	384.7	458.7	538.6	579.9
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup COC 150**

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	35.3	70.5	106.3	137.6	179.9	231.3	252.3	275.3
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	21-/29+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup MDMA 500**

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	122.9	272.8	370.6	499.5	628.4	752.1	870.4	935.7
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	21-/29+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	49+/1-	50+/0-	50+/0-	50+/0-

Accurate™ Drug of Abuse Urine Test Cup TCA 1000

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	248.7	489.5	758.2	988.3	1288.6	1536.5	1701.3	1958.2
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Accurate™ Drug of Abuse Urine Test Cup AMP 500

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	123.4	267.8	354.5	498.5	630.4	716.0	850.7	1017.4
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	25-/25+	48+/2-	50+/0-	50+/0-	50+/0-

Accurate™ Drug of Abuse Urine Test Cup MET 500

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	128.8	262.7	365.1	512.9	680.8	790.4	909.2	1021.3
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	49-/1+	26-/24+	48+/2-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	48-/2+	25-/25+	49+/1-	50+/0-	50+/0-	50+/0-

Accurate™ Drug of Abuse Urine Test Cup OPI 2000

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	535.8	1070.4	1636.6	2122.3	2632.6	3014.8	3337.5	3762.8
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Accurate™ Drug of Abuse Urine Test Cup COC 300

Concentration (ng/mL) Lot Number	-100%	-75%	-50%	-25%	cut off	+25%	+50%	+75%	+100%
	cut off	cut off	cut off	cutoff	cut off	cut off	cut off	cut off	cut off
	0	79.9	159.9	229.9	301.1	380.2	463.4	529.1	593.2
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	49+/1-	50+/0-	50+/0-	50+/0-

Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	22-/28+	49+/1-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	49+/1-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup AMP 1000**

Concentration (ng/mL) Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
	0	235.8	525.0	785.9	1086.6	1315.3	1599.2	1816.7	2040.5
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-

**Accurate™ Drug of Abuse Urine Test Cup MET 1000**

Concentration (ng/mL) Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
	0	252.5	512.2	767.2	1021.9	1251.6	1496.4	1781.4	2005.1
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

The following cutoff values are verified:

Target Drug	Cut-off level
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (OPI 2000/MOP 300)	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
Cannabinoids (THC 50)	50 ng/mL

b. Linearity

Not applicable

c. Stability

The devices are stable at 2-30°C 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.

(-) Cotinine	Diphenhydramine HCl	Noscapine
(±)-4-Methylephedrine-D3	D,L-Propranolol	O-Hydroxyhippuric acid
3-Hydroxytyramine	D,L-Tyrosine	Olanzapine
Acetaminophen	Doxylamine	Oxalic acid
Acetophenetidin	D-Pseudoephedrine	Oxolinic acid
Acetylsalicylic acid	Ecgonine methyl ester	Oxymetazoline
Albumin(100mg/dL)	EMDP	Papaverine
Alpha Methadol	Erythromycin	Penicillin-G
Aminopyrine	Ethanol (1%)	Perphenazine
Amoxicillin	Fenoprofen	Phenacetin
Ampicillin	Furosemide	Phenelzine
Apomorphine	Gabapentin	Phenethylamine
Ascorbic acid	Gatifloxacin	Phenylpropanolamine
Aspartame	Gentisic acid	Prednisone
Aspirin	Glucose	Procaine
Atropine	Hemoglobin	Promethazine
Azithromycin	Hydralazine	Quetiapine
Benzilic acid	Hydrochlorothiazide	Quinine
Benzoic acid	Hydrocortisone	Ranitidine
Benzphetamine	Ibuprofen	Salicylic acid
Bilirubin	Isoxsuprine	Serotonin



Cannabidiol	Ketamine	Serotonin (5- Hydroxytyramine)
Carfentanil	Ketoprofen	Sertraline
Chloralhydrate	LAAM HCl	Sulfamethazine
Chloramphenicol	Labetalol	Sulindac
Chloroquine	L-Ephedrine	Telmisartan
Chlorothiazide	L-Epinephrine	Tetrahydrocortisone 3-( $\beta$ -Dglucuronide)
Chlorpromazine	Loperamide	Tetrahydrocortisone, 3-acetate
Cholesterol	Loratadine	Tetrahydrozoline
Clonidine	L-phenylephrine	Thiamine
Cortisone	Magnesium	Thioridazine
Creatinine	Maprotiline	Triamterene
D,L-Tryptophan	Meperidine	Trifluoperazine
D,L-Isoproterenol	Meprobamate	Trimethobenzamide
D,L-Octopamine	Methoxyphenamine	Trimethoprim
D,L-Epinephrine	N-Acetylprocainamide	Uric acid
Delorazepam	Nalidixic acid	Verapamil
Deoxycorticosterone	Naproxen	Vitamin B2
Desloratadine	Niacinamide	Vitamin C
Dextromethorphan	Nicotine	Zaleplon
Diclofenac	Nifedipine	Zomepirac
Diclofenac sodium	Nordoxepin	$\beta$ -Estradiol
Diflunisal	Norethindrone	
Digoxin	Norfentanyl	

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.

Percent cross-reactivity, provided in the below table, was calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result, multiplied by 100; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results represented by a dash in the table below:

<b>BUP 10 (Buprenorphine, Cutoff=10 ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Buprenorphine -3-D-Glucuronide	160	6.25%
Norbuprenorphine	10	100%
Norbuprenorphine-3-D-Glucuronide	200	5%
Morphine	>100,000	-
Oxymorphone	>100,000	--
Hydromorphone	>100,000	--

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

<b>THC 50 (11-nor-<math>\Delta</math>9-THC-9-COOH, Cutoff=50 ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
11-nor- $\Delta$ 8-THC 50-9-COOH	30	167%
(-)-11-nor-9-carboxy- $\Delta$ 9-THC 50	50	100%
11-nor- $\Delta$ 9-THC 50-carboxy glucuronide	100	50%
11-hydroxy- $\Delta$ 9-Tetrahydrocannabinol	5000	1%
$\Delta$ 8- Tetrahydrocannabinol	1300	3.8%
$\Delta$ 9- Tetrahydrocannabinol	5000	1%
Cannabinol	20000	0.25%
Cannabidiol	>100000	--

<b>OXY 100 (Oxycodone, Cutoff=100 ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Ethyl Oxycodone	75,000	0.13%
Hydrocodone	5,000	2%
Hydromorphone	25,000	0.4%
Levorphanol tartrate	25,000	0.4%
Naloxone hydrochloride	10,000	1%
Naltrexone hydrochloride	50,000	0.2%
Oxymorphone	200	50%
Oxymorphone-D3	200	50%
Dihydrocodeine	>100,000	--
Codeine	>100,000	--
Morphine	>100,000	--
Acetylmorphine	>100,000	--

Buprenorphine	>100,000	--
Ethylmorphine	>100,000	--
Thebaine	>100,000	--

<b>COC 150 (Benzoylcegonine, Cutoff=150 ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Cocaethylene	150	100%
Cocaine HCl	150	100%
Ecgonine	25,000	0.6%
Norcocaine	50,000	0.3%
Ecgonine methyl Ester	>100000	--

<b>BAR 300 (Secobarbital, Cutoff=300ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Alphenal	150	200%
Amobarbital	300	100%
Aprobarbital	250	120%
Butobarbital	2,500	12%
Butethal	100	300%
Cyclopentobarbital	600	50%
Pentobarbital	250	120%
Phenobarbital	250	120%
Butalbital	2,500	12%

<b>BZO 300 (Oxazepam, Cutoff=300ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
a-Hydroxyalprazolam	1,260	23.8%
Alprazolam	200	150%
Bromazepam	1,560	19.2%
Chlordiazepoxide	1,560	19.2%
Clobazam	100	300%
Clonazepam	2,500	12%
Clorazepate Dipotassium	200	150%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	2,500	12%
Flunitrazepam	400	75%
D,L-Lorazepam	1,560	19.2%
Midazolam	12,500	2.4%

Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	400	75%
R,S-Lorazepam glucuronide	160	187.5%
Temazepam	100	300%
Triazolam	2,500	12%
Demoxepam	2,000	15%
Flurazepam	500	60%
Delorazepam	>100,000	--

<b>EDDP 300 (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Cutoff = 300 ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross-Reactivity</b>
Methadone	>100,000	--
EMDP	>100,000	--
Doxylamine	>100,000	--
Disopyramide	>100,000	--
LAAM (Levo-alpha-acetylmethadol) HCl	>100,000	--
Alpha Methadol	>100,000	--

<b>MTD 300 (Methadone, Cutoff=300ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross-Reactivity</b>
Doxylamine	>100,000	--
EDDP	>100,000	--
EMDP	>100,000	--
LAAM	>100,000	--
Alpha Methadol	>100,000	--

<b>MOP 300 (Morphine, Cutoff=300ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross-Reactivity</b>
6-acetylmorphine	400	75%
Codeine	300	100%
Dihydrocodeine	1,000	30%
EthylMorphine	100	300%
Heroin	600	50%
6-Monoacetylmorphine	150	200%
Hydrocodone	10,000	3%
Hydromorphone	500	60%
Levorphanol tartrate	10,000	3%
Nalorphine HCl	50,000	0.6%

Thebaine	6,240	4.8%
s-Monoacetylmorphine	300	100%
Morphine-3- $\beta$ -d-glucuronide	1,000	30%
Normorphine	>100,000	--
Oxycodone	>100000	--
Oxymorphone	>100000	--
Norcodeine	>100000	--
Procaine	>100000	--

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

<b>MDMA 500 (3,4-Methylenedioxyamphetamine HCl, Cutoff=500ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	300	166.7%
(+/-)-Methylenedioxyamphetamine(MDA)	3,000	16.7%
L-Methamphetamine	50,000	1%
D-Methamphetamine	>100,000	--
D-Amphetamine	>100,000	--
L-Amphetamine	>100,000	--

<b>AMP 500 (Amphetamine, Cutoff=500ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Hydroxyamphetamine	4,000	12.5%
(+/-)-Methylenedioxyamphetamine(MDA)	200	250%
D,L-Amphetamine	500	100%
Diethylstilbestrol	2,500	20%
L-Amphetamine	25,000	2%
p-Hydroxyamphetamine	50,000	1%
Phentermine	4,000	12.5%
$\beta$ -Phenylethylamine	50,000	1%
Tyramine	50,000	1%
p-Hydroxynorephedrine	50,000	1%
D,L-Norephedrine	50,000	1%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	100,000	0.5%

D-Methamphetamine	>100,000	--
L-Methamphetamine	>100,000	--
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	>100,000	--
Ephedrine HCl	>100,000	--
Phenylpropanolamine	>100,000	--
Benzphetamine	>100,000	--
L-Ephedrine	>100,000	--
L-Epinephrine	>100,000	--
D,L-Epinephrine	>100,000	--

<b>MET 500 (D(+)-Methamphetamine, Cutoff=500ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	10,000	5%
(±)-MDMA	1,250	40%
L-Methamphetamine	12,500	4%
Fenfluramine	25,000	2%
p-Hydroxymethamphetamine	5,000	10%
D,L-Methamphetamine	500	100%
β-Phenylethylamine	25,000	2%
Mephetermine	25,000	2%
L-Amphetamine	40,000	1.25%
Ephedrine HCl	100,000	0.5%
(1R,2S)-(-)-Ephedrine	100,000	0.5%
D-Amphetamine	>100,000	--
Chloroquine	>100,000	--
(+/-)3,4- Methylenedioxyamphetamine(MDA)	>100,000	--
L-Phenylephrine	>100,000	--

<b>TCA 1000 (Nortriptyline, Cutoff=1000ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Amitriptyline	1,500	66.7%
Chlorpheniramine	50,000	2%
Clomipramine	10,000	10%
Cyclobenzaprine Hydrochloride	5,000	20%
Desipramine	1,000	100%
Doxepine	2,000	50%
Duloxetine	10,000	10%

Imipramine	1,000	100%
Norclomipramine	12,500	8%
Nordoxepine	1,000	100%
Promazine	50,000	2%
Trimipramine	10,000	10%
Maprotiline	>100,000	--
Promethazine hydrochloride	>100,000	--

<b>COC 300 (Benzoylecgonine, Cutoff=300ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Cocaethylene	300	100%
Cocaine HCl	300	100%
Ecgonine	50,000	0.6%
Norcocaine	100,000	0.3%
Ecgonine methyl ester	>100,000	--

<b>AMP 1000 (d-Amphetamine, Cutoff=1000ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
Hydroxyamphetamine	8000	12.5%
(+/-)-Methylenedioxyamphetamine(MDA)	400	250%
D,L-Amphetamine	1,000	100%
Diethylstilbestrol	5,000	20%
L-Amphetamine	50,000	2%
p-Hydroxyamphetamine	100,000	1%
Phentermine	8,000	12.5%
β-Phenylethylamine	100,000	1%
Tyramine	100,000	1%
p-Hydroxynorephedrine	100,000	1%
D,L-Norephedrine	100,000	1%
D-Methamphetamine	>100000	--
L-Methamphetamine	>100000	--
Ephedrine HCl	>100000	--
(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	>100000	--
Phenylpropanolamine	>100000	--
Benzphetamine	>100000	--
L-Ephedrine	>100,000	--
L-Epinephrine	>100,000	--
D,L-Epinephrine	>100,000	--

<b>MET 1000 (D(+)-Methamphetamine, Cutoff=1000ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	20,000	5%
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	2,500	40%
L-Methamphetamine	25,000	4%
Fenfluramine	50,000	2%
p-Hydroxymethamphetamine	10,000	10%
D,L-Methamphetamine	1,000	100%
β-Phenylethylamine	50,000	2%
Mephetermine	50,000	2%
L-Amphetamine	75,000	1.33%
D-Amphetamine	>100000	--
D,L-Amphetamine	>100000	--
Chloroquine	>100000	--
Ephedrine HCl	>100000	--
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	--
Trimethobenzamide	>100000	--
L-Phenylephrine	>100000	--
(1R,2S)-(-)-Ephedrine	>100000	--

<b>OPI 2000 (Morphine, Cutoff=2000ng/mL)</b>	<b>Minimum concentration required to obtain a positive result (ng/mL)</b>	<b>% Cross- Reactivity</b>
6-acetylmorphine	2,500	80%
Codeine	1,000	200%
Dihydrocodeine	1,500	133.3%
EthylMorphine	2,500	80%
6-Monoacetylmorphine	1500	133%
Heroin	5,000	40%
Hydrocodone	5,000	40%
Hydromorphone	25,000	8%
Levorphanol tartrate	10,000	20%
Nalorphine HCl	5,000	40%
Norcodeine	4,000	50%
Normorphine	5,000	40%
Oxymorphone	75,000	2.7%
s-Monoacetylmorphine	2,000	100%



Thebaine	13,000	15.4%
Morphine 3-β-D-glucuronide	2,000	100%
Oxycodone	>100,000	--
Procaine	>100,000	--

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 each sample 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. No interference was observed at any specific gravity condition tested.

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 each sample 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 interference with the test device.

2. Comparison Studies

The method comparison studies for Healstone Accurate™ Drug of Abuse 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™ Drug of Abuse Urine Test Cup:

**AMP 500**

Healstone 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%)
Operator A	Positive	0	0	2	20	18
	Negative	10	19	9	2	0
Operator B	Positive	0	0	1	19	18
	Negative	10	19	10	3	0
Operator C	Positive	0	0	1	20	18
	Negative	10	19	10	2	0

**Discordant Results for AMP 500:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
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Operator A	TN-SAMP06072	450.4	+
Operator A	TN-SAMP06044	467.2	+
Operator B	TN-SAMP06072	450.4	+
Operator C	TN-SAMP06044	467.2	+
Operator A	TN-SAMP06006	518.5	-
Operator A	TN-SAMP06022	526.4	-
Operator B	TN-SAMP06041	532.0	-
Operator B	TN-SAMP06057	532.5	-
Operator B	TN-SAMP06073	539.1	-
Operator C	TN-SAMP06006	518.5	-
Operator C	TN-SAMP06057	532.5	-

**BUP 10**

Healstone 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%)
Operator A	Positive	0	0	0	13	24
	Negative	10	15	15	3	0
Operator B	Positive	0	0	1	13	24
	Negative	10	15	14	3	0
Operator C	Positive	0	0	3	16	24
	Negative	10	15	12	0	0

**Discordant Results for BUP 10:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator B	TN-BUP06042	9.6	+
Operator C	TN-BUP06040	9.5	+
Operator C	TN-BUP06042	9.6	+
Operator C	TN-BUP06013	9.8	+
Operator A	TN-BUP06048	10.0	-
Operator A	TN-BUP06058	10.1	-
Operator A	TN-BUP06002	10.8	-
Operator B	TN-BUP06037	10.2	-
Operator B	TN-BUP06002	10.8	-
Operator B	TN-BUP06023	11.0	-

**BAR 300**

Healstone 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%)
Operator A	Positive	0	0	2	17	22
	Negative	10	15	13	1	0
Operator B	Positive	0	0	2	14	22
	Negative	10	15	13	4	0
Operator C	Positive	0	0	0	15	22
	Negative	10	15	15	3	0

**Discordant Results for BAR 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-BAR06061	266.1	+
Operator A	TN-BAR06013	288.3	+
Operator B	TN-BAR06046	286.3	+
Operator B	TN-BAR06076	299.7	+
Operator A	TN-BAR06054	317.2	-
Operator B	TN-BAR06011	314.7	-
Operator B	TN-BAR06074	315.8	-
Operator B	TN-BAR06039	320.1	-
Operator B	TN-BAR06004	324.9	-
Operator C	TN-BAR06074	315.8	-
Operator C	TN-BAR06054	317.2	-
Operator C	TN-BAR06039	320.1	-

**BZO 300**

Healstone 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%)
Operator A	Positive	0	0	2	16	24
	Negative	10	16	12	0	0
Operator B	Positive	0	0	2	16	24
	Negative	10	16	12	0	0
Operator C	Positive	0	0	2	16	24

	Negative	10	16	12	0	0
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**Discordant Results for BZO 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-BZO06041	294.7	+
Operator A	TN-BZO06006	296.2	+
Operator B	TN-BZO06022	239.6	+
Operator B	TN-BZO06041	294.7	+
Operator C	TN-BZO06076	233.4	+
Operator C	TN-BZO06006	296.2	+

**COC 150**

Healstone 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%)
Operator A	Positive	0	0	3	14	25
	Negative	10	13	14	1	0
Operator B	Positive	0	0	2	14	25
	Negative	10	13	15	1	0
Operator C	Positive	0	0	1	15	25
	Negative	10	13	16	0	0

**Discordant Results for COC 150:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-SCOC06066	126.0	+
Operator A	TN-SCOC06067	134.4	+
Operator A	TN-SCOC06005	141.4	+
Operator B	TN-SCOC06005	141.4	+
Operator B	TN-SCOC06040	146.6	+
Operator C	TN-SCOC06066	126.0	+
Operator A	TN-SCOC06025	178.4	-
Operator B	TN-SCOC06049	153.2	-

**EDDP 300**

Healstone 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%)
Operator A	Positive	0	0	3	15	23
	Negative	10	15	12	2	0
Operator B	Positive	0	0	1	16	23
	Negative	10	15	14	1	0
Operator C	Positive	0	0	1	16	23
	Negative	10	15	14	1	0

**Discordant Results for EDDP 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-EDDP06031	236.0	+
Operator A	TN-EDDP06054	292.9	+
Operator A	TN-EDDP06078	294.9	+
Operator B	TN-EDDP06065	251.0	+
Operator C	TN-EDDP06074	274.7	+
Operator A	TN-EDDP06038	341.8	-
Operator A	TN-EDDP06003	342.4	-
Operator B	TN-EDDP06047	331.2	-
Operator C	TN-EDDP06047	331.2	-

**MET 500**

Healstone 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%)
Operator A	Positive	0	0	2	18	20
	Negative	10	20	8	2	0
Operator B	Positive	0	0	1	17	20
	Negative	10	20	9	3	0
Operator C	Positive	0	0	0	16	20
	Negative	10	20	10	4	0

**Discordant Results for MET 500:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-SMET06057	433.5	+
Operator A	TN-SMET06033	489.7	+
Operator B	TN-SMET06068	497.6	+
Operator A	TN-SMET06014	569.7	-
Operator A	TN-SMET06078	594.0	-
Operator B	TN-SMET06012	540.8	-
Operator B	TN-SMET06014	569.7	-
Operator B	TN-SMET06077	571.4	-
Operator C	TN-SMET06012	540.8	-
Operator C	TN-SMET06014	569.7	-
Operator C	TN-SMET06007	587.6	-
Operator C	TN-SMET06042	610.4	-

### MDMA 500

Healstone 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%)
Operator A	Positive	0	0	3	19	20
	Negative	10	13	14	1	0
Operator B	Positive	0	0	3	17	20
	Negative	10	13	14	3	0
Operator C	Positive	0	0	1	17	20
	Negative	10	13	16	3	0

### Discordant Results for MDMA 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-MDMA06032	478.7	+
Operator A	TN-MDMA06004	479.3	+
Operator A	TN-MDMA06005	496.8	+
Operator B	TN-MDMA06038	459.1	+
Operator B	TN-MDMA06076	473.3	+
Operator B	TN-MDMA06005	496.8	+
Operator C	TN-MDMA06005	496.8	+
Operator A	TN-MDMA06075	518.6	-
Operator B	TN-MDMA06065	501.8	-

Operator B	TN-MDMA06057	529.3	-
Operator B	TN-MDMA06022	587	-
Operator C	TN-MDMA06057	529.3	-
Operator C	TN-MDMA06067	529.3	-
Operator C	TN-MDMA06047	595.7	-

**MOP 300**

Healstone 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%)
Operator A	Positive	0	0	1	10	28
	Negative	10	17	12	2	0
Operator B	Positive	0	0	0	11	28
	Negative	10	17	13	1	0
Operator C	Positive	0	0	0	11	28
	Negative	10	17	13	1	0

**Discordant Results for MOP 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-MOP06014	295.8	+
Operator A	TN-MOP06061	308.6	-
Operator A	TN-MOP06074	314.9	-
Operator B	TN-MOP06061	308.6	-
Operator C	TN-MOP06074	314.9	-

**MTD 300**

Healstone 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%)
Operator A	Positive	0	0	1	17	22
	Negative	10	18	11	1	0
Operator B	Positive	0	0	0	15	22
	Negative	10	18	12	3	0

Operator C	Positive	0	0	1	17	22
	Negative	10	18	11	1	0

**Discordant Results for MTD 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-MTD06078	273.6	+
Operator C	TN-MTD06078	273.6	+
Operator A	TN-MTD06072	305.1	-
Operator B	TN-MTD06042	301.7	-
Operator B	TN-MTD06072	305.1	-
Operator B	TN-MTD06077	333.9	-
Operator C	TN-MTD06024	339.6	-

**OXY 100**

Healstone 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%)
Operator A	Positive	0	0	0	16	21
	Negative	10	15	15	3	0
Operator B	Positive	0	0	1	18	21
	Negative	10	15	14	1	0
Operator C	Positive	0	0	1	16	21
	Negative	10	15	14	3	0

**Discordant Results for OXY 100:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator B	TN-OXY06021	93.3	+
Operator C	TN-OXY06021	93.3	+
Operator A	TN-OXY06040	107.1	-
Operator A	TN-OXY06010	109.6	-
Operator A	TN-OXY06002	128.7	-
Operator B	TN-OXY06010	109.6	-
Operator C	TN-OXY06005	106.8	-
Operator C	TN-OXY06040	107.1	-
Operator C	TN-OXY06010	109.6	-



**PCP 25**

Healstone 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%)
Operator A	Positive	0	0	1	12	27
	Negative	10	18	11	1	0
Operator B	Positive	0	0	2	12	27
	Negative	10	18	10	1	0
Operator C	Positive	0	0	0	12	27
	Negative	10	18	12	1	0

**Discordant Results for PCP 25:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-PCP06052	22.0	+
Operator B	TN-PCP06052	22.0	+
Operator B	TN-PCP06031	20.6	+
Operator A	TN-PCP06069	27.1	-
Operator B	TN-PCP06069	27.1	-
Operator C	TN-PCP06076	27.5	-

**PPX 300**

Healstone 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%)
Operator A	Positive	0	0	2	15	24
	Negative	10	17	11	1	0
Operator B	Positive	0	0	0	13	24
	Negative	10	17	13	3	0
Operator C	Positive	0	0	2	15	24
	Negative	10	17	11	1	0

**Discordant Results for PPX 300:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
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Operator A	TN-PPX06035	289.0	+
Operator A	TN-PPX06070	292.4	+
Operator C	TN-PPX06035	289.0	+
Operator C	TN-PPX06070	292.4	+
Operator A	TN-PPX06020	335.1	-
Operator B	TN-PPX06038	331.9	-
Operator B	TN-PPX06040	331.9	-
Operator B	TN-PPX06003	350.5	-
Operator C	TN-PPX06040	331.9	-

### TCA 1000

Healstone 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%)
Operator A	Positive	0	0	3	14	22
	Negative	10	14	13	4	0
Operator B	Positive	0	0	3	16	22
	Negative	10	14	13	2	0
Operator C	Positive	0	0	1	16	22
	Negative	10	14	15	2	0

### Discordant Results for TCA 1000:

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-TCA06066	888.4	+
Operator A	TN-TCA06050	908.9	+
Operator A	TN-TCA06015	919.8	+
Operator B	TN-TCA06018	890.8	+
Operator B	TN-TCA06031	917.1	+
Operator B	TN-TCA06015	919.8	+
Operator C	TN-TCA06050	908.9	+
Operator A	TN-TCA06054	1071.4	-
Operator A	TN-TCA06044	1085.0	-
Operator A	TN-TCA06055	1097.2	-
Operator A	TN-TCA06019	1108.7	-
Operator B	TN-TCA06044	1085.0	-
Operator B	TN-TCA06019	1108.7	-
Operator C	TN-TCA06044	1085.0	-

Operator C	TN-TCA06073	1100.4	-
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**THC 50**

Healstone 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%)
Operator A	Positive	0	0	1	15	22
	Negative	10	16	13	3	0
Operator B	Positive	0	0	0	14	22
	Negative	10	16	14	4	0
Operator C	Positive	0	0	1	15	22
	Negative	10	16	13	3	0

**Discordant Results for THC 50:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-THC06041	47.3	+
Operator C	TN-THC06072	46.6	+
Operator A	TN-THC06070	51.8	-
Operator A	TN-THC06060	56.8	-
Operator A	TN-THC06001	57.4	-
Operator B	TN-THC06070	51.8	-
Operator B	TN-THC06021	52.4	-
Operator B	TN-THC06036	53.0	-
Operator B	TN-THC06001	57.4	-
Operator C	TN-THC06036	53.0	-
Operator C	TN-THC06069	57.7	-
Operator C	TN-THC06040	57.9	-

**AMP 1000**

Healstone 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%)
Operator A	Positive	0	0	1	16	20
	Negative	10	14	15	4	0

Operator B	Positive	0	0	4	17	20
	Negative	10	14	12	3	0
Operator C	Positive	0	0	2	18	20
	Negative	10	14	14	2	0

**Discordant Results for AMP 1000:**

Operator	Sample Number	LC/MS Result (ng/mL)	Healstone Accurate™ Result
Operator A	TN-AMP06043	955.5	+
Operator B	TN-AMP06043	955.5	+
Operator B	TN-AMP06077	960.5	+
Operator B	TN-AMP06007	986.2	+
Operator B	TN-AMP06008	996.1	+
Operator C	TN-AMP06059	948.8	+
Operator C	TN-AMP06008	996.1	+
Operator A	TN-AMP06048	1087.4	-
Operator A	TN-AMP06038	1097.7	-
Operator A	TN-AMP06003	1147.4	-
Operator A	TN-AMP06078	1147.4	-
Operator B	TN-AMP06048	1087.4	-
Operator B	TN-AMP06038	1097.7	-
Operator B	TN-AMP06078	1147.4	-
Operator C	TN-AMP06003	1147.4	-
Operator C	TN-AMP06058	1178.0	-

**COC 300**

Healstone 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%)
Operator A	Positive	0	0	2	17	22
	Negative	10	13	15	1	0
Operator B	Positive	0	0	3	17	22
	Negative	10	13	14	1	0
Operator C	Positive	0	0	2	16	22
	Negative	10	13	15	2	0

**Discordant Results for COC 300:**

Operator	Sample Number	LC/MS Result	Healstone Accurate™ Result

Operator A	TN-COC06012	278.7	+
Operator A	TN-COC06059	287.7	+
Operator B	TN-COC06035	269.9	+
Operator B	TN-COC06038	287.7	+
Operator B	TN-COC06061	296.1	+
Operator C	TN-COC06038	287.7	+
Operator C	TN-COC06059	287.7	+
Operator A	TN-COC06011	313.9	-
Operator B	TN-COC06052	304.4	-
Operator C	TN-COC06040	336.6	-
Operator C	TN-COC06026	337.1	-

**MET 1000**

Healstone 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%)
Operator A	Positive	0	0	3	13	26
	Negative	10	14	13	1	0
Operator B	Positive	0	0	2	12	26
	Negative	10	14	14	2	0
Operator C	Positive	0	0	2	12	26
	Negative	10	14	14	2	0

**Discordant Results for MET 1000:**

Operator	Sample Number	LC/MS Result	Healstone Accurate™ Result
Operator A	TN-MET06004	932.7	+
Operator A	TN-MET06038	935.0	+
Operator A	TN-MET06061	950.8	+
Operator B	TN-MET06060	924.1	+
Operator B	TN-MET06061	950.8	+
Operator C	TN-MET06038	935.0	+
Operator C	TN-MET06061	950.8	+
Operator A	TN-MET06054	1001.0	-
Operator B	TN-MET06054	1001.0	-
Operator B	TN-MET06026	1045.7	-
Operator C	TN-MET06054	1001.0	-
Operator C	TN-MET06026	1045.7	-

**OPI 2000**

Healstone 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%)
Operator A	Positive	0	0	0	19	17
	Negative	10	16	14	4	0
Operator B	Positive	0	0	0	20	17
	Negative	10	16	14	3	0
Operator C	Positive	0	0	1	19	17
	Negative	10	16	13	4	0

**Discordant Results for OPI 2000:**

Operator	Sample Number	LC/MS Result	Healstone Accurate™ Result
Operator C	TN-SMOP06018	1727.0	+
Operator A	TN-SMOP06013	2218.9	-
Operator A	TN-SMOP06078	2244.7	-
Operator A	TN-SMOP06054	2309.0	-
Operator A	TN-SMOP06019	2340.1	-
Operator B	TN-SMOP06043	2064.9	-
Operator B	TN-SMOP06008	2094.7	-
Operator B	TN-SMOP06040	2226.2	-
Operator C	TN-SMOP06043	2064.9	-
Operator C	TN-SMOP06008	2094.7	-
Operator C	TN-SMOP06013	2218.9	-
Operator C	TN-SMOP06071	2276.4	-

**Lay-user study:**

A lay user study was performed using urine samples 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. A total of 280 participants with diverse educational and professional backgrounds aged 20 years and older were recruited from three sites. Eighty-one males and 59 females tested Accurate™ Drug of Abuse Urine Test Cup Configuration 1 (including AMP 1000, MET 1000, MOP 300, COC 300); 90 male and 50 females tested Accurate™ Drug of Abuse Urine Test Cup Configuration 2 (including AMP 500, MET 500, OPI 2000, COC 150). Each participant was provided one package insert, one blind labeled test solution, and one test device. The results are summarized below:

Lay-User Study Results for Accurate™ Drug of Abuse Urine Test Cup Configuration 1 (including AMP 1000, MET 1000, MOP 300, COC 300):

Drug	Cutoff (ng/mL)	Results	Concentration						
			- 100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
BZO	300	Negative	20	20	20	17	2	0	0
		Positive	0	0	0	3	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	85%	90%	100%	100%
TCA	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
BAR	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
MET	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
COC	300	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
THC	50	Negative	20	20	20	17	2	0	0
		Positive	0	0	0	3	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	85%	90%	100%	100%
AMP	1000	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90%	90%	100%	100%
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%	95%	100%	100%
BUP	10	Negative	20	20	20	17	2	0	0
		Positive	0	0	0	3	18	20	20
		Total	20	20	20	20	20	20	20

		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>OXY</b>	<b>100</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>MOP</b>	<b>300</b>	<b>Negative</b>	20	20	20	19	2	0	0
		<b>Positive</b>	0	0	0	1	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	95%	90%	100%	100%
<b>PCP</b>	<b>25</b>	<b>Negative</b>	20	20	20	18	3	0	0
		<b>Positive</b>	0	0	0	2	17	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	85%	100%	100%
<b>MTD</b>	<b>300</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>MDMA</b>	<b>500</b>	<b>Negative</b>	20	20	20	18	3	0	0
		<b>Positive</b>	0	0	0	2	17	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	85%	100%	100%
<b>EDDP</b>	<b>300</b>	<b>Negative</b>	20	20	20	18	0	0	0
		<b>Positive</b>	0	0	0	2	20	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	100%	100%	100%

**Lay-User Study Results for Accurate™ Drug of Abuse Urine Test Cup Configuration 2 (AMP 500, MET 500, OPI 2000, COC 1500):**

<b>Drug</b>	<b>Cutoff (ng/mL)</b>	<b>Results</b>	<b>Concentration</b>						
			<b>- 100% cutoff</b>	<b>-75% cutoff</b>	<b>-50% cutoff</b>	<b>-25% cutoff</b>	<b>+25% cutoff</b>	<b>+50% cutoff</b>	<b>+75% cutoff</b>
<b>BZO</b>	<b>300</b>	<b>Negative</b>	20	20	20	18	3	0	0
		<b>Positive</b>	0	0	0	2	17	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	85%	100%	100%
<b>TCA</b>	<b>1000</b>	<b>Negative</b>	20	20	20	17	3	0	0
		<b>Positive</b>	0	0	0	3	17	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	85%	100%	100%
<b>BAR</b>	<b>300</b>	<b>Negative</b>	20	20	20	19	2	0	0



		<b>Positive</b>	0	0	0	1	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	95%	90%	100%	100%
<b>MET</b>	<b>500</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>COC</b>	<b>150</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>THC</b>	<b>50</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>AMP</b>	<b>500</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>PPX</b>	<b>300</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>BUP</b>	<b>10</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>OXY</b>	<b>100</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>OPI</b>	<b>2000</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>PCP</b>	<b>25</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>MTD</b>	<b>300</b>	<b>Negative</b>	20	20	20	18	2	0	0
		<b>Positive</b>	0	0	0	2	18	20	20

		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	90%	90%	100%	100%
<b>MDMA</b>	<b>500</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	100%	100%
<b>EDDP</b>	<b>300</b>	<b>Negative</b>	20	20	20	17	2	0	0
		<b>Positive</b>	0	0	0	3	18	20	20
		<b>Total</b>	20	20	20	20	20	20	20
		<b>Agreement (%)</b>	100%	100%	100%	85%	90%	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.

## 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 Healstone Accurate™ Drug of Abuse Urine Test Cup and Healstone Accurate™ Drug of Abuse Urine Test Cup Rx are substantially equivalent to the predicate devices.