



May 5, 2022

Qingdao HIGHTOP Biotech Co., Ltd.
% Joe Shia
Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K220685

Trade/Device Name: Hightop® Multi-Drug Urine Test Cup, Hightop® Multi-Drug 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, NGG, QBF, QAW, NFW, LCM
Dated: March 6, 2022
Received: March 8, 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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, Ph.D.
Deputy 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

Indications for Use

510(k) Number (if known)

k220685

Device Name

Hightop® Multi-Drug Urine Test Cup

Indications for Use (Describe)

Hightop® Multi-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 Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	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 (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 ng/mL

Hightop® Multi-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. It is intended for OTC use.

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.

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

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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)

Device Name

Hightop® Multi-Drug Urine Test Cup Rx

Indications for Use (Describe)

Hightop® Multi-Drug Urine Test Cup Rx 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 Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	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 (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
Cannabinoids (THC)	50 ng/mL

Hightop® Multi-Drug Urine Test Cup Rx 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. It is intended for prescription use.

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)

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Department of Health and Human Services
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510(k) SUMMARY

K220685

- 1 Date April 29, 2022
- 2 Submitter Qingdao HIGHTOP Biotech Co., Ltd.
No.369 Hedong Road, Qingdao, Shandong 266112
China
- 3 Contact Person Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite J
Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com
- 4 Device Name Hightop® Multi-Drug Urine Test Cup
Hightop® Multi-Drug 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 Methylenedioxymetha mphetamine (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
LCM Phencyclidine (PCP)	Unclassified	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 K182701

Wondfo T-Cup® Multi-Drug Urine Test Cup

7. Intended Use

Hightop® Multi-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 Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	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 (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 ng/mL

Hightop® Multi-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. It is intended for OTC use.

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.

Hightop® Multi-Drug Urine Test Cup Rx 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 Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	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 (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
Cannabinoids (THC)	50 ng/mL

Hightop® Multi-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. It is intended for prescription use.

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

The Hightop® Multi-Drug Urine Test Cup and Hightop® Multi-Drug 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 Hightop® Cup and two desiccants, and a package insert. The Hightop® Multi-Drug Urine Test Cup is intended for over-the-counter use and the Hightop® Multi-Drug Urine Test Cup Rx is intended for prescription use.

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 Cannabinoids 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 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	
Configurations	Test Cup		Cup
Intended Use	Prescription Use and over-the-counter use		For over-the-counter use

10. Test Principle

Hightop[®] Multi-Drug Urine Test Cup and Hightop[®] Multi-Drug 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. For each concentration, tests were performed two runs per day for 20 days using three lots of test Cups. The results obtained are summarized in the following tables:

Hightop® Multi-Drug Urine Test Cup BUP 10

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	20.639	18.961	16.144	12.894	10.931	7.847	4.699	2.372	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup PCP 25

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	45.873	40.806	34.745	28.986	23.342	17.475	11.980	6.035	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup THC 50

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	91.719	77.980	68.828	56.254	44.616	33.999	23.206	11.577	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	15-/25+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	16-/24+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup OXY 100

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	190.930	166.80	145.48	121.95	97.199	74.091	48.055	23.512	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup BAR 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	521.930	478.35	432.76	355.67	310.579	237.31	142.88	73.822	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup BZO 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	565.071	480.34	416.67	354.25	273.078	202.73	136.25	69.388	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	15-/25+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	16-/24+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup EDDP 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	554.757	487.55	420.46	343.50	283.163	214.94	144.88	71.416	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup MTD 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	560.075	460.6	436.87	359.45	281.504	215.81	152.45	73.320	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup MOP 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	647.611	559.70	492.4	402.2	318.962	210.61	163.37	81.274	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup PPX 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	605.886	527.60	448.738	394.47	314.961	233.98	153.15	79.325	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup COC 150

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	319.266	272.97	241.8	201.02	158.168	117.53	79.916	41.227	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup MDMA 500

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	1064.78	933.69	805.91	656.18	532.253	405.34	264.48	130.38	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup TCA 1000

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	1826.46	1582.9	1356.8	1146.2	913.883	676.01	456.57	242.25	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup AMP 500

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	916.094	807.506	689.93	577.14	462.436	347.06	225.67	124.313	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	14-/26+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup MET 500

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	952.643	814.24	679.94	578.75	476.642	357.6	241.67	131.18	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup OPI 2000

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	4047.51	3667.3	3241.0	2611.8	1966.56	1548.3	1080.0	535.72	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup COC 300

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	624.542	542.14	479.71	402.03	319.266	241.8	158.17	79.916	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup AMP 1000

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	1814.57	1583.3	1396.3	1157.0	916.094	689.93	462.44	225.67	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	12-/28+	40-/0+	40-/0+	40-/0+	40-/0+

Hightop® Multi-Drug Urine Test Cup MET 1000

Concentration by LC/MS (ng/mL)	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
Lot Number	1837.1	1593.0	1378.7	1155.5	952.643	679.94	476.64	241.67	0
Lot I	0-/40+	0-/40+	0-/40+	0-/40+	13-/27+	40-/0+	40-/0+	40-/0+	40-/0+
Lot II	0-/40+	0-/40+	0-/40+	0-/40+	10-/30+	40-/0+	40-/0+	40-/0+	40-/0+
Lot III	0-/40+	0-/40+	0-/40+	0-/40+	11-/29+	40-/0+	40-/0+	40-/0+	40-/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 (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
Cannabinoids (THC 50)	50 ng/mL

b. Linearity

Not applicable

c. Stability

The devices are stable at 4-30°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 -25% cutoff and +25% cutoff level.

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

Acetaminophen	Acetophenetidin	Acetylsalicylic Acid
Acyclovir	Amiodarone Hydrochloride	Apomorphine
Afrin	Albumin (100mg/dL)	Amlodipine Mesylate
Aminophylline	Amoxicillin	Aripiprazole
Aminopyrine	Ampicillin	Aspartame
Benzilic Acid	Atropine	Atomoxetine
Benzoic Acid	Carbamazepine	Atorvastatin Calcium
Bilirubin	Cefradine	Chloramphenicol
Bupropion	Cephalexin	Chlorothiazide
Captopril	Chloral Hydrate	Chloroquine
Ciprofloxacin Hydrochloride	Clonidine	Cholesterol
Citalopram	Clopidogrel Hydrogen Sulphate	(-) Cotinine
Clarithromycin	Clozapine	chlorpheniramine
Deoxy- corticosterone	D,L-Tyrosine	D,L-Octopamine
Dextromethorphan	Digoxin	D,L-Propranolol
Diclofenac	Diphenhydramine	D-Norpropoxy- phene
Diflunisal	Dirithromycin	Domperidone

D-Pseudo- ephedrine	Ecgonine Methyl Ester	Doxylamine
Duloxetine	Effexor	Epinephrine Hydrochloride
Dicyclomine	Enalapril Maleate	Erythromycin
β-Estradiol	Fentanyl Citrate	Esomeprazole Magnesium
Ethanol (1%)	Fluoxetine Hydrochloride	Furosemide
Fenofibrate	Fluvoxamine	Gabapentin
Fenoprofen	Glucose	Gentisic Acid
Glibenclamide	Haloperidol	3-Hydroxy- tyramine
Gliclazide	Hemoglobin	Isosorbide Dinitrate
Glipizide	Ketamine	Isoxsuprine
Ibuprofen	Kratom powder	Lamotrigine
Ketoconazole	Labetalol	Levofloxacin Hydrochloride
Ketoprofen	Liverite	Levonorgestrel
Lidocaine Hydrochloride	Loperamide	Levothyroxine Sodium
Lisinopril	Loratadine	Minocycline
Lithium Carbonate	Naproxen	Nalidixic Acid
Metoprolol Tartrate	Mifepristone	Niacinamide
Magnesium	Mirtazapine	Nifedipine
Meperidine	Montelukast Sodium	Nikethamide
Meprobamate	Phenelzine	Sulfamethazine
Mosapride Citrate	Pioglitazone Hydrochloride	Sulindac
Maprotiline	Piracetam	Tetrahydrocortisone 3 -acetate
Nimodipine	Pravastatin Sodium	Tetrahydrocortisone 3-(β-D-glucuronide)
Norethindrone	Prednisone	Tetrahydrozoline
N-Acetylprocain-amide	Propylthiouracil	Tetracycline
O-Hydroxyhippu-ric Acid	Promethazine	Thiamine
Olanzapine	Quetiapine Fumarate	Thioridazine
Omeprazole	Quinine	Topiramate
Oxalic Acid	Ranitidine	Tramadol Hydrochloride
Oxolinic Acid	Rifampicin	Trazodone Hydrochloride
Oxymetazoline	Risperidone	Triamterene
Ondansetran	Salicylic Acid	Trifluoperazine
Paliperidone	Serotonin	Trimethoprim
Pantoprazole	Sertraline Hydrochloride	Uric Acid
Papaverine	Sildenafil Citrate	Valproate
Paroxetine Hydrochloride	Simvastatin	Verapamil
Penfluridol	Sodium Valproate	Vitamin B2
PenicillinV Potassium	Spironolactone	Vitamin C
Penicillin-G		

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 as the cutoff concentration divided by the concentration of analyte tested that yielded 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:

BUP 10 (Buprenorphine, Cutoff=10 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Buprenorphine -3-D-Glucuronide	15	66.67%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	250	4%
Morphine	>100000	-
Oxymorphone	>100000	-
Hydromorphone	>100000	-

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

THC 50 (11-nor-Δ9-THC-9-COOH, Cutoff=50 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
(-)-11-nor-9-carboxy- Δ 9-THC	500	10%
11-nor- Δ 8-THC-9-COOH	30	166.67%
11-nor- Δ 9-THC-carboxy glucuronide	100000	0.05%
Cannabidiol	100000	0.05%
Cannabinol	100000	0.05%
Δ 8- Tetrahydrocannabinol	20000	0.25%
Δ 9- Tetrahydrocannabinol	20000	0.25%
11-hydroxy- Δ 9-Tetrahydrocannabinol	100,000	0.05%

OXY 100 (Oxycodone, Cutoff=100 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Dihydrocodeine	10000	1%
Hydrocodone	10000	1%
Oxymorphone	500	20%

Codeine	10000	1%
Hydromorphone	50000	0.2%
Morphine	50000	0.2%
Acetylmorphine	>100000	-
Buprenorphine	>100000	-
Ethylmorphine	10000	1%
Thebaine	>100000	-

COC 150 (Benzoylcegonine, Cutoff=150 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Cocaine	500	30%
Cocaethylene	6000	2.5%
Ecgonine	40000	0.375%
Ecgonine methyl ester	>100000	-
Norcocaine	>100000	-

BAR 300 (Secobarbital, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Amobarbital	300	100%
Alphenol	>100000	-
Aprobarbital	300	100%
Butobarbital	300	100%
Butethal	300	100%
Butalbital	2500	12%
Cyclopentobarbital	300	100%
Pentobarbital	300	100%
Phenobarbital	300	100%

BZO 300 (Oxazepam, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Alprazolam	200	150%
a-Hydroxyalprazolam	1250	24%
Bromazepam	500	60%
Chlordiazepoxide	1250	24%
Clobazam	100	300%
Clonazepam	2500	12%
Clorazepate dipotassium	200	150%
Delorazepam	1250	24%
Desalkylflurazepam	100	300%

Diazepam	100	300%
Estazolam	5000	6%
Flunitrazepam	50000	0.6%
Midazolam	12500	2.4%
Nitrazepam	100	300%
Norchlordiazepoxide	200	150%
Nordiazepam	500	60%
Temazepam	50	600%
Triazolam	2500	12%
Demoxepam	2000	15%
Flurazepam	500	60%
D,L-Lorazepam	2000	15%

EDDP 300 (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Cutoff = 300 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Methadone	>100000	-
EMDP	>100000	-
Doxylamine	>100000	-
Disopyramide	>100000	-
LAAM (Levo-alpha-acetylmethadol) HCl	>100000	-
Alpha Methadol	>100000	-

MTD 300 (Methadone, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Doxylamine	>100000	-
EDDP	>100000	-
EMDP	>100000	-
LAAM	>100000	-
Alpha Methadol	>100000	-

MOP 300 (Morphine, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Normorphine	>100000	-
Codeine	300	100%
s-Monoacetylmorphine	300	100%
Ethyl Morphine	200	150%
Heroin	1250	24%
Hydrocodone	10000	3%
Hydromorphone	5000	6%

Morphinie-3-β-d-glucuronide	2500	12%
Oxycodone	>100000	-
Oxymorphone	>100000	-
Thebaine	20000	1.5%
Levorphanol	10000	3%
6-Monoacetylmorphine (6-MAM)	300	100%
Norcodeine	100000	0.3%
Procaine	>100000	-

PPX 300 (d-Propoxyphene, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
d-Norpropoxyphene	5000	6%

MDMA 500 (3,4-Methylenedioxyamphetamine HCl, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
3,4-Methylenedioxyamphetamine HCl (MDA)	50000	1%
3,4-Methylenedioxyethylamphetamine (MDE)	2500	20%
d-methamphetamine	>100000	-
d-amphetamine	>100000	-
l-methamphetamine	50000	1%
l-amphetamine	>100000	-

AMP (Amphetamine) (Amphetamine, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
l-Amphetamine	500	100%
dl- Amphetamine	500	100%
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	1000	50%
Phentermine	5000	10%
Hydroxyamphetamine	100000	0.5%
d-Methamphetamine	>100000	-
l-Methamphetamine	>100000	-
(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	>100000	-
(+/-)3,4-Methylenedioxyamphetamine (MDMA)	>100000	-
β-Phenylethylamine	100000	0.5%
Tyramine	100000	0.5%
p-Hydroxynorephedrine	100000	0.5%
Phenylpropanolamine	100000	0.5%

(±)Phenylpropanolamine	>100000	-
p-Hydroxyamphetamine	100000	0.5%
d/l-Norephedrine	100000	0.5%
Benzphetamine	>100000	-
l-Ephedrine	100000	0.5%
l-Epinephrine	>100000	-
d/l-Epinephrine	>100000	-

MET 500 (D(+)-Methamphetamine, Cutoff=500ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
(+/-)3,4-Methylenedioxy-n-ethylamphetamine(MDE)	25000	2%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	12500	4%
D-Amphetamine	>100000	-
L-Amphetamine	>100000	-
Chloroquine	10000	5%
(+/-)-Ephedrine	25000	2%
(-)-Methamphetamine	25000	2%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	5000	10%
β-Phenylethylamine	>100000	-
Trimethobenzamide	>100000	-
d,l-Amphetamine	>100000	-
Mephetermine	25000	2%
(1R,2S)-(-)-Ephedrine	50000	1%
l-phenylephrine	50000	1%
L-Methamphetamine	50000	1%

TCA 1000 (Nortriptyline, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Nordoxepine	10000	10%
Trimipramine	20000	5%
Amitriptyline	1250	80%
Promazine	>100000	-
Desipramine	3000	33.33%
Imipramine	1000	100%
Clomipramine	40000	2.5%

Doxepin	5000	20%
Maprotiline	100000	1%
Promethazine	>100000	-
Cyclobenzaprine	10000	10%
Norclomipramine	12500	8%

COC 300 (Benzoylecgonine, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Cocaine	1000	30%
Cocaethylene	12500	2.4%
Ecgonine	50000	0.6%
Ecgonine methyl ester	>100000	-
Norcocaine	>100000	-

AMP 1000 (d-Amphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
l-Amphetamine	1000	100%
dl- Amphetamine	1000	100%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	2000	50%
Phentermine	10000	10%
Hydroxyamphetamine	>100000	-
d-Methamphetamine	>100000	-
l-Methamphetamine	>100000	-
(+/-)3,4-Methylenedioxyethylamphetamine(MDE)	>100000	-
(+/-)3,4- Methylenedioxymethamphetamine(MDMA)	>100000	-
β -Phenylethylamine	100000	1%
Tyramine	100000	1%
p-Hydroxynorephedrine	100000	1%
Phenylpropanolamine	>100000	-
(\pm)Phenylpropanolamine	>100000	-
p-Hydroxyamphetamine	100000	1%
d/l-Norephedrine	>100000	-
Benzphetamine	>100000	-
l-Ephedrine	100000	1%
l-Epinephrine	>100000	-
d/l-Epinephrine	>100000	-

MET 1000 (D(+)-Methamphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDE)	50000	2%
D/L-Methamphetamine	1000	100%
p-Hydroxymethamphetamine	25000	4%
D-Amphetamine	>100000	-
L-Amphetamine	>100000	-
Chloroquine	50000	2%
(+/-)-Ephedrine	50000	2%
(-)-Methamphetamine	50000	2%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	8000	12.5%
β-Phenylethylamine	>100000	-
Trimethobenzamide	>100000	-
d,l-Amphetamine	>100000	-
Mephetermine	50000	2%
(1R,2S)-(-)-Ephedrine	>100000	-
l-phenylephrine	>100000	-
L-Methamphetamine	100000	1%

OPI 2000 (Morphine, Cutoff=2000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
Normorphine	>100000	-
Codeine	5000	40%
s-Monoacetylmorphine	2000	100%
Ethyl Morphine	10000	20%
Heroin	>100000	-
Hydrocodone	25000	8%
Hydromorphone	25000	8%
Morphine-3-β-d-glucuronide	2000	100%
Oxycodone	>100000	-
Oxymorphone	>100000	-
Thebaine	>100000	-
Levorphanol	50000	4%
6-Monoacetylmorphine (6-MAM)	25000	8%
Norcodeine	>100000	-
Procaine	>100000	-

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 +25% cutoff and -25% cutoff levels. Three Operators tested each sample using test devices from three different lots. The results were all positive for samples at +25% cutoff and all negative for samples at -25% 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 +25% cutoff and -25% cutoff levels. Three Operators tested each sample using test devices from three different lots. The results were all positive for samples at +25% cutoff and all negative for samples at -25% 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 Hightop® Multi-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 results. The results are presented in the table below:

For Hightop® Multi-Drug Urine Test Cup:

AMP 500

Hightop® 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%)
Operator A	Positive	0	0	1	18	22
	Negative	8	16	15	0	0
Operator B	Positive	0	0	2	18	22
	Negative	8	16	14	0	0
Operator C	Positive	0	0	2	18	22
	Negative	8	16	14	0	0

Discordant Results for AMP 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00013426	476.193	+
Operator B	00013400	484.179	+
Operator B	00013096	489.928	+
Operator C	00013426	476.193	+
Operator A	00013096	489.928	+

BUP 10

Hightop® 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%)
Operator A	Positive	0	0	1	18	21
	Negative	8	15	16	1	0
Operator B	Positive	0	0	2	19	21
	Negative	8	15	15	0	0
Operator C	Positive	0	0	0	19	21
	Negative	8	15	17	0	0

Discordant Results for BUP 10:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	1035421349	12.071	-
Operator A	1035423433	8.613	+
Operator B	1035423433	8.613	+
Operator B	1035422023	9.159	+

BAR 300

Hightop® 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%)
Operator A	Positive	0	0	1	19	20
	Negative	8	16	15	1	0
Operator B	Positive	0	0	1	20	20
	Negative	8	16	15	0	0
Operator C	Positive	0	0	1	18	20
	Negative	8	16	15	2	0

Discordant Results for BAR 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	1035421235	252.898	+
Operator B	1035421036	257.522	+
Operator C	1035421142	254.749	+

Operator A	1035420985	307.065	-
Operator C	1035420985	307.065	-
Operator C	1035422170	316.751	-

BZO 300

Hightop® 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%)
Operator A	Positive	0	0	1	16	23
	Negative	8	16	15	1	0
Operator B	Positive	0	0	1	16	23
	Negative	8	16	15	1	0
Operator C	Positive	0	0	3	16	23
	Negative	8	16	13	1	0

Discordant Results for BZO 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	1035422739	291.117	+
Operator B	1035422739	291.117	+
Operator C	1035422739	291.117	+
Operator C	1035422210	267.676	+
Operator C	1035422651	290.721	+
Operator A	1035422395	301.084	-
Operator B	1035422395	301.084	-
Operator C	1035422395	301.084	-

COC 150

Hightop® 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%)
Operator A	Positive	0	0	1	16	24
	Negative	8	16	15	0	0
Operator B	Positive	0	0	0	16	24
	Negative	8	16	16	0	0
Operator C	Positive	0	0	1	16	24
	Negative	8	16	15	0	0

Discordant Results for COC 150:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00012562	132.433	+
Operator C	00012562	132.433	+

EDDP 300

Hightop [®] 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%)
Operator A	Positive	0	0	1	21	19
	Negative	8	16	16	0	0
Operator B	Positive	0	0	1	21	19
	Negative	8	16	16	0	0
Operator C	Positive	0	0	0	21	19
	Negative	8	16	17	0	0

Discordant Results for EDDP 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00011835	284.508	+
Operator B	00011900	285.830	+

MET 500

Hightop [®] 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%)
Operator A	Positive	0	0	2	19	21
	Negative	8	14	16	0	0
Operator B	Positive	0	0	0	19	21
	Negative	8	14	18	0	0
Operator C	Positive	0	0	1	19	21
	Negative	8	14	17	0	0

Discordant Results for MET 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00012486	467.910	+
Operator A	00012066	491.588	+
Operator C	00012486	467.910	+

MDMA 500

Hightop® 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%)
Operator A	Positive	0	0	1	22	18
	Negative	8	16	15	0	0
Operator B	Positive	0	0	1	22	18
	Negative	8	16	15	0	0
Operator C	Positive	0	0	0	21	18
	Negative	8	16	16	1	0

Discordant Results for MDMA 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00010229	492.926	+
Operator B	00010229	492.926	+
Operator C	00009611	508.877	-

MOP 300

Hightop® 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%)
Operator A	Positive	0	0	0	21	19
	Negative	8	14	18	0	0
Operator B	Positive	0	0	0	21	19
	Negative	8	14	18	0	0
Operator C	Positive	0	0	1	21	19
	Negative	8	14	17	0	0

Discordant Results for MOP 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator C	00011769	296.790	+

MTD 300

Hightop® Cup		Drug-Free	Low Negative by LC/MS	Near Cutoff Negative by LC/MS	Near Cutoff Positive by LC/MS	High Positive by LC/MS
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			LC/MS (less than -50%)	(Between -50% and the Cutoff)	(Between the cutoff and +50%)	(greater than +50%)
Operator A	Positive	0	0	0	18	20
	Negative	8	17	15	2	0
Operator B	Positive	0	0	2	20	20
	Negative	8	17	13	0	0
Operator C	Positive	0	0	0	20	20
	Negative	8	17	15	0	0

Discordant Results for MTD 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator B	00012658	287.804	+
Operator B	00011740	296.375	+
Operator A	00011815	327.246	-
Operator A	00012146	341.195	-

OXY 100

Hightop® 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%)
Operator A	Positive	0	0	2	20	20
	Negative	8	16	14	0	0
Operator B	Positive	0	0	1	20	20
	Negative	8	16	15	0	0
Operator C	Positive	0	0	2	19	20
	Negative	8	16	14	1	0

Discordant Results for OXY 100:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00013642	96.266	+
Operator C	00013741	97.870	+
Operator A	00013878	99.691	+
Operator B	00013878	99.691	+
Operator C	00013878	99.691	+
Operator C	00012547	100.512	-

PCP 25

Hightop® Cup		Drug-Free	Low Negative by	Near Cutoff Negative by LC/MS	Near Cutoff Positive by LC/MS	High Positive by LC/MS
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			LC/MS (less than -50%)	(Between -50% and the Cutoff)	(Between the cutoff and +50%)	(greater than +50%)
Operator A	Positive	0	0	1	17	20
	Negative	8	16	15	3	0
Operator B	Positive	0	0	0	20	20
	Negative	8	16	16	0	0
Operator C	Positive	0	0	0	18	20
	Negative	8	16	16	2	0

Discordant Results for PCP 25:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00009369	21.999	+
Operator A	00008179	27.262	-
Operator A	00008152	27.660	-
Operator C	00008152	27.660	-
Operator A	00012809	27.671	-
Operator C	00012809	27.671	-

PPX 300

Hightop [®] 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%)
Operator A	Positive	0	0	0	14	24
	Negative	8	16	16	2	0
Operator B	Positive	0	0	1	16	24
	Negative	8	16	15	0	0
Operator C	Positive	0	0	2	16	24
	Negative	8	16	14	0	0

Discordant Results for PPX 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator C	00009392	289.027	+
Operator B	00013736	299.806	+
Operator C	00013736	299.806	+
Operator A	00007439	308.846	-
Operator A	00010214	325.332	-

TCA 1000

Hightop [®] 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%)
Operator A	Positive	0	0	0	17	21
	Negative	8	17	15	2	0
Operator B	Positive	0	0	0	16	21
	Negative	8	17	15	3	0
Operator C	Positive	0	0	0	19	21
	Negative	8	17	15	0	0

Discordant Results for TCA 1000:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	00012850	1001.210	-
Operator A	00013628	1009.815	-
Operator B	00012850	1001.210	-
Operator B	00013628	1009.815	-
Operator B	00011935	1015.492	-

THC 50

Hightop [®] 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%)
Operator A	Positive	0	0	2	21	19
	Negative	8	16	14	0	0
Operator B	Positive	0	0	0	19	19
	Negative	8	16	16	2	0
Operator C	Positive	0	0	2	21	19
	Negative	8	16	14	0	0

Discordant Results for THC 50:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator A	1035422469	40.426	+
Operator C	1035422620	42.267	+
Operator C	1035423426	49.136	+
Operator A	1035423426	49.136	+

Operator B	1035423067	50.150	-
Operator B	1035421602	50.970	-

AMP 1000

Hightop® 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%)
Operator A	Positive	0	0	0	16	21
	Negative	8	17	15	3	0
Operator B	Positive	0	0	0	18	21
	Negative	8	17	15	1	0
Operator C	Positive	0	0	1	16	21
	Negative	8	17	14	3	0

Discordant Results for AMP 1000:

Operator	Sample Number	LC/MS Result (ng/mL)	Hightop Result
Operator C	00013637	967.618	+
Operator A	00013639	1001.742	-
Operator C	00013639	1001.742	-
Operator A	00011718	1008.830	-
Operator B	00011718	1008.830	-
Operator C	00011718	1008.830	-
Operator A	00013437	1009.916	-
Operator C	00013437	1009.916	-

COC 300

Hightop® 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%)
Operator A	Positive	0	0	2	19	21
	Negative	8	17	13	0	0
Operator B	Positive	0	0	2	19	21
	Negative	8	17	13	0	0
Operator C	Positive	0	0	1	19	21
	Negative	8	17	14	0	0

Discordant Results for COC 300:

Operator	Sample Number	LC/MS Result	Hightop Result
Operator A	00012552	267.123	+
Operator B	00012552	267.123	+
Operator A	00012542	274.118	+
Operator B	00011814	283.062	+
Operator C	00011814	283.062	+

MET 1000

Hightop [®] 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%)
Operator A	Positive	0	0	0	20	18
	Negative	8	17	15	2	0
Operator B	Positive	0	0	0	22	18
	Negative	8	17	15	0	0
Operator C	Positive	0	0	0	21	18
	Negative	8	17	15	1	0

Discordant Results for MET 1000:

Operator	Sample Number	LC/MS Result	Hightop Result
Operator A	00013726	1037.600	-
Operator A	00012643	1041.167	-
Operator C	00012643	1041.167	-

OPI 2000

Hightop [®] 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%)
Operator A	Positive	0	0	0	18	20
	Negative	8	17	15	2	0
Operator B	Positive	0	0	0	20	20
	Negative	8	17	15	0	0
Operator C	Positive	0	0	0	18	20
	Negative	8	17	15	2	0

Discordant Results for OPI 2000:

Operator	Sample Number	LC/MS Result	Hightop Result
Operator A	00007823	2000.404	-

Operator A	00013647	2007.513	-
Operator C	00007823	2000.404	-
Operator C	00013647	2007.513	-

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 or 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. Seventy-two males and 68 females tested Hightop® Multi-Drug Urine Test Cup Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150); 71 male and 69 females tested Hightop® Multi-Drug Urine Test Cup Configuration 2 (including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300). 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 Hightop® Multi-Drug Urine Test Cup Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150):

Assay	Results	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP 500	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BAR 300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
BZO 300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
BUP 10	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%

COC 150	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
EDDP 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MDMA 500	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MET 500	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MOP 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MTD 300	Negative	20	20	20	18	0	0	0
	Positive	0	0	0	2	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	100%	100%	100%
OXY 100	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PCP 25	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PPX 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20

	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
TCA 1000	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
THC 50	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%

Lay-User Study Results for Hightop[®] Multi-Drug Urine Test Cup Configuration 2 (AMP 1000, MET 1000, MOP 2000 (OPI), COC 300):

Assay	Results	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP 1000	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
BAR 300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
BZO 300	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	100%	100%	100%
BUP 10	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
COC 300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20

	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
EDDP 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MDMA 500	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MET 1000	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
OPI 2000	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MTD 300	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
OXY 100	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PCP 25	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
PPX 300	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20

	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
TCA 1000	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
THC 50	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%

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

Clinical Studies:

Not applicable.

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 Hightop[®] Multi-Drug Urine Test Cup and Hightop[®] Multi-Drug Urine Test Cup Rx are substantially equivalent to the predicate devices.