VivaChek Biotech (Hangzhou) Co., Ltd.
℅ Joe Shia
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, Maryland 20877

Re: K233062
Trade/Device Name: BioSieve™ Multi-Drug Urine Test Panel; BioSieve™ Multi-Drug Urine Test Panel Rx
Regulation Number: 21 CFR 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NFY, NGL, PTH, NFV, PTG, NGG, LCM, QBF, QAW, NFW
Dated: September 21, 2023
Received: September 26, 2023

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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph A. Kotarek -S

Digitally signed by Joseph A. Kotarek -S
Date: 2023.11.02 14:50:57 -04'00'

Joseph Kotarek, Ph.D.
Branch Chief
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233062

Device Name
BioSieve™ Multi-Drug Urine Test Panel

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

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL 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

BioSieve™ Multi-Drug Urine Test Panel offers any combinations from 1 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.

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233062

Device Name
BioSieve™ Multi-Drug Urine Test Panel Rx

Indications for Use *(Describe)*
BioSieve™ Multi-Drug Urine Test Panel 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	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	D-Amphetamine	1,000 or 500
Barbiturates (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	300 or 150
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Ecstasy (MDMA)	D,L- Methylenedioxy-methamphetamine	500
Methamphetamine (MET)	D-Methamphetamine	1,000 or 500
Morphine (MOP/OPI)	Morphine	2,000 or 300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Nortriptyline (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50

BioSieve™ Multi-Drug Urine Test Panel Rx offers any combinations from 1 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) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Department of Health and Human Services
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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."

510(k) SUMMARY

K233062

1 Date October 25, 2023

2 Submitter VivaChek Biotech (Hangzhou) Co., Ltd.
Level 2, Block 2, 146 East Chaofeng Rd.
Hangzhou, China

3 Contact Person Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4 Device Name BioSieve™ Multi-Drug Urine Test Panel
BioSieve™ Multi-Drug Urine Test Panel Rx

5 Classification Class II

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

Morphine (MOP/OPI)		
PTG Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGL Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
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 K202567
   Wondfo T-Dip® Multi-Drug Urine Test Panel

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

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL 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

BioSieve™ Multi-Drug Urine Test Panel offers any combinations from 1 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 test may yield positive results for the prescription drugs Buprenorphine, Oxazepam, Secobarbital, Nortriptyline, 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 alternative chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

BioSieve™ Multi-Drug Urine Test Panel 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	**Calibrator**	**Cut-off (ng/mL)**
Amphetamine (AMP)	D-Amphetamine	1,000 or 500
Secobarbital (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	300 or 150
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Ecstasy (MDMA)	D,L- Methylenedioxy-methamphetamine	500
Methamphetamine (MET)	D-Methamphetamine	1,000 or 500
Morphine (MOP/OPI)	Morphine	2,000 or 300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Nortriptyline (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50

BioSieve™ Multi-Drug Urine Test Panel Rx offers any combinations from 1 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 BioSieve™ Multi-Drug Urine Test Panel and BioSieve™ Multi-Drug Urine Test Panel Rx are rapid, single-use in vitro diagnostic devices. Each test kit contains a test device in one pouch. One pouch contains a test BioSieve™ Panel and two desiccants, and a package insert. The BioSieve™ Multi-Drug Urine Test Panel is intended for over-the-counter use and the BioSieve™ Multi-Drug Urine Test Panel Rx is intended for prescription use.

9. Substantial Equivalence Information

Item	**Proposed Device**		**Predicate (K202567)**
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 Panel		Panel
Intended Use	Prescription Use and over-the-counter use		Prescription Use and over-the-counter use

10. Test Principle

BioSieve™ Multi-Drug Urine Test Panel and BioSieve™ Multi-Drug Urine Test Panel 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 Panel 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 25 days using three lots of test Panels. The results obtained are summarized in the following tables:

BioSieve™ Multi-Drug Urine Test Panel BUP 10

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	20.0	17.1	13.6	11.8	10.2	6.9	5.4	2.7	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel PCP 25

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	52.1	43.1	37.3	29.4	25.2	17.7	12.2	6.5	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel THC 50

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	96.5	84.3	75.7	60.1	52.5	35.9	24.1	12.1	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel OXY 100

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	200.3	177.1	158.9	131.7	108.5	78.0	51.6	27.6	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel BAR 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	588.4	525.8	457.6	383.8	301.6	228.3	157.1	80.2	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel BZO 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	596.1	536.5	470.4	370.3	290.4	219.8	157.3	78.5	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel EDDP 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	646.2	545.3	455.1	371.0	290.7	229.5	148.8	77.0	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel MTD 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	620.5	547.0	469.9	380.9	328.6	240.2	143.9	71.4	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel MOP 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	622.4	530.2	468.8	381.8	322.8	220.8	159.0	75.4	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel PPX 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	622.3	562.7	451.3	383.3	297.7	218.3	152.5	75.8	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel COC 150

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	298.2	246.1	237.0	193.6	157.7	106.5	76.2	36.0	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel MDMA 500

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1048.5	861.5	740.8	614.9	522.8	342.0	250.6	128.4	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel TCA 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	2175.2	1841.2	1597.5	1261.6	1081.5	708.2	493.1	251.5	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel AMP 500

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1011.8	846.4	772.7	646.8	544.3	357.6	225.0	120.9	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel MET 500

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1072.7	873.9	731.7	633.1	477.8	386.1	249.2	122.5	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel OPI 2000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	4208.2	3672.9	3119.0	2590.5	2050.0	1460.4	1007.5	493.0	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel COC 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	610.6	558.5	461.6	373.4	329.9	235.6	156.7	74.5	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel AMP 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1933.3	1805.2	1562.7	1262.0	1051.1	812.0	540.9	271.9	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+

BioSieve™ Multi-Drug Urine Test Panel MET 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1954.6	1824.2	1593.1	1304.9	1003.4	736.7	464.8	251.1	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	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 (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 2-30℃ for 24 months based on real time stability studies at 2ºC and 30℃.

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	Effexor	Nikethamide
Acetophenetidin	Enalapril Maleate	Nimodipine
Acetylsalicylic Acid	Epinephrine Hydrochloride	Nitroglycerin
Acyclovir	Erythromycin	Norethindrone
Afrin	Esomeprazole Magnesium	O-Hydroxyhippuric Acid
Albumin (100mg/dL)	β-Estradiol	Olanzapine
Aminophylline	Ethanol (1%)	Omeprazole
Aminopyrine	Fenofibrate	Ondansetran
Amiodarone Hydrochloride	Fenoprofen	Oxalic Acid
Amlodipine Mesylate	Fentanyl Citrate	Oxolinic Acid
Amoxicillin	Fluoxetine Hydrochloride	Oxymetazoline
Ampicillin	Fluvoxamine	Paliperidone
Apomorphine	Furosemide	Pantoprazole
Aripiprazole	Gabapentin	Papaverine
Aspartame	Gentisic Acid	Paroxetine Hydrochloride
Atomoxetine	Glibenclamide	Penfluridol
Atorvastatin Calcium	Gliclazide	Penicillin-G

Atropine	Glipizide	PenicillinV Potassium
Benzilic Acid	Glucose	Phenelzine
Benzoic Acid	Haloperidol	Pioglitazone Hydrochloride
Bilirubin	Hemoglobin	Piracetam
Bupropion	Hydrochlorothiazide	Pravastatin Sodium
Captopril	Hydrocortisone	Prednisone
Carbamazepine	3-Hydroxytyramine	Promethazine
Cefradine	Ibuprofen	Propylthiouracil
Cephalexin	Isosorbide Dinitrate	Quetiapine Fumarate
Chloral Hydrate	Isoxsuprine	Quinine
Chloramphenicol	Ketamine	Ranitidine
Chlorothiazide	Ketoconazole	Rifampicin
chlorpheniramine	Ketoprofen	Risperidone
Cholesterol	Kratom powder	Salicylic Acid
Ciprofloxacin Hydrochloride	Labetalol	Serotonin
Citalopram	Lamotrigine	Sertraline Hydrochloride
Clarithromycin	Levofloxacin Hydrochloride	Sildenafil Citrate
Clonidine	Levonorgestrel	Simvastatin
Clopidogrel Hydrogen Sulphate	Levothyroxine Sodium	Sodium Valproate
Clozapine	Lidocaine Hydrochloride	Spironolactone
Conjugated Estrogens	Lisinopril	Sulfamethazine
Cortisone	Lithium Carbonate	Sulindac
(-) Cotinine	Liverite	Tetracycline
Creatinine	Loperamide	Tetrahydrocortisone 3- (β-D glucuronide)
D-Pseudoephedrine	Loratadine	Tetrahydrocortsone 3 -acetate
D,L-Octopamine	Magnesium	Tetrahydrozoline
D,L-Propranolol	Meperidine	Thiamine
D,L-Tyrosine	Meprobamate	Thioridazine
Deoxy- corticosterone	Metoprolol Tartrate	Topiramate
Dextromethorphan	Mifepristone	Tramadol Hydrochloride
Diclofenac	Minocycline	Trazodone Hydrochloride
Dicyclomine	Mirtazapine	Triamterene
Diflunisal	Montelukast Sodium	Trifluoperazine
Digoxin	Mosapride Citrate	Trimethoprim
Diphenhydramine	N-Acetylprocain-amide	Uric Acid
Dirithromycin	Nalidixic Acid	Valproate
Domperidone	Naproxen	Verapamil
Doxylamine	Niacinamide	Vitamin B2
Duloxetine	Nifedipine	Vitamin C
Ecgonine Methyl Ester		

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	200	5%
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	50	100%
11-nor-Δ^8-THC-9-COOH	50	100%
11-nor-Δ^9-THC-carboxy glucuronide	100	50%
Cannabidiol	100,000	--
Cannabinol	100,000	--
Δ^8- Tetrahydrocannabinol	15,000	0.3%
Δ^9- Tetrahydrocannabinol	15,000	0.3%
11-hydroxy-Δ^9-Tetrahydrocannabinol	5,000	1%

OXY 100 (Oxycodone, Cutoff=100 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Dihydrocodeine	20,000	0.5%
Hydrocodone	80	125%

Oxymorphone	1,000	10%
Codeine	100,000	--
Hydromorphone	36,000	0.28%
Morphine	100,000	--
Acetylmorphine	100,000	--
Buprenorphine	100,000	--
Ethylmorphine	100,000	--
Thebaine	100,000	--

COC 150 (Benzoylecgonine, Cutoff=150 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Cocaine	375	40%
Cocaethylene	6,250	2.4%
Ecgonine	16,000	0.9%
Ecgonine methyl ester	100,000	--
Norcocaine	100,000	--

BAR 300 (Secobarbital, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Amobarbital	300	100%
Alphenol	600	50%
Aprobarbital	200	150%
Butabarbital	100	300%
Butethal	200	150%
Butalbital	2,000	15%
Cyclopentobarbital	400	75%
Pentobarbital	200	150%
Phenobarbital	200	150%

BZO 300 (Oxazepam, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Alprazolam	190	157.9%
a-Hydroxyalprazolam	300	100%
Bromazepam	500	60%
Chlordiazepoxide	1,500	20%
Clobazam	110	272.7%
Clonazepam	100,000	--
Clorazepate dipotassium	300	100%
Delorazepam	100,000	--

Desalkylflurazepam	200	150%
Diazepam	190	157.9%
Estazolam	5,000	6%
Flunitrazepam	400	75%
Midazolam	2,200	13.6%
Nitrazepam	200	150%
Norchlordiazepoxide	800	37.5%
Nordiazepam	150	200%
Temazepam	100	300%
Triazolam	6,000	5%
Demoxepam	2,000	15%
Flurazepam	100,000	--
D,L-Lorazepam	75,000	0.4%

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	300	100%
Codeine	300	100%
s-Monoacetylmorphine	300	100%
Ethyl Morphine	200	150%
Heroin	300	100%
Hydrocodone	700	42.9%

Hydromorphone	200	150%
Morphinie-3-β-d-glucuronide	1,000	30%
Oxycodone	100,000	--
Oxymorphone	100,000	--
Thebaine	20,000	1.5%
Levorphanol	10,000	3%
6-Monoacetylmorphine (6-MAM)	300	100%
Norcodeine	6,250	4.8%
Procaine	100,000	--

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

MDMA 500 (3,4-Methylenedioxymethamphetamine HCl, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
3,4-Methylenedioxyamphetamine HCl (MDA)	4,000	12.5%
3,4-Methylenedioxyethylamphetamine (MDE)	400	125%
d-methamphetamine	>100000	-
d-amphetamine	>100000	-
l-methamphetamine	>100000	-
l-amphetamine	>100000	-

AMP (Amphetamine) (Amphetamine, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
l-Amphetamine	>100000	-
dl- Amphetamine	1,500	33.3%
（+/-）3,4-Methylenedioxyamphetamine (MDA)	500	100%
Phentermine	6,000	8.3%
Hydroxyamphetamine	>100000	-
d-Methamphetamine	>100000	-
l-Methamphetamine	>100000	-
(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100000	-
β-Phenylethylamine	>100000	-
Tyramine	>100000	-
p-Hydroxynorephedrine	>100000	-

Phenylpropanolamine	>100000	-
(±)Phenylpropanolamine	>100000	-
p-Hydroxyamphetamine	>100000	-
d/l-Norephedrine	>100000	-
Benzphetamine	>100000	-
l-Ephedrine	>100000	-
l-Epinephrine	>100000	-
d/l-Epinephrine	>100000	-
Ephedrine	>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)	12,500	4%
D/L-Methamphetamine	500	100%
p-Hydroxymethamphetamine	15,000	3.3%
D-Amphetamine	>100000	-
L-Amphetamine	>100000	-
Chloroquine	50,000	1%
(+/-)-Ephedrine	100,000	--
(-)-Methamphetamine	65,000	0.8%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4,000	12.5%
β-Phenylethylamine	25,000	2%
Trimethobenzamide	10,000	5%
d,l-Amphetamine	>100000	-
Mephentermine	25,000	2%
(1R,2S)-(-)-Ephedrine	>100000	-
l-phenylephrine	>100000	-
L-Methamphetamine	65,000	0.8%

TCA 1000 (Nortriptyline, Cutoff=1000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Nordoxepine	1,000	100%
Trimipramine	3,000	33.3%
Amitriptyline	450	222.2%
Promazine	1,500	66.7%
Desipramine	200	500%

Imipramine	80	1250%
Clomipramine	1,200	83.3%
Doxepin	2,000	50%
Maprotiline	2,000	50%
Promethazine	>100,000	--
Cyclobenzaprine	800	125%
Norclomipramine	12,500	8%

COC 300 (Benzoylecgonine, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Cocaine	780	38.5%
Cocaethylene	12,500	2.4%
Ecgonine	32,000	0.9%
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	>100000	-
dl- Amphetamine	3,000	33.3%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1,000	100%,
Phentermine	6,000	16.7%
Hydroxyamphetamine	>100000	-
d-Methamphetamine	>100000	-
l-Methamphetamine	>100000	-
(+/-)3,4-Methylenedioxyethylamphetamine(MDE)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine(MDMA)	>100000	-
β-Phenylethylamine	>100000	-
Tyramine	>100000	-
p-Hydroxynorephedrine	>100000	-
Phenylpropanolamine	>100000	-
(±)Phenylpropanolamine	>100000	-
p-Hydroxyamphetamine	>100000	-
d/l-Norephedrine	>100000	-
Benzphetamine	>100000	-
l-Ephedrine	>100000	-
l-Epinephrine	>100000	-
d/l-Epinephrine	>100000	-

Ephedrine	>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)	25,000	4%
D/L-Methamphetamine	1,000	100%
p-Hydroxymethamphetamine	30,000	3.3%
D-Amphetamine	>100000	-
L-Amphetamine	>100000	-
Chloroquine	50,000	2%
(+/-)-Ephedrine	>100000	-
(-)-Methamphetamine	>100000	-
(+/-)3,4-Methylenedioxyamphetamine (MDA)	>100000	-
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	8,000	12.5%
β-Phenylethylamine	50,000	2%
Trimethobenzamide	20,000	5%
d,l-Amphetamine	>100000	-
Mephetermine	50,000	2%
(1R,2S)-(-)-Ephedrine	>100000	-
l-phenylephrine	>100000	-
L-Methamphetamine	>100000	-

OPI 2000 (Morphine, Cutoff=2000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Normorphine	50,000	4%
Codeine	2,000	100%
s-Monoacetylmorphine	2,000	100%
Ethyl Morphine	1,500	133.3%
Heroin	2,000	100%
Hydrocodone	12,500	16%
Hydromorphone	3,500	57.1%
Morphinie-3-β-d-glucuronide	2,000	100%
Oxycodone	25,000	8%
Oxymorphone	25,000	8%
Thebaine	50,000	4%
Levorphanol	75,000	2.7%
6-Monoacetylmorphine (6-MAM)	2,000	100%

Norcodeine	12,500	16%
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 +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.

g. Reading Time Study

Reading time studies were performed for drug free urine samples and urine samples spiked with drug concentrations of -50% cutoff, -25% cutoff, +25% cutoff and +50% cutoff. It demonstrated that test results can be read from 5 to 10 minutes.

2. Comparison Studies

The method comparison studies for BioSieve™ Multi-Drug Urine Test Panel 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 BioSieve™ Multi-Drug Urine Test Panel:

AMP 500

BioSieve™ Panel		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	10	12	16	0	0
Operator B	Positive	0	0	0	20	20
	Negative	10	12	18	0	0
Operator C	Positive	0	0	1	20	20

	Negative	10	12	17	0	0

Discordant Results for AMP 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	AMP132	385.9	+
Operator A	AMP136	499.0	+
Operator C	AMP028	477.4	+

BUP 10

BioSieve™ Panel		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	20
	Negative	10	15	14	2	0
Operator B	Positive	0	0	2	19	20
	Negative	10	15	13	1	0
Operator C	Positive	0	0	2	19	20
	Negative	10	15	13	1	0

Discordant Results for BUP 10:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	BUP010	11.3	-
Operator A	BUP029	10.2	-
Operator B	BUP029	10.2	-
Operator C	BUP029	10.2	-
Operator A	BUP070	9.9	+
Operator B	BUP052	9.5	+
Operator B	BUP070	9.9	+
Operator C	BUP058	9.8	+
Operator C	BUP070	9.9	+

BAR 300

BioSieve™ Panel		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	20
	Negative	10	16	13	3	0
Operator B	Positive	0	0	0	19	20

	Negative	10	16	14	1	0
Operator C	Positive	0	0	1	18	20
	Negative	10	16	13	2	0

Discordant Results for BAR 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	BAR017	300.9	-
Operator A	BAR011	303.8	-
Operator A	BAR033	312.2	-
Operator B	BAR017	300.9	-
Operator C	BAR017	300.9	-
Operator C	BAR011	303.8	-
Operator A	BAR054	285.0	+
Operator C	BAR054	285.0	+

BZO 300

BioSieve™ Panel		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	23
	Negative	10	15	15	0	0
Operator B	Positive	0	0	0	15	23
	Negative	10	15	15	2	0
Operator C	Positive	0	0	0	15	23
	Negative	10	15	15	2	0

Discordant Results for BZO 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator B	BZO018	303.6	-
Operator B	BZO058	307.2	-
Operator C	BZO018	303.6	-
Operator C	BZO058	307.2	-

COC 150

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

				(Between -50% and the Cutoff)	(Between the cutoff and +50%)	
Operator A	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator B	Positive	0	0	1	17	22
	Negative	10	16	13	1	0
Operator C	Positive	0	0	2	17	22
	Negative	10	16	12	1	0

Discordant Results for COC 150:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	COC046	144.8	+
Operator B	COC146	148.9	+
Operator C	COC046	144.8	+
Operator C	COC146	148.9	+
Operator B	COC128	162.8	-
Operator C	COC128	162.8	-

EDDP 300

BioSieve™ Panel		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	21
	Negative	10	15	14	2	0
Operator B	Positive	0	0	2	19	21
	Negative	10	15	13	0	0
Operator C	Positive	0	0	1	18	21
	Negative	10	15	14	1	0

Discordant Results for EDDP 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	EDDP069	288.4	+
Operator B	EDDP069	288.4	+
Operator B	EDDP075	290.6	+
Operator C	EDDP075	290.6	+
Operator A	EDDP010	318.6	-
Operator A	EDDP061	318.5	-
Operator C	EDDP010	318.6	-

MET 500

BioSieve™ Panel		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	10	15	15	2	0
Operator B	Positive	0	0	0	19	20
	Negative	10	15	15	1	0
Operator C	Positive	0	0	0	19	20
	Negative	10	15	15	1	0

Discordant Results for MET 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	MET062	519.5	-
Operator A	MET102	521.1	-
Operator B	MET102	521.1	-
Operator C	MET062	519.5	-

MDMA 500

BioSieve™ Panel		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	10	17	11	0	0
Operator B	Positive	0	0	1	20	20
	Negative	10	17	12	0	0
Operator C	Positive	0	0	2	20	20
	Negative	10	17	11	0	0

Discordant Results for MDMA 500:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	MDMA026	488.3	+
Operator A	MDMA060	492.0	+
Operator B	MDMA060	492.0	+
Operator C	MDMA026	488.3	+
Operator C	MDMA060	492.0	+

MOP 300

BioSieve™ Panel		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	14	15	1	0
Operator B	Positive	0	0	2	18	22
	Negative	10	14	14	0	0
Operator C	Positive	0	0	2	18	22
	Negative	10	14	14	0	0

Discordant Results for MOP 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	MOP057	293.2	+
Operator B	MOP150	282.8	+
Operator B	MOP057	293.2	+
Operator C	MOP057	293.2	+
Operator C	MOP150	282.8	+
Operator A	MOP114	315.6	-

MTD 300

BioSieve™ Panel		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	16	12	2	0
Operator B	Positive	0	0	1	19	20
	Negative	10	16	13	1	0
Operator C	Positive	0	0	1	20	20
	Negative	10	16	13	0	0

Discordant Results for MTD 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	MTD022	298.2	+
Operator A	MTD049	289.2	+
Operator B	MTD022	298.2	+
Operator C	MTD049	289.2	+
Operator A	MTD003	309.1	-

Operator A	MTD045	301.7	-
Operator B	MTD045	301.7	-

OXY 100

BioSieve™ Panel		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	10	14	14	0	0
Operator B	Positive	0	0	1	18	21
	Negative	10	14	15	1	0
Operator C	Positive	0	0	1	17	21
	Negative	10	14	15	2	0

Discordant Results for OXY 100:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	OXY012	96.3	+
Operator A	OXY071	95.2	+
Operator B	OXY071	95.2	+
Operator C	OXY012	96.3	+
Operator B	OXY002	101.4	-
Operator C	OXY002	101.4	-
Operator C	OXY006	111.0	-

PCP 25

BioSieve™ Panel		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	18	10	2	0
Operator B	Positive	0	0	1	21	18
	Negative	10	18	11	1	0
Operator C	Positive	0	0	2	21	18
	Negative	10	18	10	1	0

Discordant Results for PCP 25:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	PCP003	22.4	+

Operator A	PCP034	20.2	+
Operator B	PCP060	22.7	+
Operator C	PCP003	22.4	+
Operator C	PCP034	20.2	+
Operator A	PCP012	29.2	-
Operator A	PCP023	25.5	-
Operator B	PCP023	25.5	-
Operator C	PCP012	29.2	-

PPX 300

BioSieve™ Panel		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	21
	Negative	10	16	12	2	0
Operator B	Positive	0	0	1	17	21
	Negative	10	16	13	2	0
Operator C	Positive	0	0	2	18	21
	Negative	10	16	12	1	0

Discordant Results for PPX 300:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	PPX024	292.5	+
Operator A	PPX029	291.4	+
Operator B	PPX029	291.4	+
Operator C	PPX024	292.5	+
Operator C	PPX029	291.4	+
Operator A	PPX043	300.7	-
Operator A	PPX053	300.8	-
Operator B	PPX043	300.7	-
Operator B	PPX053	300.8	-
Operator C	PPX043	300.7	-

TCA 1000

BioSieve™ Panel		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	22

	Negative	10	15	14	2	0
Operator B	Positive	0	0	1	17	22
	Negative	10	15	14	1	0
Operator C	Positive	0	0	2	17	22
	Negative	10	15	13	1	0

Discordant Results for TCA 1000:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	TCA043	969.0	+
Operator B	TCA005	991.3	+
Operator C	TCA005	991.3	+
Operator C	TCA043	969.0	+
Operator A	TCA010	1015.1	-
Operator A	TCA052	1015.9	-
Operator B	TCA052	1015.9	-
Operator C	TCA010	1015.1	-

THC 50

BioSieve™ Panel		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	22
	Negative	10	16	12	2	0
Operator B	Positive	0	0	1	16	22
	Negative	10	16	13	2	0
Operator C	Positive	0	0	1	16	22
	Negative	10	16	13	2	0

Discordant Results for THC 50:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator A	THC014	47.8	+
Operator A	THC054	46.8	+
Operator B	THC054	46.8	+
Operator C	THC014	47.8	+
Operator A	THC062	50.9	-
Operator A	THC069	53.5	-
Operator B	THC069	53.5	-
Operator B	THC076	53.9	-
Operator C	THC036	50.5	-

Operator C	THC062	50.9	-

AMP 1000

BioSieve™ Panel		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	10	15	15	2	0
Operator B	Positive	0	0	0	18	21
	Negative	10	15	15	1	0
Operator C	Positive	0	0	1	18	21
	Negative	10	15	14	1	0

Discordant Results for AMP 1000:

Operator	Sample Number	LC/MS Result (ng/mL)	Result
Operator C	AMP116	998.8	+
Operator A	AMP095	1035.1	-
Operator A	AMP102	1048.4	-
Operator B	AMP102	1048.4	-
Operator C	AMP102	1048.4	-

COC 300

BioSieve™ Panel		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	23
	Negative	10	14	14	1	0
Operator B	Positive	0	0	1	15	23
	Negative	10	14	15	2	0
Operator C	Positive	0	0	2	17	23
	Negative	10	14	14	0	0

Discordant Results for COC 300:

Operator	Sample Number	LC/MS Result	Result
Operator A	COC028	296.4	+
Operator A	COC143	283.8	+
Operator B	COC028	296.4	+

Operator C	COC028	296.4	+
Operator C	COC143	283.8	+
Operator A	COC138	318.7	-
Operator B	COC033	317.7	-
Operator B	COC138	318.7	-

MET 1000

BioSieve™ Panel		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	19
	Negative	10	13	17	1	0
Operator B	Positive	0	0	0	19	19
	Negative	10	13	17	2	0
Operator C	Positive	0	0	0	20	19
	Negative	10	13	17	1	0

Discordant Results for MET 1000:

Operator	Sample Number	LC/MS Result	Result
Operator A	MET123	1049.5	-
Operator B	MET123	1049.5	-
Operator B	MET138	1068.2	-
Operator C	MET138	1068.2	-

OPI 2000

BioSieve™ Panel		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	22
	Negative	10	16	14	2	0
Operator B	Positive	0	0	1	18	22
	Negative	10	16	13	0	0
Operator C	Positive	0	0	0	17	22
	Negative	10	16	14	1	0

Discordant Results for OPI 2000:

Operator	Sample Number	LC/MS Result	Result
Operator B	MOP076	1943.3	+

Operator A	MOP089	2070.0	-
Operator A	MOP139	2105.7	-
Operator C	MOP125	2156.7	-

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. Sixty-four males and 76 females tested BioSieve™ Multi-Drug Urine Test Panel Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150); 67 male and 73 females tested BioSieve™ Multi-Drug Urine Test Panel 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 BioSieve™ Multi-Drug Urine Test Panel 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	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
BUP	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	95	100	100
BAR	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
BZO	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
COC	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

EDDP	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
MDMA	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	100	100	100
MET	**Negative**	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	95	100	100
MOP	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
MTD	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
OXY	**Negative**	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	95	100	100
PCP	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
PPX	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	100	100	100
TCA	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
THC	**Negative**	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	90	100	100

Lay-User Study Results for BioSieve™ Multi-Drug Urine Test Panel 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	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
BUP	Negative	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
BAR	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
BZO	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
COC	Negative	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	95	100	100
EDDP	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
MDMA	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
MET	Negative	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	100	100	100
OPI	Negative	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20

	Agreement (%)	100	100	100	95	100	100	100
MTD	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
OXY	**Negative**	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	95	100	100
PCP	**Negative**	20	20	20	20	1	0	0
	Positive	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	100	95	100	100
PPX	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
TCA	**Negative**	20	20	20	19	0	0	0
	Positive	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	95	100	100	100
THC	**Negative**	20	20	20	18	0	0	0
	Positive	0	0	0	2	20	20	20
	Total	20	20	20	20	20	20	20
	Agreement (%)	100	100	100	90	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.

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 BioSieve™ Multi-Drug Urine Test Panel and BioSieve™ Multi-Drug Urine Test Panel Rx are substantially equivalent to the predicate devices.