May 22, 2026

Vivachek Biotech (Hangzhou) Co., Ltd.
% Jenny Xia
Director
LSI International, Inc.
504e Diamond Ave., Suite H
Gaithersburg, Maryland 20877

Re: K261280
Trade/Device Name: BioSieve Multi-Drug Urine Test Panel;BioSieve Multi-Drug Urine Home Test Panel
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NGL , NFY , PTH , NFV , PTG , NGG , LCM , QBF , QAW , NFW
Dated: April 17, 2026
Received: April 17, 2026

Dear Jenny Xia:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

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

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

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH A. KOTAREK -S

Digitally signed by JOSEPH A. KOTAREK -S
Date: 2026.05.22 13:42:46 -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

Indications for Use

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

510(k) Number *(if known)*
k261280

Device Name
BioSieve Multi-Drug Urine Test Panel
BioSieve Multi-Drug Urine Home Test Panel

Indications for Use *(Describe)*
BioSieveTM 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, Cannabinoids, Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl 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
Marjuana (THC)	11-nor-Δ9-THC-9 COOH	50
Tramadol (TRA)	Tramadol	100
Fentanyl (FYL)	Fentanyl	1
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Norfentanyl (NFYL)	Norfentanyl	5

The single or multi-test panel can consist of up to nineteen (19) of the above listed analytes in any combination. It is for in vitro diagnostic use only.
The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Careful consideration and 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.

BioSieveTM Multi-Drug Urine Home Test Panel is competitive binding, lateral flow immunochromatographic assay 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, Marijuana, Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl in human urine at the cutoff concentrations of:

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

The single or multi-test panel can consist of up to nineteen (19) of the above listed analytes in any combination. 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. Careful consideration and 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.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K261280

1 Date May 22, 2026

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

3 Contact Person Jenny Xia
LSI International Inc.
504 East Diamond Ave., Suite H
Gaithersburg, MD 20877
Telephone: 301-525-6856
Fax: 301-916-6213
Email: jxia@lsi-consulting.org

4 Device Name BioSieve Multi-Drug Urine Test Panel
BioSieve Multi-Drug Urine Home Test Panel

5 Classification Class II

Product Code **Target Drug**	**Regulation Section**	**Panel**
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
NGL Buprenorphine (BUP) Morphine (MOP/OPI) Oxycodone (OXY) 6-Monoacetylmorphine(6-MAM) Fentanyl (FYL) Norfentanyl (NFYL) Tramadol (TRA)	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

Methadone (MTD)		
NGG Methamphetamine (MET) Methylenedioxymethamphetamine (MDMA)	862.3610, Methamphetamine 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 K233062
   BioSieve Multi-Drug Urine Test Panel and BioSieve Multi-Drug Urine Test Panel Rx

7. Intended Use
   BioSieveTM 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, Cannabinoids, Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl 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
Tramadol (TRA)	Tramadol	100
Fentanyl (FYL)	Fentanyl	1
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10
Norfentanyl (NFYL)	Norfentanyl	5

The single or multi-test panel can consist of up to nineteen (19) of the above listed analytes in any combination. It is for in vitro diagnostic use only.
The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Careful consideration and 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.

BioSieveTM Multi-Drug Urine Home Test Panel is competitive binding, lateral flow immunochromatographic assay 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, Marijuana, Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl in human urine at the cutoff concentrations of:

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

Marijuana (THC)	50 ng/mL
Tramadol (TRA)	100 ng/mL
Fentanyl (FYL)	1 ng/mL
6-Monoacetylmorphine (6-MAM)	10 ng/mL
Norfentanyl (NFYL)	5 ng/mL

The single or multi-test panel can consist of up to nineteen (19) of the above listed analytes in any combination. 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. Careful consideration and 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.

8. Device Description

The BioSieve Multi-Drug Urine Test Panel and BioSieve Multi-Drug Urine Home Test Panel 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 device is in a ready-to-use format and no longer requires assembly before use.

9. Substantial Equivalence Information

<table>
<tr><th>Item</th><th colspan="2">Proposed Device</th><th>Predicate (K233062)</th></tr>
<tr><td>Intended use</td><td colspan="2">Qualitative detection of drugs of abuse in urine.
Over-the-counter use.</td><td>Same</td></tr>
<tr><td>Methodology</td><td colspan="2">Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction</td><td>Same</td></tr>
<tr><td>Type of Test</td><td colspan="2">Qualitative</td><td>Same</td></tr>
<tr><td>Specimen Type</td><td colspan="2">Human urine</td><td>Same</td></tr>
<tr><td rowspan="6">Target Drug and Cut Off Values</td><td>Target Drug</td><td>Cutoff (ng/mL)</td><td rowspan="6">Same except no 6-Monoacetylmorphine, Fentanyl, Norfentanyl and Tramadol</td></tr>
<tr><td>Amphetamine (AMP)</td><td>1000 or 500</td></tr>
<tr><td>Buprenorphine (BUP)</td><td>10</td></tr>
<tr><td>Secobarbital (BAR)</td><td>300</td></tr>
<tr><td>Oxazepam (BZO)</td><td>300</td></tr>
</table>

	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	
	Tramadol (TRA)	100	
	Fentanyl (FYL)	1	
	6-Monoacetylmorphine (6-MAM)	10	
	Norfentanyl (NFYL)	5	
Configurations	Test Panel		Panel

10. Test Principle

BioSieve Multi-Drug Urine Test Panel and BioSieve Multi-Drug Urine Home Test Panel 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, Marijuana, Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl 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 drugs in drug-free urine samples. Each drug concentration was confirmed by LC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed two runs per day for 25 days in a randomized order. The results obtained are summarized in the following tables only for Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl. The rest data were reported in the k233062.

TRA100

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
	202.64	176.98	151.08	124.45	102.50	75.68	51.80	25.90	0
Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	49-/1+	50-/0+	50-/0+	50-/0+
Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+

FYL1

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
	1.82	1.76	1.52	1.26	0.96	0.76	0.50	0.25	0
Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	23-/27+	48-/2+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+

6-MAM10

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
	20.55	17.66	15.48	12.85	10.20	7.59	5.04	2.53	0

Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	48-/2+	50-/0+	50-/0+	50-/0+
Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	48-/2+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	23-/27+	49-/1+	50-/0+	50-/0+	50-/0+

NFYL5

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
	10.27	8.63	7.72	6.31	5.28	3.72	2.54	1.22	0
Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	27-/23+	48-/2+	50-/0+	50-/0+	50-/0+
Lot 2	0-/50+	0-/50+	0-/50+	2-/48+	27-/23+	49-/1+	50-/0+	50-/0+	50-/0+
Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	49-/1+	50-/0+	50-/0+	50-/0+

The following cutoff values are verified:

Target Drug	**Cut-off level**
Tramadol (TRA)	100 ng/mL
Fentanyl (FYL)	1 ng/mL
6-monoacetylmorphine (6-MAM)	10 ng/mL
Norfentanyl (NFYL)	5 ng/mL

b. Linearity

Not applicable

c. Stability

The devices are stable at 2-30℃ for 36 months based on accelerated stability studies at 55℃.

d. Interference

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

Compounds that show no interference at a concentration of 100μg/mL are summarized in the following table, and no interference for albumin at 100mg/dL and no interference for ethanol at 1%.

(-) Cotinine	Domperidone	Norethindrone

3-Hydroxytyramine	Dopamine HCl	Norpropoxyphene(except PPX test)
7-Aminoclonazepam(except BZO test)	Doxepine(except TCA test)	Norpseudoephedrine
7-Aminoflunitrazepam(except BZO test)	Doxylamine	Nortriptyline(except TCA test)
7-Aminonitrazepam(except BZO test)	D-Pseudoephedrine	Noscapine
Acetaminophen	Duloxetine(except TCA test)	Octopamine
Acetone (1000 mg/dL)	Ecgonine methyl ester	O-Hydroxyhippuric acid
Acetophenetidin	Effexor	Olanzapine
Acetylsalicylic acid	EMDP	Omeprazole
Acyclovir	Enalapril Maleate	Oxalic acid (100mg/dL)
Afrin	Ephedrine hydrochloride	Oxazepam (except BZO test)
Albumin(100mg/dL)	Erythromycin	Oxazepam Glucuronide(except BZO test)
Albuterol	Esomeprazole Magnesium	Oxolinic acid
Albuterol sulfate(Proair HFA)	Estradiol	Oxymetazoline
Alpha Methadol	Estrone	Ondansetran
Aminophylline	Ethanol(1%)	Paliperidone
Aminopyrine	Fenfluramine(except MET test)	Pantoprazole
Amiodarone Hydrochloride	Fenofibrate	Papaverine
Amitriptyline(except TCA test)	Fenoprofen	Paroxetine Hydrochloride
Amlodipine besylate	Fentanyl Citrate(except FYL and NFYL test)	Penfluridol
Amlodipine Mesylate	Fluoxetine Hydrochloride	Penicillin-G
Amobarbital(except BAR test)	Fluphenazine	PenicillinV Potassium
Amoxicillin	Fluvoxamine	Perphenazine
Ampicillin	Fotemustine	Phenacetin
Apomorphine	Furosemide	Phencyclidine(except PCP test)
Aripiprazole	Gabapentin	Phenelzine
Ascorbic acid	Galactose	Phenylethylamine(except MET test)
Aspartame	Gatifloxacin	Phenobarbital(except BAR test)
Aspirin	Gemfibrozil	Phentermine(except AMP test)
Atomoxetine	Gentisic acid	Phenylpropanolamine
Atorvastatin Calcium	Glibenclamide	Pioglitazone Hydrochloride
Atropine	Gliclazide	Piracetam
Azithromycin	Glipizide	Pravastatin Sodium
Baclofen	Glucose(3000 mg/dL)	Prednisone
Benzilic acid	Guaiacolglyceryl ether	Pregablin
Benzocaine	Haloperidol	Procaine

Benzoic acid	Hemoglobin	Promazine(except TCA test)
Benzoylecogonine(except COC test)	Hexobarbital	Promethazine
Benzphetamine	Hydralazine	Propoxyphene(except PPX test)
Benzylpiperiazine	Hydrochlorothiazide	Propranolol
Bilirubin	Hydrocortisone	Propylthiouracil
Boric Acid (1%)	Hydroxybutyric Acid	Pseudoephedrine
Bromo-2,5,Dimethoxyphenethylamine	Ibuprofen	Pyridoxine
Bupropion	Imipramine(except TCA test)	Pyrilamine
Caffeine	Isoproterenol	Pyrogallol
Cannabidiol	Isosorbide Dinitrate	Quetiapine
Captopril	Isoxsuprine	Quetiapine Fumarate
Carbamazepine	Ketamine	Quinidine
Carfentanil(except FYLand NFYL test)	Ketoconazole	Quinine
Carisoprodol	Ketoprofen	Quinolinic Acid
Cefradine	Kratom powder	Ranitidine
Cephalexin	LAAM HCl	Riboflavin
Cetirizine	Labetalol	Rifampicin
Chloral hydrate	Lamotrigine	Risperidone(except NFYL test)
Chloramphenicol	L-Ephedrine	Salicylic acid
Chlordiazepoxide(except BZO test)	L-Epinephrine	Secobarbital(except BAR test)
Chloroquine	Levofloxacin Hydrochloride	Serotonin
Chlorothiazide	Levonorgestrel	Serotonin (5- Hydroxytyramine)
Chlorpheniramine(except TCA test)	Levothyroxine Sodium	Sertraline
Chlorpromazine	Lidocaine Hydrochloride	Sertraline Hydrochloride
Cholesterol	Lisinopril	Sildenafil Citrate
Ciprofloxacin Hydrochloride	Lithium Carbonate	Simvastatin
Citalopram	Liverite	Sodium Azide
Clarithromycin	Loperamide	Sodium Valproate
Clofibrate	Loratidine	Spironolactone
Clomipramine(except TCA test)	Lorazepam Glucuronide(except BZO test)	Sulfamethazine
Clonidine	L-phenylephrine	Sulindac
Clopidogrel Hydrogen Sulphate	LSD	Telmisartan
Clozapine	L-thyroxine	Tetracycline
Conjugated Estrogens	Magnesium	Tetrahydrocortisone 3-(β-Dglucuronide)
Cortisone	Maprotiline	Tetrahydrocortisone, 3-acetate

Creatine Hydrate	Meperidine	Tetrahydrozoline
Creatinine	Meprobamate	THC (except THC test)
Cyclobenzaprine(except TCA test)	Metformin	Theophylline
Cyproheptadine	Methapyrilene	Thiamine
D,L-Epinephrine	Methaqualone	Thioridazine
D,L-Isoproterenol	Methoxyphenamine (except MET test)	Topiramate
D,L-Lorazepam (except BZO test)	Methylphenidate	Tramadol Hydrochloride
D,L-Octopamine	Metoprolol Tartrate	Trazodone Hydrochloride
D,L-Propranolol	Metronidazole	Triamterene
D,L-Tryptophan	Mifepristone	Trifluoperazine
D,L-Tyrosine	Mirtazapine	Trifluoromethylphenyl-piperazine
Delorazepam	Montelukast Sodium	Trimethobenzamide
Demoxepam(except BZO test)	Mosapride Citrate	Trimethoprim
Deoxycorticosterone	Minocycline	Tryptamine
Desloratadine	N-Acetylprocainamide	Tyramine (except AMP test)
Desipramine(except TCA, PPX test)	Nacl (4000 mg/dL)	Urea (2000 mg/dL)
Dextromethorphan	Nalidixic acid	Uric acid
Diclofenac	Naloxone hydrochloride(except OXY test)	Valproic acid (250 μg/mL)
Diclofenac sodium	Naltrexone hydrochloride(except OXY test)	Venlafaxine HCl
Dicyclomine	Naproxen	Verapamil
Diflunisal	N-desmethyl Tapentadol	Vitamin B2
Digoxin	Niacinamide	Vitamin C
Dimethyl-aminoantipyrine	Nicotine	Zaleplon
Diphenhydramine	Nicotinic Acid	Zolpidem
Diphenhydramine HCl	Nifedipine	Zomepirac
Diphenylhydantoin	Nikethamide	β-Estradiol
Dirithromycin	Nimodipine	γ-Cyclodextrin
Disopyramide	Nitroglycerin	γ-Globulin (500mg/dL)

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 was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100. The results obtained are summarized in the following tables only for Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl. The rest data were reported in the k233062.

Tramadol (Cutoff=100ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Tramadol	100	100%
n-Desmethyl Tramadol	200	50%
o-Desmethyl Tramadol	1,000	10%
o-Desmethyl Venlafaxine	>100,000	--
Venlafaxine HCl	>100,000	--
Rac N, O-didesmethyltramadol	15,000	0.67%
O-desmethyl tramadol beta-D-glucoronide	90	111.11%
Ketamine	>100,000	--
Dehydronorketamine	10,000	1%
Norketamine	20,000	0.50%
Phencyclidine (PCP)	>100,000	--

6-monoacetylmorphine (Cutoff=10ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
6-Monoacetylmorphine (6-MAM)	10	100%
Heroin	40	25%
Morphine	>100,000	--
Normorphine	>100,000	--
Nalorphine hydrochloride	>100,000	--
Hydrocodone	>100,000	--
Hydromorphone	>100,000	--
Chlordiazepoxide	>100,000	--
Clobazam	>100,000	--
D-Amphetamine	>100,000	--
(±)-Amphetamine	>100,000	--
Levorphanol tartrate	>100,000	--
Codeine	>100,000	--
Ethylmorphine	>100,000	--
Morphine3-β-D-glucuronide	>100,000	--
Norcodeine	>100,000	--
Oxycodone	>100,000	--
Oxymorphone	>100,000	--
Procaine hydrochloride	>100,000	--
Thebaine	>100,000	--
6-Acetylcodeine	>100,000	--
Buprenorphine	>100,000	--
Dihydrocodeine	>100,000	--
Dextromethorphan	>100,000	--
Imipramine hydrochloride	>100,000	--
Meperidine	>100,000	--

(±)-Methadone	>100,000	--
Mitragynine(kratom)	>100,000	--
Morphine-6-β-D-glucuronide	>100,000	--
Naloxone hydrochloride	>100,000	--
Naltrexone hydrochloride	>100,000	--
Naproxen	>100,000	--
Norbuprenorphine	>100,000	--
Norbuprenorphine-3-D-Glucuronide	>100,000	--
Noroxycodone hydrochloride	>100,000	--
Noroxymorphone hydrochloride	>100,000	--
Norpropoxyphene	>100,000	--
Oxymorphone-3β-D-glucuronide	>100,000	--
Tapentadol hydrochloride	>100,000	--
Tramadol hydrochloride	>100,000	--
Acetylcodeine	>100,000	--
Levacetylmethadol (LAAM)	>100,000	--
Noroxycodone HCL	>100,000	--

Fentanyl (Cutoff=1ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±) β-hydroxythiofentanyl	10	10%
(±)-3-cis-methyl fentanyl	4	25%
4-Fluoro-isobutyrylfentanyl	3	33.33%
Acetyl fentanyl	1	100%
Acryl fentanyl	2	50%
Butyryl fentanyl	2	50%
Fentanyl	1	100%
Furanyl fentanyl	2	50%
Isobutyryl fentanyl	2	50%
Ocfentanil	1	100%
Para-fluoro fentanyl	2	50%
Para-fluorobutyryl fentanyl	4	25%
Valeryl fentanyl	5	20%
ω-1-Hydroxyfentanyl	20,000	--
Acetyl norfentanyl	>100,000	--
Alfentanil	>100,000	--
Norcarfentanil	>100,000	--
Norfentanyl	>100,000	--
Remifentanil	1,500	0.07%
Risperidone	>100,000	--
Sufentanil	50	2%
Carfentanil	5	20%
Despropionyl fentanyl (4-ANPP)	300	0.33%

Isotonitaze	>100,000	--
AH-7921 HCL	>100,000	--
9-HydroxyRisperidone	15,000	0.007%
Thienyl Fentnayl	150	0.66%
Trans-d, I 3-Methylfentanyl	150	0.66%
MT-45	>100,000	--
Labetalol Hydrochloride	>100,000	--
U-47700	>100,000	--

Norfentanyl (Cutoff=5ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(±)-β-Hydroxythiofentanyl	100	5%
4-Fluoro-isobutyryl Fentanyl	1,000	0.50%
9-HydroxyRisperidone	10,000	0.05%
Acetyl Fentanyl	200	2.50%
Acetyl Norfentanyl	200	2.50%
Acryl Fentanyl	200	2.50%
Alfentanil	>10,000	--
Butyryl Fentanyl	200	2.50%
(±)-3-cis-methyl fentanyl	1,000	0.50%
Fentanyl	80	6.25%
Furanyl Fentanyl	1,000	0.50%
Isobutyryl Fentanyl	1,000	0.50%
Labetalol Hydrochloride	>100,000	--
MT-45	8,000	--
Norfentanyl	5	100%
Ocfentanil	2,000	0.25%
Para-fluorobutyryl fentanyl	1,000	0.50%
Para-fluoro fentanyl	300	1.67%
Risperidone	37,500	0.01%
Thienyl Fentnayl	100	5%
Valeryl Fentanyl	1,000	0.50%
ω- 1-Hydroxyfentanyl	>50,000	--
trans-d, l-3-methylfentanyl	200	2.50%
Carfentanil	>10,000	--
Despropionyl fentanyl (4-ANPP)	>20,000	--
Norcarfentanil	>10,000	--
Remifentanil	>10,000	--
Sufentanil	3,000	0.17%
Trazodone	>10,000	--
U-47700	>100,000	--
Cis-d, I 3-Methylfentanyl	70	7.14%

Negative fentanyl and norfentanyl results were obtained for all opioids compounds tested at 100 µg/mL. There is no cross-reactivity with fentanyl and norfentanyl for these compounds.

6-Acetyl morphine	Methadone	Tapentadol
Amphetamine	Morphine	Tilidine
Buprenorphine	Morphine-3-glucuronide	Tramadol
Buprenorphineglucuronide	Norbuprenorphine	Tramadol-O-Desmethyl
Codeine	Norcodeine	Tramadol-N-Desmethyl
Dihydrocodeine	Norketamine	Dextromethorphan
EDDP	Normeperidine	Ketamine
EMDP	Normorphine	Meperidine
Fluoxetine	Noroxycodone	Naloxone
Heroin	Oxycodone	Naltrexone
Hydrocodone	Oxymorphone	Thioridazine
Hydromorphone	Pentazocine (Talwin)	
Levorphanol	Pipamperone	

f. Effect of Urine Specific Gravity and Urine pH

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

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

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 only for Tramadol, Fentanyl, 6-Monoacetylmorphine and Norfentanyl. The rest data were reported in the k233062.

TRA 100

BioSieve Panel		Drug-Free	Low Negative by	Near Cutoff Negative by LC/MS	Near Cutoff Positive by LC/MS	High Positive by LC/MS

			LC/MS (less than -50%)	(Between -50% and the Cutoff)	(Between the cutoff and +50%)	(greater than +50%)
Operator A	Positive	0	0	1	18	21
	Negative	10	15	14	1	0
Operator B	Positive	0	0	1	19	21
	Negative	10	15	14	0	0
Operator C	Positive	0	0	1	19	21
	Negative	10	15	14	0	0

Discordant Results for TRA 100:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve Result
Operator A	VCTC054	97.45	+
Operator A	VCTC119	101.37	-
Operator B	VCTC079	96.18	+
Operator C	VCTC008	95.69	+

FYL 1

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	18	10	2	0
Operator B	Positive	0	0	1	19	20
	Negative	10	18	11	1	0
Operator C	Positive	0	0	1	19	20
	Negative	10	18	11	1	0

Discordant Results for FYL 1:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve Result
Operator A	VCFC010	0.934	+
Operator A, B	VCFC059	0.985	+
Operator A	VCFC057	1.063	-
Operator A, B, C	VCFC066	1.084	-
Operator C	VCFC048	0.946	+

6-MAM 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	0	20	20
	Negative	10	16	14	0	0
Operator B	Positive	0	0	1	19	20
	Negative	10	16	13	1	0
Operator C	Positive	0	0	0	19	20
	Negative	10	16	14	1	0

Discordant Results for 6-MAM 10:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve Result
Operator B	VCMC088	7.89	+
Operator B	VCMC132	10.08	-
Operator C	VCMC033	10.65	-

NFYL 5

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	19	20
	Negative	10	17	12	1	0
Operator B	Positive	0	0	1	18	20
	Negative	10	17	12	2	0
Operator C	Positive	0	0	0	19	20
	Negative	10	17	13	1	0

Discordant Results for NFYL 5:

Operator	Sample Number	LC/MS Result (ng/mL)	BioSieve Result
Operator A, B	VCNC013	4.49	+
Operator A, B, C	VCNC036	5.03	-
Operator B	VCNC057	5.34	-

Lay-user study:

A lay user study was performed at three sites representative of intended use sites using urine samples prepared at the following concentrations: -100%, +/-75%, +/-50%, and +/-25% of the

cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. A total of 280 participants with diverse educational and professional backgrounds aged 20 years and older were recruited from these three sites. A total of 132 males and 148 females tested BioSieve Multi-Drug Urine Test Panel. 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):

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	500	Negative	20	20	20	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
BUP	10	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	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
		Agreement (%)	100	100	100	95	100	100	100
BZO	300	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	150	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
EDDP	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
		Agreement (%)	100	100	100	95	100	100	100
MDMA	500	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
MET	500	Negative	20	20	20	19	1	0	0

		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
MOP	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
		Agreement (%)	100	100	100	95	100	100	100
MTD	300	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	100	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
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
		Agreement (%)	100	100	100	100	100	100	100
PPX	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
TCA	1000	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	90	95	100	100
THC	50	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
TRA	100	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	90	100	100
FYL	1	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
6-MAM	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	90	95	100	100
NFYL	5	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

Lay-User Study Results for BioSieve Multi-Drug Urine Test Panel Configuration 2 (AMP 1000, MET 1000, MOP 2000 (OPI), COC 300):

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	1000	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
BUP	10	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	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
		Agreement (%)	100	100	100	100	100	100	100
BZO	300	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	300	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
EDDP	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
		Agreement (%)	100	100	100	95	100	100	100
MDMA	500	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	1000	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
OPI	2000	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
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
		Agreement (%)	100	100	100	95	95	100	100
OXY	100	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
PCP	25	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	90	95	100	100
PPX	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	95	100	100
TCA	1000	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
THC	50	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	90	95	100	100
TRA	100	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	90	95	100	100
FYL	1	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
6-MAM	10	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100	100	100	95	90	100	100
NFYL	5	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

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 8.

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 BioSieve Multi-Drug Urine Test Panel and BioSieve Multi-Drug Urine Home Test Panel are substantially equivalent to the predicate device.