



November 9, 2018

Shenzhen Bioeasy Biotechnology Co., Ltd.
% Joe Shia, Director
LSI International
504E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: k182530

Trade/Device Name: BIOEASY Multi-Drug Test Cup
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NFW, NFY, NGG, NGI, NFV, NGL, PTH, NGM, PTG, QAW, QBF
Dated: September 9, 2018
Received: September 14, 2018

Dear Joe Shia:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k182530

Device Name
BIOEASY Multi-Drug Test Cup

Indications for Use (Describe)

BIOEASY Multi-Drug Test Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug(Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the BIOEASY Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.
For in vitro diagnostic use only.

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

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K182530
510(k) SUMMARY

1. Date: November 9, 2018
2. Submitter: Shenzhen Bioeasy Biotechnology Co., Ltd.
No.2-1, Liuxian 1st Road
Baoan District
Shenzhen, China 518101
3. Contact person: Joe Shia
LSI International Inc.
504 East Diamond Ave.
Gaithersburg, MD 20877
Telephone: 240-505-7880
Email: shiajl@yahoo.com
4. Device Name: BIOEASY Multi-Drug Test Cup

Classification: Class 2

Product Code	Classification	Regulation Section	Panel
NFT Amphetamine	II	21 CFR § 862.3100, Amphetamine Test System	Toxicology (91)
NFW Cannabinoids	II	21 CFR § 862.3870, Cannabinoids Test System	Toxicology (91)
NFY Cocaine	II	21 CFR § 862.3250, Cocaine and Cocaine Metabolites Test System	Toxicology (91)
NGG Methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGI Morphine	II	21 CFR § 862.3640, Morphine Test System	Toxicology (91)
NFV Oxazepam	II	21 CFR § 862.3170, Benzodiazepine Test System	Toxicology (91)
NGL Oxycodone	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
PTH Secobarbital	II	21 CFR § 862.3150, Barbiturate Test System	Toxicology (91)
NGL Buprenorphine	II	21 CFR § 862.3650, Opiate Test System	Toxicology (91)
NGG Methylenedioxy- methamphetamine	II	21 CFR § 862.3610, Methamphetamine Test System	Toxicology (91)
NGM Phencyclidine	unclassified	Enzyme Immunoassay Phencyclidine	Toxicology (91)
PTG Methadone	II	21 CFR § 862.3620, Methadone Test System	Toxicology (91)
QAW Nortriptyline	II	21 CFR, 862.3910 Tricyclic Antidepressant Drugs Test System	Toxicology (91)
QBF Propoxyphene	II	21 CFR, 862.3700 Propoxyphene Test System	Toxicology (91)

5. Predicate Devices: K153050

The CO-INNOVATION BIOTECH Rapid Multi-Drug Test Dip Card and Rapid Multi-Drug Test Cup

6. Indications for Use

BIOEASY Multi-Drug Test Cup Tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and d-Propoxyphene in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine	1000 ng/mL
Oxazepam	300 ng/mL
Cocaine	300 ng/mL
Marijuana	50 ng/mL
Methamphetamine	1000 ng/mL
Morphine	300 ng/mL
Oxycodone	100 ng/mL
Secobarbital	300 ng/mL
Buprenorphine	10 ng/mL
Methylenedioxy-methamphetamine	500 ng/mL
Phencyclidine	25 ng/mL
Methadone	300 ng/mL
Nortriptyline	1000 ng/mL
d-Propoxyphene	300 ng/mL

Configuration of the BIOEASY Multi-Drug Test Cup tests can consist of any combination of the above listed drug analytes.

The test 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 exercised with any drug of abuse test result, particularly when the preliminary result is positive. The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

For in vitro diagnostic use only.

7. Device Description

The BIOEASY Multi-Drug Test Cup tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene (target analytes) in human urine. The products are single-use in vitro diagnostic devices. Each test kit contains a Test Device, a package insert and a urine cup for sample collection. Each test device is sealed with a desiccant in an aluminum pouch

8. Substantial Equivalence Information

A summary comparison of features of the BIOEASY Multi-Drug Test Cup tests and the predicate devices is provided in following table.

Table 1: Features Comparison of BIOEASY Multi-Drug Test Cup tests and the Predicate Devices

Item	Device	Predicate - K153050
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same (but the number of drugs detected is different)
Calibrator and Cut-Off Values	Amphetamine (AMP): 1,000 ng/ml Oxazepam (BZO):300 ng/ml Cocaine(COC): 300 ng/ml Marijuana (THC):50 ng/ml Methamphetamine (MET): 1,000 ng/ml Morphine (MOR): 300ng/ml Oxycodone(OXY) : 100 ng/ml Secobarbital (BAR): 300 ng/ml Buprenorphine (BUP): 10 ng/ml Methylenedioxy-methamphetamine(MDMA): 500 ng/ml Phencyclidine (PCP): 25 ng/ml Methadone (MTD): 300 ng/ml Nortriptyline (TCA): 1000 ng/ml Propoxyphene (PPX): 300 ng/ml	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Intended Use	For over-the-counter	Same
Configurations	Cup	Same

9. Test Principle

The BIOEASY Multi-Drug Test Cup tests are rapid tests for the qualitative detection of Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine, Oxycodone, Secobarbital, Buprenorphine, Methylenedioxy-methamphetamine, Phencyclidine, Methadone, Nortriptyline and Propoxyphene in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. A band should form in the control region of the devices

regardless of the presence of drug or metabolite in the sample to indicate that the tests have been performed properly.

10. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off, +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative 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 per device in a randomized order. The results obtained are summarized in the following tables.

Amphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Secobarbital

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Buprenorphine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Methylenedioxy-methamphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Methamphetamine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Methadone

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	27-/23+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	29-/21+	50+/0-	50+/0-	50+/0-	50+/0-

Oxycodone

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Phencyclidine

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Propoxyphene

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-

Nortriptyline

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	21-/29+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Marijuana

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	28-/22+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

c. Stability

The devices are stable at 4-30 °C for 24 months based on the accelerated stability study at 45 °C. Real time stability determinations are ongoing at both 4 °C and 30 °C.

d. Interference

Potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested using three batches of each device. Compounds that showed no interference at a concentration of 100µg/mL (albumin was tested at 100 mg/dL) are summarized in the following tables.

Acetaminophen	β-Estradiol	Oxalic acid
Acetophenetidin	Erythromycin	Oxolinic acid
N-Acetylprocainamide	Ethanol	Oxymetazoline
Acetylsalicylic acid	Fenoprofen	Papaverine
Albumin (100 mg/dL)	Furosemide	Penicillin G
Aminopyrine	Gentisic acid	Perphenazine
Amoxicillin	Hemoglobin	Phenelzine
Ampicillin	Hydralazine	Prednisone
Apomorphine	Hydrochlorothiazide	(±)-Propranolol
Ascorbic acid	Hydrocortisone	Pseudoephedrine
Aspartame	O-Hydroxyhippuric acid	Quinine
Atropine	3-Hydroxytyramine	Ranitidine
Benzilic acid	Ibuprofen	Salicylic acid
Benzoic acid	Isoproterenol	Serotonin (5- Hydroxytyramine)
Bilirubin	Isoxsuprine	Sulfamethazine
Chloral hydrate	Ketamine	Sulindac
Chloramphenicol	Ketoprofen	Tetrahydrocortisone 3-(β-Dglucuronide)
Chlorothiazide	Labetalol	Tetrahydrocortisone 3-acetate
Chlorpromazine	Loperamide	Tetrahydrozoline
Cholesterol	Meperidine	Thiamine
Clonidine	Meprobamate	Thioridazine
Cortisone	Methoxyphenamine	Triamterene
(-)-Cotinine	Nalidixic acid	Trifluoperazine
Creatinine	Naloxone	Trimethoprim
Deoxycorticosterone	Naltrexone	DL-Tryptophan
Dextromethorphan	Naproxen	Tyramine
Diclofenac	Niacinamide	DL-Tyrosine

Diffenhydramine	Nifedipine	Uric acid
Digoxin	Norethindrone	Verapamil
Diphenhydramine	Noscapine	Zomepirac
Ecgonine methyl ester	(±)-Octopamine	

e. Specificity

To test specificity, drug metabolites and other components that are likely to interfere in urine samples were tested using three batches of each device. The lowest concentration that caused a positive result for each compound are listed below.

AMP(Amphetamine) (D - Amphetamine, Cut-off=1000 ng/mL)	Result	%Cross-Reactivity
D - Amphetamine	Positive at <u>1000</u> ng/mL	100%
L - Amphetamine	Positive at <u>20000</u> ng/mL	5%
DL - Amphetamine	Positive at <u>3000</u> ng/mL	33%
Phentermine	Positive at <u>30000</u> ng/mL	3.3%
Hydroxyamphetamine	Positive at <u>8000</u> ng/mL	12.5%
Methylenedioxyamphetamine (MDA)	Positive at <u>20000</u> ng/mL	5%
d-Methamphetamine	Positive > <u>100000</u> ng/mL	<1%
1-Methamphetamine	Positive > <u>100000</u> ng/mL	<1%
Ephedrine	Positive > <u>100000</u> ng/mL	<1%
Methylenedioxyethylamphetamine (MDE)	Positive > <u>100000</u> ng/mL	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Positive > <u>100000</u> ng/mL	<1%

BAR(Barbital) (Secobarbital, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Secobarbital	Positive at <u>300</u> ng/mL	100%
Amobarbital	Positive at <u>1000</u> ng/mL	30%
Alphenal	Positive at <u>62.5</u> ng/mL	480%
Aprobarbital	Positive at <u>250</u> ng/mL	120%
Butabarbital	Positive at <u>100</u> ng/mL	300%
Butethal	Positive at <u>500</u> ng/mL	60%
Butalbital	Positive at <u>5000</u> ng/mL	6%
Cyclopentobarbital	Positive at <u>500</u> ng/mL	60%
Pentobarbital	Positive at <u>200</u> ng/mL	150%
Phenobarbital	Positive at <u>300</u> ng/mL	100%

BUP(Buprenorphine) (Buprenorphine, Cut-off=10 ng/mL)	Result	%Cross-Reactivity
Buprenorphine	Positive at <u>10</u> ng/mL	100%
Buprenorphine -3-D-Glucuronide	Positive at <u>10</u> ng/mL	100%
Norbuprenorphine	Positive at <u>50</u> ng/mL	20%
Norbuprenorphine-3-D-Glucuronide	Positive at <u>10</u> ng/mL	10%
Morphine	Positive > <u>100000</u> ng/mL	<0.01%
Oxymorphone	Positive > <u>100000</u> ng/mL	<0.01%
Hydromorphone	Positive > <u>100000</u> ng/mL	<0.01%

BZO(Benzodiazepines)	Result	%Cross-Reactivity
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(Oxazepam, Cut-off=300 ng/mL)		
Oxazepam	Positive at <u>300</u> ng/mL	100%
Alprazolam	Positive at <u>150</u> ng/mL	200%
a-Hydroxyalprazolam	Positive at <u>1000</u> ng/mL	30%
Bromazepam	Positive at <u>1000</u> ng/mL	30%
Chlordiazepoxide	Positive at <u>63</u> ng/mL	476.2%
Clonazepam	Positive at <u>2500</u> ng/mL	12%
Clobazam	Positive at <u>75</u> ng/mL	400%
Clorazepate dipotassium	Positive at <u>100</u> ng/mL	300%
Desalkylflurazepam	Positive at <u>500</u> ng/mL	60%
Diazepam	Positive at <u>500</u> ng/mL	60%
Estazolam	Positive at <u>500</u> ng/mL	60%
Flunitrazepam	Positive > <u>50000</u> ng/mL	<0.6%
D,L-Lorazepam	Positive at <u>10000</u> ng/mL	3%
Midazolam	Positive at <u>10000</u> ng/mL	3%
Nitrazepam	Positive at <u>75</u> ng/mL	400%
Norchlordiazepoxide	Positive at <u>62.5</u> ng/mL	480%
Nordiazepam	Positive at <u>125</u> ng/mL	240%
Temazepam	Positive at <u>75</u> ng/mL	400%
Triazolam	Positive at <u>1000</u> ng/mL	33%

COC(Cocaine) (Benzoylecgonine, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Benzoylecgonine	Positive at <u>300</u> ng/mL	100%
Cocaine HCl	Positive at <u>750</u> ng/mL	40%
Cocaethylene	Positive at <u>12500</u> ng/mL	2.4%
Ecgonine	Positive at <u>32000</u> ng/mL	0.9%
Norcocaine	Positive at <u>100000</u> ng/mL	0.3%

MDMA(Methylenedioxymethamphetamine) (Methylenedioxymethamphetamine, Cut-off=500 ng/mL)	Result	%Cross-Reactivity
Methylenedioxymethamphetamine (MDMA)	Positive at <u>500</u> ng/mL	100%
3,4-Methylenedioxyamphetamine (MDA)	Positive at <u>5000</u> ng/mL	10%
3,4-Methylenedioxyethylamphetamine (MDEA)	Positive at <u>300</u> ng/mL	166.7%
d-methamphetamine	Positive > <u>50000</u> ng/mL	<1%
d-amphetamine	Positive > <u>50000</u> ng/mL	<1%
l-amphetamine	Positive > <u>50000</u> ng/mL	<1%
l-methamphetamine	Positive > <u>50000</u> ng/mL	<1%

MET(Methamphetamine) (D(+)-Methamphetamine, Cut-off=1000 ng/mL)	Result	%Cross-Reactivity
D(+)-Methamphetamine	Positive at <u>1000</u> ng/mL	100%
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	Positive at <u>10000</u> ng/mL	10%
D/L-Methamphetamine	Positive at <u>1000</u> ng/mL	100%
p-Hydroxymethamphetamine	Positive at <u>10000</u> ng/mL	10%

D-Amphetamine	Positive > <u>100000</u> ng/mL	<1%
L-Amphetamine	Positive > <u>100000</u> ng/mL	<1%
Chloroquine	Positive at <u>50000</u> ng/mL	2%
(+/-)-Ephedrine	Positive at <u>4000</u> ng/mL	25%
L-Methamphetamine	Positive at <u>10000</u> ng/mL	10%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	Positive > <u>100000</u> ng/mL	<1%
β-Phenylethylamine	Positive at <u>7500</u> ng/mL	13.3%
Trimethobenzamide	Positive at <u>20000</u> ng/mL	5%
(+/-)3,4-methylenedioxymethamphetamine(MDMA)	Positive at <u>10000</u> ng/mL	10%

MOP(Morphine) (Morphine, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Morphine	Positive at <u>300</u> ng/mL	100%
Codeine	Positive at <u>300</u> ng/mL	100%
Ethylmorphine	Positive at <u>310</u> ng/mL	96.8%
Hydrocodone	Positive at <u>25000</u> ng/mL	1.2%
Hydromorphone	Positive <u>10000</u> ng/mL	3%
Levorphanol	Positive > <u>100000</u> ng/mL	<0.3%
6-Acetylmorphine	Positive at <u>250</u> ng/mL	120%
Morphine-3- β -D-glucuronide	Positive at <u>10000</u> ng/mL	3%
Normorphine	Positive at <u>100000</u> ng/mL	0.3%
Oxycodone	Positive > <u>10000</u> ng/mL	<3%
Oxymorphone	Positive > <u>10000</u> ng/mL	<3%
Procaine	Positive > <u>10000</u> ng/mL	3%
Thebaine	Positive > <u>10000</u> ng/mL	<3%
Heroin	Positive at <u>500</u> ng/mL	60%

MTD(Methadone) (Methadone, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Methadone	Positive at <u>300</u> ng/mL	100%
Doxylamine	Positive at <u>5000</u> ng/mL	6%
LAAM	Positive at <u>10000</u> ng/mL	3%
Alpha Methadol	Positive at <u>2000</u> ng/mL	15%
EDDP	Positive > <u>100000</u> ng/mL	<0.3%
EMDP	Positive > <u>100000</u> ng/mL	<0.3%

OXY(Oxycodone) (Oxycodone, Cut-off=300 ng/mL)	Result	%Cross-Reactivity
Oxycodone	Positive at <u>100</u> ng/mL	100%
Dihydrocodeine	Positive > <u>100000</u> ng/mL	<0.1%
Codeine	Positive > <u>100000</u> ng/mL	<0.1%
Hydromorphone	Positive > <u>100000</u> ng/mL	<0.1%
Morphine	Positive > <u>100000</u> ng/mL	<0.1%
Buprenorphine	Positive > <u>100000</u> ng/mL	<0.1%
Ethylmorphine	Positive > <u>100000</u> ng/mL	<0.1%
Oxymorphone	Positive at <u>250</u> ng/mL	40%

Hydrocodone	Positive at <u>3125</u> ng/mL	3.2%
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PCP(Phencyclidine) (Phencyclidine, Cut-off=25 ng/mL)	Result	%Cross-Reactivity
Phencyclidine	Positive at <u>25</u> ng/mL	100%
4-Hydroxyphencyclidine	Positive at <u>75</u> ng/mL	33.3%

PPX(Propoxyphene) (d-Propoxyphene, Cut-off=300ng/mL)	Result	%Cross-Reactivity
d-Propoxyphene	Positive at <u>300</u> ng/mL	100%
D-Norpropoxyphene	Positive at <u>333</u> ng/mL	90.1%

TCA(Nortriptyline) (Nortriptyline, Cut-off=1000 ng/mL)	Result	%Cross-Reactivity
Nortriptyline	Positive at <u>1000</u> ng/mL	100%
Amitriptyline	Positive at <u>750</u> ng/mL	133.3%
Clomipramine	Positive at <u>10000</u> ng/mL	10%
Desipramine	Positive at <u>200</u> ng/mL	500%
Doxepin	Positive at <u>1250</u> ng/mL	80%
Imipramine	Positive at <u>625</u> ng/mL	160%
Maprotiline	Positive at <u>2000</u> ng/mL	50%
Nordoxepin	Positive at <u>1000</u> ng/mL	100%
Promazine	Positive at <u>1500</u> ng/mL	66.7%
Promethazine	Positive at <u>25000</u> ng/mL	4%
Trimipramine	Positive at <u>3000</u> ng/mL	33.3%
Cyclobenzaprine	Positive at <u>5000</u> ng/mL	20%
Norclomipramine	Positive at <u>3000</u> ng/mL	33.3%

THC(Cannabinoids) (11-nor-Δ9-THC-9-COOH, Cut-off = 50 ng/mL)	Result	% Cross-Reactivity
11-nor-Δ9-THC-9-COOH	Positive at <u>50</u> ng/mL	100%
11-Hydroxy-Δ9-Tetrahydrocannabinol	Positive at <u>50</u> ng/mL	100%
11-Nor-Δ8-Tetrahydrocannabinol-9-COOH	Positive at <u>50</u> ng/mL	100%
Cannabinol	Positive at <u>20000</u> ng/mL	0.25%
Δ8-Tetrahydrocannabinol	Positive at <u>15000</u> ng/mL	0.33%
Δ9-Tetrahydrocannabinol	Positive at <u>15000</u> ng/mL	0.33%
Cannabidiol	Positive > <u>100000</u> ng/mL	<0.05%
11-Nor-Δ9-THC-carboxy glucuronide	Positive at <u>75</u> ng/mL	66.7%
(-)-11-nor-9-carboxy-Δ 9-THC	Positive at <u>50</u> ng/mL	100%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.000 to 1.035 specific gravity or urine samples with pH 4 to 9 were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for different devices.

2. Comparison Studies

Method comparison studies for the BIOEASY Multi-Drug Test Cup tests were performed in-house with three laboratory assistants for each device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to LC/MS results. The results are presented in the tables below.

Amphetamine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	19
	Negative	5	16	17	2	0
Viewer B	Positive	0	0	4	20	19
	Negative	5	16	15	1	0
Viewer C	Positive	0	0	3	19	19
	Negative	5	16	16	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	AMPC439	981	Positive
Viewer A	AMPC449	768	Positive
Viewer B	AMPC439	981	Positive
Viewer B	AMPC449	768	Positive
Viewer B	AMPC412	976	Positive
Viewer B	AMPC387	981	Positive
Viewer C	AMPC412	976	Positive
Viewer C	AMPC493	961	Positive
Viewer C	AMPC387	981	Positive
Viewer A	AMPC341	1010	Negative
Viewer A	AMPC482	1010	Negative
Viewer B	AMPC482	1010	Negative
Viewer C	AMPC341	1010	Negative
Viewer C	AMPC352	1120	Negative

Secobarbital

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	17	22
	Negative	6	15	17	1	0
Viewer B	Positive	0	0	2	16	22
	Negative	6	15	17	2	0
Viewer	Positive	0	0	1	17	22

C	Negative	6	15	18	1	0
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Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BARC477	291	Positive
Viewer A	BARC375	265	Positive
Viewer B	BARC477	291	Positive
Viewer B	BARC375	265	Positive
Viewer C	BARC364	269	Positive
Viewer A	BARC384	312	Negative
Viewer B	BARC384	312	Negative
Viewer B	BARC414	315	Negative
Viewer C	BARC414	315	Negative

Buprenorphine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	20	18
	Negative	5	18	16	2	0
Viewer B	Positive	0	0	0	20	18
	Negative	5	18	17	2	0
Viewer C	Positive	0	0	2	21	18
	Negative	5	18	15	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BUPC379	9.67	Positive
Viewer C	BUPC359	8.94	Positive
Viewer C	BUPC379	9.67	Positive
Viewer A	BUPC322	10.1	Negative
Viewer A	BUPC429	11.2	Negative
Viewer B	BUPC322	10.1	Negative
Viewer B	BUPC348	10.2	Negative
Viewer C	BUPC348	10.2	Negative

Oxazepam

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)

Viewer A	Positive	0	0	2	20	18
	Negative	5	15	18	2	0
Viewer B	Positive	0	0	1	21	18
	Negative	5	15	19	1	0
Viewer C	Positive	0	0	2	21	18
	Negative	5	15	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	BZOC343	298	Positive
Viewer A	BZOC322	296	Positive
Viewer B	BZOC322	296	Positive
Viewer C	BZOC343	298	Positive
Viewer C	BZOC435	292	Positive
Viewer A	BZOC301	314	Negative
Viewer A	BZOC348	312	Negative
Viewer B	BZOC348	312	Negative
Viewer C	BZOC301	314	Negative

Cocaine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	21	19
	Negative	6	17	15	0	0
Viewer B	Positive	0	0	2	20	19
	Negative	6	17	15	1	0
Viewer C	Positive	0	0	1	20	19
	Negative	6	17	14	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	COCC368	298	Positive
Viewer A	COCC340	294	Positive
Viewer B	COCC368	298	Positive
Viewer B	COCC315	282	Positive
Viewer C	COCC340	294	Positive
Viewer B	COCC317	301	Negative
Viewer C	COCC317	301	Negative

Methylenedioxymethamphetamine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	19	20
	Negative	5	16	18	1	0
Viewer B	Positive	0	0	2	19	20
	Negative	5	16	17	1	0
Viewer C	Positive	0	0	2	19	20
	Negative	5	16	17	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MDMAC310	490	Positive
Viewer B	MDMAC306	497.5	Positive
Viewer B	MDMAC365	484.5	Positive
Viewer C	MDMAC310	490	Positive
Viewer C	MDMAC306	497.5	Positive
Viewer A	MDMAC316	505	Negative
Viewer B	MDMAC316	505	Negative
Viewer C	MDMAC484	565	Negative

Methamphetamine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	20	18
	Negative	5	16	17	2	0
Viewer B	Positive	0	0	1	21	18
	Negative	5	16	18	1	0
Viewer C	Positive	0	0	1	21	18
	Negative	5	16	18	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	METC498	921	Positive
Viewer A	METC479	984	Positive
Viewer B	METC467	973	Positive
Viewer C	METC479	984	Positive
Viewer A	METC343	1020	Negative
Viewer A	METC473	1110	Negative
Viewer B	METC473	1110	Negative

Viewer C	METC343	1020	Negative
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Morphine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	18	21
	Negative	5	16	17	1	0
Viewer B	Positive	0	0	2	18	21
	Negative	5	16	17	1	0
Viewer C	Positive	0	0	2	17	21
	Negative	5	16	17	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MOPC355	287	Positive
Viewer A	MOPC429	298	Positive
Viewer B	MOPC408	286	Positive
Viewer B	MOPC429	298	Positive
Viewer C	MOPC408	286	Positive
Viewer C	MOPC433	276	Positive
Viewer A	MOPC393	301	Negative
Viewer B	MOPC416	339	Negative
Viewer C	MOPC416	339	Negative
Viewer C	MOPC393	301	Negative

Methadone

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	21	18
	Negative	5	15	18	1	0
Viewer B	Positive	0	0	2	20	18
	Negative	5	15	18	2	0
Viewer C	Positive	0	0	3	22	18
	Negative	5	15	17	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	MTDC314	289	Positive
Viewer A	MTDC389	299	Positive

Viewer B	MTDC314	289	Positive
Viewer B	MTDC408	290	Positive
Viewer C	MTDC389	299	Positive
Viewer C	MTDC373	279	Positive
Viewer C	MTDC408	290	Positive
Viewer A	MTDC447	309	Negative
Viewer B	MTDC447	309	Negative
Viewer B	MTDC427	336	Negative

Oxycodone

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	4	18	22
	Negative	6	15	15	0	0
Viewer B	Positive	0	0	3	18	22
	Negative	6	15	16	0	0
Viewer C	Positive	0	0	3	18	22
	Negative	6	15	16	0	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	OXYC467	97.5	Positive
Viewer A	OXYC369	94.6	Positive
Viewer A	OXYC334	98.4	Positive
Viewer A	OXYC470	95.1	Positive
Viewer B	OXYC467	97.5	Positive
Viewer B	OXYC310	96.1	Positive
Viewer B	OXYC470	95.1	Positive
Viewer C	OXYC310	96.1	Positive
Viewer C	OXYC369	94.6	Positive
Viewer C	OXYC334	98.4	Positive

Phencyclidine

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	3	18	18	2	0
Viewer B	Positive	0	0	2	20	20
	Negative	3	18	17	0	0

Viewer C	Positive	0	0	2	19	20
	Negative	3	18	17	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	PCPC441	24.8	Positive
Viewer B	PCPC411	24.7	Positive
Viewer B	PCPC441	24.8	Positive
Viewer C	PCPC462	24.7	Positive
Viewer C	PCPC411	24.7	Positive
Viewer A	PCPC477	25.3	Negative
Viewer A	PCPC368	27.8	Negative
Viewer C	PCPC477	25.3	Negative

Propoxyphene

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	18	20
	Negative	5	15	19	2	0
Viewer B	Positive	0	0	2	19	20
	Negative	5	15	18	1	0
Viewer C	Positive	0	0	1	19	20
	Negative	5	15	19	1	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	PPXC472	286	Positive
Viewer B	PPXC472	286	Positive
Viewer B	PPXC320	278	Positive
Viewer C	PPXC320	278	Positive
Viewer A	PPXC493	318	Negative
Viewer A	PPXC382	306	Negative
Viewer B	PPXC382	306	Negative
Viewer C	PPXC493	318	Negative

Nortriptyline

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer	Positive	0	0	2	20	19

A	Negative	5	15	18	1	0
Viewer B	Positive	0	0	2	18	19
	Negative	5	15	18	3	0
Viewer C	Positive	0	0	2	19	19
	Negative	5	15	18	2	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	TCAC319	979	Positive
Viewer A	TCAC470	944	Positive
Viewer B	TCAC319	979	Positive
Viewer B	TCAC346	958	Positive
Viewer C	TCAC346	958	Positive
Viewer C	TCAC470	944	Positive
Viewer A	TCAC479	1190	Negative
Viewer B	TCAC398	1050	Negative
Viewer B	TCAC331	1180	Negative
Viewer B	TCAC479	1190	Negative
Viewer C	TCAC398	1050	Negative
Viewer C	TCAC331	1180	Negative

Marijuana

		Negative	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	19	18
	Negative	6	14	18	3	0
Viewer B	Positive	0	0	2	20	18
	Negative	6	14	18	2	0
Viewer C	Positive	0	0	2	19	18
	Negative	6	14	18	3	0

Discordant Results

Viewer	Sample Number	LC/MS Result	BIOEASY Cup Viewer Results
Viewer A	THCC402	46	Positive
Viewer A	THCC368	48.8	Positive
Viewer B	THCC363	46.95	Positive
Viewer B	THCC402	46	Positive
Viewer C	THCC363	46.95	Positive
Viewer C	THCC368	48.8	Positive
Viewer A	THCC478	55.5	Negative
Viewer A	THCC493	50.5	Negative
Viewer A	THCC496	57.5	Negative
Viewer B	THCC478	55.5	Negative

Viewer B	THCC318	56	Negative
Viewer C	THCC493	50.5	Negative
Viewer C	THCC318	56	Negative
Viewer C	THCC496	57.5	Negative

Lay-user study

A lay user study was performed at three intended user sites with 300 lay persons for the device. The lay users had diverse educational and professional backgrounds and ranged in age from 18 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Each device was tested. Summary results are shown below.

The results summary for AMP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS (ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	261	0	20	100
-50% Cutoff	160	507	0	160	100
-25% Cutoff	20	771	1	19	95
+25% Cutoff	20	1290	19	1	95
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1870	20	0	100

The results summary for BAR:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	75.9	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	220	1	19	95
+25% Cutoff	20	360	19	1	95
+50% Cutoff	40	429	40	0	100
+75% Cutoff	20	501	20	0	100

The results summary for COC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	81.5	0	20	100
-50% Cutoff	160	151	0	160	100
-25% Cutoff	20	225	1	19	95
+25% Cutoff	20	395	19	1	95
+50% Cutoff	40	455	40	0	100

+75% Cutoff	20	520	20	0	100
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The results summary for BUP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	2.57	0	20	100
-50% Cutoff	160	5.14	0	160	100
-25% Cutoff	20	6.76	1	19	95
+25% Cutoff	20	12.8	19	1	95
+50% Cutoff	40	15.1	40	0	100
+75% Cutoff	20	17.2	20	0	100

The results summary for MET:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	268	0	20	100
-50% Cutoff	160	526	0	160	100
-25% Cutoff	20	769	1	19	95
+25% Cutoff	20	1270	19	1	95
+50% Cutoff	40	1560	40	0	100
+75% Cutoff	20	1780	20	0	100

The results summary for MTD:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	76.8	0	20	100
-50% Cutoff	160	147	0	160	100
-25% Cutoff	20	226	1	19	95
+25% Cutoff	20	375	19	1	95
+50% Cutoff	40	441	40	0	100
+75% Cutoff	20	504	20	0	100

The results summary for MOP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	79	0	20	100
-50% Cutoff	160	158	0	160	100
-25% Cutoff	20	246	1	19	95
+25% Cutoff	20	389	20	0	100
+50% Cutoff	40	469	40	0	100

+75% Cutoff	20	530	20	0	100
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The results summary for OXY:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	24.5	0	20	100
-50% Cutoff	160	49.3	0	160	100
-25% Cutoff	20	71.1	1	19	95
+25% Cutoff	20	118	19	1	95
+50% Cutoff	40	147	40	0	100
+75% Cutoff	20	169	20	0	100

The results summary for PCP:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	6.27	0	20	100
-50% Cutoff	160	12.5	0	160	100
-25% Cutoff	20	17.9	1	19	95
+25% Cutoff	20	30.8	19	1	95
+50% Cutoff	40	36.4	40	0	100
+75% Cutoff	20	42.8	20	0	100

The results summary for THC:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	13	0	20	100
-50% Cutoff	160	25.3	0	160	100
-25% Cutoff	20	41	1	19	95
+25% Cutoff	20	65	19	1	95
+50% Cutoff	40	79	40	0	100
+75% Cutoff	20	93	20	0	100

The results summary for BZO:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	70.8	0	20	100
-50% Cutoff	160	148	0	160	100
-25% Cutoff	20	224	1	19	95
+25% Cutoff	20	390	19	1	95
+50% Cutoff	40	452	40	0	100
+75% Cutoff	20	504	20	0	100

The results summary for MDMA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	137	0	20	100
-50% Cutoff	160	250	0	160	100
-25% Cutoff	20	351	1	19	95
+25% Cutoff	20	600	19	1	95
+50% Cutoff	40	745	40	0	100
+75% Cutoff	20	925	20	0	100

The results summary for TCA:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	273	0	20	100
-50% Cutoff	160	509	0	160	100
-25% Cutoff	20	809	1	19	95
+25% Cutoff	20	1190	18	2	90
+50% Cutoff	40	1510	40	0	100
+75% Cutoff	20	1680	20	0	100

The results summary for PPX:

% of Cutoff	Number of samples	Drug Concentration by LC/MS/MS(ng/mL)	Lay person Results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	77.4	0	20	100
-50% Cutoff	160	150	0	160	100
-25% Cutoff	20	227	1	19	95
+25% Cutoff	20	351	19	1	95
+50% Cutoff	40	420	40	0	100
+75% Cutoff	20	492	20	0	100

Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

3. Clinical Studies

Not applicable.

11. Conclusion

Based on the test principle and acceptable performance characteristics including precision, cut-off, interference, specificity, method comparison, and lay-user studies of the device, it's concluded that the BIOEASY Multi-Drug Test Cup tests are substantially equivalent to the predicate.