December 14, 2018

SHANGHAI VENTURE BIO-TECH CO., LTD.
% Ethan Liu, RA Specialist
Shanghai Thinkwell Consulting Co., Ltd.
Floor 6, No.211, Xin Ling Road, Minhang District
Shanghai, 201100
China

Re: k180879
Trade/Device Name: BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use
BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use
BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use
BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, JXM, NFT, DIO, NFY, NFV, DJC, NGG, DNK, NGI, LDJ, NFW
Dated: October 30, 2018
Received: November 5, 2018

Dear Ethan Liu:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k180879

Device Name
BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use

Indications for Use *(Describe)*
BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use is a rapid lateral flow immunoassay for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrators	Cut-off Level
Amphetamine (AMP)	d-Amphetamine	1000ng/ml
Oxazepam	Oxazepam	300ng/ml
Cocaine (COC)	Benzoylecgonine	300ng/ml
Methamphetamine (MET)	d-Methamphetamine	1000ng/ml
Morphine(MOP)	Morphine	300ng/ml
Marijuana (THC)	Delta-9-THC-COOH	50ng/ml

Easy cup test and Split Key Cup test may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 6 analytes.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. The test is intended for over the counter use.

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k180879

Device Name
BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use

Indications for Use *(Describe)*
BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use is a rapid lateral flow immunoassay for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrators	Cut-off Level
Amphetamine (AMP)	d-Amphetamine	1000ng/ml
Oxazepam	Oxazepam	300ng/ml
Cocaine (COC)	Benzoylecgonine	300ng/ml
Methamphetamine (MET)	d-Methamphetamine	1000ng/ml
Morphine(MOP)	Morphine	300ng/ml
Marijuana (THC)	Delta-9-THC-COOH	50ng/ml

Easy cup test and split key cup test may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 6 analytes.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. The test is intended for prescription use.

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

K180879

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

5.1 Submitter

Submitted by:	SHANGHAI VENTURE BIO-TECH Co., Ltd.
	Room 313, Building 2, No. 2715 Longwu Road, Xuhui District, Shanghai, China.
Contact Person:	Ethan Liu
	Phone:0086-15216699240
	Fax: 0086-21-60732022
	Email:xtdeepwater@126.com
Date Prepared:	Dec 14, 2018

5.2 Device

5.2.1 Trade name

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use

5.2.2 Classification

Product Code	CFR #	Panel

DKZ, NFT	21 CFR, 862.3100 Amphetamine Test System	Toxicology
JXM, NFV	21 CFR, 862.3170 Benzodiazepine Test System	Toxicology
DIO, NFY	21 CFR, 862.3250 Cocaine and cocaine metabolite test system.	Toxicology
DJC, NGG	21 CFR, 862.3610 Methamphetamine Test System	Toxicology
LDJ, NFW	21 CFR, 862.3870 Cannabinoid Test System	Toxicology
DNK, NGI	21 CFR, 862.3640 Morphine test system	Toxicology

5.3 Predicate Device

k173303

INSTANT-VIEW plus Multi-Drug of Abuse Urine Test - Simple Cup (OTC Use)

INSTANT-VIEW plus Multi-Drug Urine Test - Simple Cup (Prescription Use)

5.4 Device Description

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use is immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and 11-Nor-∆9-Tetrahydrocannabinol-9-COOH (target analytes) in human urine. The tests are the first step in a two-step process. The second step is to send the sample for laboratory testing if preliminary positive results are obtained.

5.5 Indication for Use

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use is a rapid lateral flow immunoassay for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrators	Cut-off Level
Amphetamine (AMP)	d-Amphetamine	1000ng/ml
Oxazepam	Oxazepam	300ng/ml
Cocaine (COC)	Benzoylecgonine	300ng/ml
Methamphetamine (MET)	d-Methamphetamine	1000ng/ml
Morphine(MOP)	Morphine	300ng/ml
Marijuana(THC)	Delta-9-THC-COOH	50ng/ml

Easy cup test and Split key cup test may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 6 analytes.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method.
Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. The test is intended for over the counter use.

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use is a rapid lateral flow immunoassay for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Test	Calibrators	Cut-off Level
Amphetamine (AMP)	d-Amphetamine	1000ng/ml

Oxazepam	Oxazepam	300ng/ml
Cocaine (COC)	Benzoylecgonine	300ng/ml
Methamphetamine (MET)	d-Methamphetamine	1000ng/ml
Morphine(MOP)	Morphine	300ng/ml
Marijuana(THC)	Delta-9-THC-COOH	50ng/ml

Easy cup test and Split key cup test may be configured as single drug tests or multiple drug tests in any combination of the drug analytes listed in the table above up to a maximum of 6 analytes.
The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry is the preferred confirmatory method.
Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
For in vitro diagnostic use only. The test is intended for prescription use.

5.6 Substantial Equivalence

A summary comparison of features of the BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use and the predicate devices is provided in following tables.

Table 1: Features comparison of Amphetamine Tests and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	d-Amphetamine	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
Cut-off Values	1000ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

Table 2: Features comparison of Cocaine Tests and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	Cocaine	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
Cut-off Values	300ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

Table 3: Features comparison of Oxazepam Test Kits and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	Oxazepam	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
Cut-off Values	300ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

Table 4: Features comparison of Methamphetamine Tests and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	d-Methamphetamine	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
Cut-off Values	1000ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

Table 5: Features comparison of Morphine Tests and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	Morphine	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
Cut-off Values	300ng/mL	2000 ng/mL
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

Table 6: Features comparison of Marijuana Tests and the Predicate Devices.

Item	Device	Predicate Device-K173303
Indication(s) for Use	For the qualitative determination of drugs of abuse in human urine.	Same
Calibrator	11-Nor-Δ9-Tetrahydrocannabinol-9-COOH	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
Cut-off Values	50ng/mL	Same
Intended Use	For over-the-counter and prescription uses.	Same
Configurations	Easy Cup and Split Key Cup	Cassette, Easy Cup, Split Key Cup and Dip Card

5.7 Test Principle

BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use are rapid tests for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylecgonine, d-Methamphetamine, Morphine and 11-Nor-Δ9-Tetrahydrocannabinol-9-COOH 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.

5.8 Performance Characteristics

5.8.1 Analytical Performance

a. Precision

Precision studies were carried out for samples with concentrations of -100% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off and +100% cut off, These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. Each concentration has three lots, and 6 operators have joined the performance. Each operator performs 9 samples for 25 days per device in a randomized order. The results obtained are summarized in the following tables.

AMP Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-
C11100065	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

11100062	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

COC Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
C11100065	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
11100062	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

C11100065	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-
11100062	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

MET Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
C11100065	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

11100062	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

MOP Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
C11100065	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
11100062	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	50+/0-	50+/0-	50+/0-	50+/0-

THC Assay

Split Key Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
C11100064	50-/0+	50-/0+	50-/0+	50-/0+	36-/14+	50+/0-	50+/0-	50+/0-	50+/0-

C11100065	50-/0+	50-/0+	50-/0+	50-/0+	38-/12+	50+/0-	50+/0-	50+/0-	50+/0-
C11100066	50-/0+	50-/0+	50-/0+	50-/0+	35-/15+	50+/0-	50+/0-	50+/0-	50+/0-

Easy Cup

Batch Number	-100% cut off	-75% cut off	-50% cut off	-25% cut off	Cut off	25% cut off	50% Cut off	75% cut off	100% cut off
11100061	50-/0+	50-/0+	50-/0+	50-/0+	36-/14+	50+/0-	50+/0-	50+/0-	50+/0-
11100062	50-/0+	50-/0+	50-/0+	50-/0+	38-/12+	50+/0-	50+/0-	50+/0-	50+/0-
11100063	50-/0+	50-/0+	50-/0+	50-/0+	35-/15+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable

c. Stability

The devices are stable at 2-30 °C for 24 months based on the real time stability at room temperature.

d. Cut-off

A total of 375 samples equally distributed at concentrations of -50% Cut-Off; -25% Cut-Off; Cut-Off; +25% Cut-Off; +50% Cut-Off were tested using three different lots of each device by three different operators. Results were all positive at and above +25% Cut-off and all negative at and below -25% Cut-off for Amphetamine, Cocaine, Oxazepam, Methamphetamine, Morphine and Marijuana.

The following cut-off values for the candidate devices have been verified.

Calibrator	Cut-off(ng/mL)
d-Amphetamine	1000

Cocaine	300
Oxazepam	300
d-Methamphetamine	1000
Morphine	300
(-)-11-Nor-Δ9-Tetrahydrocannabinol-9-COOH	50

e. 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 and Ethanol at 1% are summarized in the following tables.

AMP Assay

Methadone	Naltrexone	Naloxone	Morphine
Gatifloxacin	Procaine	Amitriptyline	Chlorpheniramine Maleate
Promethazine	Amoxicillin	Methoxyphenamine	Ketamine Hydrochloride
Ranitidine	Tramadol	Buprenorphine	Phenobarbital
Nifedipine	Diazepam	Dextromethorphan	Cocaine
Theophylline	Aspirin	Acetaminophen	Δ^9-THC
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine
Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Benzoylecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Cholesterol	Hydrocortisone	Oxycodone
Ethanol			

Oxazepam Assay

Methadone	Naltrexone	Naloxone	Morphine
Ephedrine	Pseudo Ephedrine	Gatifloxacin	Procaine
Amitriptyline	Chlorpheniramine Maleate	Promethazine	Amoxicillin
Methoxyphenamine	Ketamine Hydrochloride	Ranitidine	Tramadol
Buprenorphine	Phenobarbital	Nifedipine	Methamphetamine
Dextromethorphan	Cocaine	Theophylline	Aspirin
Acetaminophen	Δ^9-THC	Hydrocortisone	Oxycodone
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine
Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Benzoylecgonine	Secobarbital	Angiotensin	Adrenaline
MDMA	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Cholesterol	Amphetamine	Ethanol

COC Assay

Methadone	Naltrexone	Naloxone	Morphine
Ephedrine	Pseudo Ephedrine	Gatifloxacin	Procaine
Amitriptyline	Chlorpheniramine Maleate	Promethazine	Amoxicillin
Methoxyphenamine	Ketamine Hydrochloride	Ranitidine	Tramadol
Buprenorphine	Phenobarbital	Nifedipine	Methamphetamine
Dextromethorphan	Diazepam	Theophylline	Aspirin
Acetaminophen	Δ^9-THC	Hydrocortisone	Oxycodone
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine

Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Secobarbital	Angiotensin	Adrenaline	Oxalic Acid
Oxazepam	Uric Acid	Triglyceride	Prednisolone acetate
Cholesterol	MDMA	Amphetamine	Ethanol

MET Assay

Methadone	Naltrexone	Naloxone	Morphine
Ephedrine	Pseudo Ephedrine	Gatifloxacin	Procaine
Amitriptyline	Chlorpheniramine Maleate	Promethazine	Amoxicillin
Methoxyphenamine	Ketamine Hydrochloride	Ranitidine	Tramadol
Buprenorphine	Phenobarbital	Nifedipine	Diazepam
Dextromethorphan	Cocaine	Theophylline	Aspirin
Acetaminophen	Δ^9-THC	Hydrocortisone	Oxycodone
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine
Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Benzoylecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Cholesterol	Ethanol	

MOP Assay

Methadone	Naltrexone	Naloxone	Cocaine
Ephedrine	Pseudo Ephedrine	Gatifloxacin	Procaine
Amitriptyline	Chlorpheniramine Maleate	Promethazine	Amoxicillin
Methoxyphenamine	Ketamine	Ranitidine	Tramadol

	Hydrochloride		
Buprenorphine	Phenobarbital	Nifedipine	Methamphetamine
Dextromethorphan	Diazepam	Theophylline	Aspirin
Acetaminophen	Δ^9-THC	Cholesterol	Hydrocortisone
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine
Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Benzoylecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Amphetamine	MDMA	Ethanol

THC Assay

Methadone	Naltrexone	Naloxone	Morphine
Ephedrine	Pseudo Ephedrine	Gatifloxacin	Procaine
Amitriptyline	Chlorpheniramine Maleate	Promethazine	Amoxicillin
Methoxyphenamine	Ketamine Hydrochloride	Ranitidine	Tramadol
Buprenorphine	Phenobarbital	Nifedipine	Methamphetamine
Dextromethorphan	Diazepam	Theophylline	Aspirin
Acetaminophen	Cocaine	Amphetamine	MDMA
Ascorbic Acid	Hemoglobin	Bilirubin	Ibuprofen
Dolantin	Hydroxyketone	EDDP	Phencyclidine
Propoxyphene	Aminopyrine	Cotinine	Fentanyl
Benzoylecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Cholesterol	Hydrocortisone	Oxycodone
Ethanol			

f. 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 is listed below. There were no differences observed for different devices.

AMP Assay

Drugs	Concentration(ng/mL)	%Cross Reactivity
D-Amphetamine	1000	100%
D/L- Amphetamine	1500	66.7%
Phentermine	3000	33.3%
L-Amphetamine	3000	33.3%
Hydroxyamphetamine	10000	10%
Methylenedioxyamphetamine(MDA)	10000	10%
3,4-methylenedioxy-methamphetamine(MDMA)	>100,000	＜1%
Methylenedioxyethylamphetamine(MDE)	>100,000	＜1%
Ephedrine	>100,000	＜1%
Pseudophedrine	>100,000	＜1%
D-Methamphetamine	>100,000	＜1%
L-Methamphetamine	>100,000	＜1%
D/L-Methamphetamine	>100,000	＜1%

COC Assay

Drugs	Concentration(ng/mL)	%Cross Reactivity
Cocaine HCl	5000	6%
Norcocaine	25000	1.2%
Ecgonine HCl	50000	0.6%

Cocaethylene	>100000	＜0.3%
Benzoylecgonine	300	100%

Oxazepam Assay

Drugs	Concentration(ng/mL)	%Cross Reactivity
Oxazepam	300	100%
Diazepam	1000	30%
Alprazolam	1000	30%
α-Hydroxyalprazolam	5000	6%
Bromazepam	10000	3%
Chlordiazepoxide	10000	3%
Clobazam	500	60%
Clonazepam	3000	10%
Delorazepam	5000	6%
Estazolam	10000	3%
Flunitrazepam	5000	6%
Midazolam	50000	0.6%
Nitrazepam	500	60%
Nordiazepam	5000	6%
Temazepam	500	60%
Triazolam	10000	3%
Lorazepam	25000	1.2%
Clorazepate Dipotassium	> 100000	＜0.3%
Desalkylflurazepam	>100000	＜0.3%
Norchlordiazepoxide	> 100000	＜0.3%

MET Assay

Drugs	Concentration(ng/mL)	%Cross Reactivity
(±)3,4-methylenedioxy-n-ethylamphetamine(MDEA)	5000	20%
D-Methamphetamine	1000	100%
L-Methamphetamine	10000	10%
D/L- Methamphetamine	3000	33.3%
p-Hydroxymethamphetamine	50000	2%
(±)3,4-Methylenedioxyamphetamine(MDA)	20000	5%
(±)3,4-Methylenedioxymethamphetamine(MDMA)	3000	33.3%
D/L-Amphetamine	>100,000	＜1%
D- Amphetamine	>100,000	＜1%
L-Amphetamine	>100,000	＜1%

MOP Assay

Drugs	Concentration	%Cross Reactivity
Acetylmorphine	6000	5%
Hydromorphone	3000	10%
Hydrocodone	50000	0.6%
Levorphanol	1500	20%

Oxycodone	50000	0.6%
Dimethylmorphine	3000	10%
Morphine-3- Glucuronide	>100,000	＜0.3%
Morphine	300	100%
Codeine	300	100%
Heroin	300	100%
O6- Monoacetylmorphine	300	100%
Ethylmorphine	> 100000	＜0.3%

THC Assay

Drugs	Concentration	%Cross Reactivity
(-)-11-Nor-Δ9-Tetrahydrocannabinol-9-COOH	50	100%
11-Hydroxy-Δ9-Tetrahydrocannabinol	10000	0.5%
11- Nor-Δ8-Tetrahydrocannabinol-9-COOH	2500	2%
Cannabinol	5000	1%
11-Nor-Δ9-THC-carboxy glucuronide	5000	1%
(-)-11-nor-9-carboxy-Δ9-THC	10000	0.5%
Δ8- Tetrahydrocannabinol	>50000	＜0.1%
Δ9- Tetrahydrocannabinol	>50000	＜0.1%
Cannabidiol	>50000	＜0.1%

g. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity and urine pH, urine samples, with 1.002 to 1.036 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.

5.8.2. Comparison Study

Method comparison studies for BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use were performed in-house with three laboratory assistants for each device. Operators ran unaltered clinical samples, 87 samples for amphetamine, 80 samples for cocaine, 80 samples for Oxazepam, 81 samples for Methamphetamine, 81 samples for Morphine, 82 samples for Marijuana. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Amphetamine

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	19	16	11	1	0
	Positive	0	0	0	13	27
Operator 2	Negative	19	16	10	1	0
	Positive	0	0	1	13	27
Operator 3	Negative	19	16	10	0	0
	Positive	0	0	1	14	27

Discordant Results of Amphetamine Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	989	Negative
2	989	Positive
3	989	Positive
1	1035	Positive

2	1035	Negative
3	1035	Positive
1	1062	Negative
2	1062	Positive
3	1062	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	19	16	11	1	0
	Positive	0	0	0	13	27
Operator 2	Negative	19	16	10	1	0
	Positive	0	0	1	13	27
Operator 3	Negative	19	16	10	0	0
	Positive	0	0	1	14	27

Discordant Results of Amphetamine Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	989	Negative
2	989	Positive
3	989	Positive
1	1035	Positive
2	1035	Negative
3	1035	Positive
1	1062	Negative
2	1062	Positive
3	1062	Positive

Cocaine

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off

Operator 1	Negative	18	13	11	2	0
	Positive	0	0	0	15	21
Operator 2	Negative	18	13	11	1	0
	Positive	0	0	0	16	21
Operator 3	Negative	18	13	10	0	0
	Positive	0	0	1	17	21

Discordant Results of Cocaine Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	285	Negative
2	285	Negative
3	285	Positive
1	313	Negative
2	313	Negative
3	313	Positive
1	321	Negative
2	321	Positive
3	321	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	18	13	11	1	0
	Positive	0	0	0	16	21
Operator 2	Negative	18	13	11	1	0
	Positive	0	0	0	16	21
Operator 3	Negative	18	13	10	0	0
	Positive	0	0	1	17	21

Discordant Results of Cocaine Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	285	Negative
2	285	Negative
3	285	Positive
1	313	Negative
2	313	Negative
3	313	Positive
1	321	Negative
2	321	Positive
3	321	Positive

Oxazepam

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	15	10	15	1	0
	Positive	0	0	0	19	20
Operator 2	Negative	15	10	15	0	0
	Positive	0	0	0	20	20
Operator 3	Negative	15	10	14	0	0
	Positive	0	0	1	20	20

Discordant Results of Oxazepam Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	333	Negative
2	333	Positive
3	333	Positive

1	298	Negative
2	298	Negative
3	298	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	15	10	15	1	0
	Positive	0	0	0	19	20
Operator 2	Negative	15	10	15	0	0
	Positive	0	0	0	20	20
Operator 3	Negative	15	10	15	0	0
	Positive	0	0	0	20	20

Discordant Results of Oxazepam Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	333	Negative
2	333	Positive
3	333	Positive

Methamphetamine

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	17	16	8	0	0
	Positive	0	0	0	11	29
Operator 2	Negative	17	16	8	1	0
	Positive	0	0	0	10	29
Operator 3	Negative	17	16	7	0	0
	Positive	0	0	1	11	29

Discordant Results of Methamphetamine Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	1025	Positive
2	1025	Negative
3	1025	Positive
1	984	Negative
2	984	Negative
3	984	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	17	16	8	0	0
	Positive	0	0	0	11	29
Operator 2	Negative	17	16	8	1	0
	Positive	0	0	0	10	29
Operator 3	Negative	17	16	7	0	0
	Positive	0	0	1	11	29

Discordant Results of Methamphetamine Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	1025	Positive
2	1025	Negative
3	1025	Positive
1	984	Negative
2	984	Negative
3	984	Positive

Morphine

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	19	9	13	0	0
	Positive	0	0	0	15	25
Operator 2	Negative	19	9	13	2	0
	Positive	0	0	0	13	25
Operator 3	Negative	19	9	12	0	0
	Positive	0	0	1	15	25

Discordant Results of Morphine Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	323	Positive
2	323	Negative
3	323	Positive
1	335	Positive
2	335	Negative
3	335	Positive
1	293	Positive
2	293	Negative
3	293	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	19	9	12	0	0
	Positive	0	0	1	15	25
Operator 2	Negative	19	9	13	1	0
	Positive	0	0	0	14	25
Operator 3	Negative	19	9	12	0	0
	Positive	0	0	1	15	25

Discordant Results of Morphine Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	323	Positive
2	323	Negative
3	323	Positive
1	293	Positive
2	293	Negative
3	293	Positive

Marijuana

Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	18	11	13	3	0
	Positive	0	0	0	13	24
Operator 2	Negative	18	11	13	2	0
	Positive	0	0	0	14	24
Operator 3	Negative	18	11	13	0	0
	Positive	0	0	0	16	24

Discordant Results of Marijuana Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	61	Negative
2	61	Negative
3	61	Positive
1	61	Negative
2	61	Positive
3	61	Positive
1	59	Negative

2	59	Negative
3	59	Positive

Split Key Cup	Results	Negative Urine	<-50% cut off	-50% cut off-cut off	Cut off-+50% cut off	>+50% cut off
Operator 1	Negative	18	11	13	3	0
	Positive	0	0	0	13	24
Operator 2	Negative	18	11	13	1	0
	Positive	0	0	0	15	24
Operator 3	Negative	18	11	13	0	0
	Positive	0	0	0	16	24

Discordant Results of Marijuana Split Key Cup

Operator	GC/MS Result(ng/mL)	Candidate Device Result
1	61	Negative
2	61	Negative
3	61	Positive
1	61	Negative
2	61	Positive
3	61	Positive
1	59	Negative
2	59	Positive
3	59	Positive

Lay-user study

A lay user study was performed at three intended user sites for BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use separately. The lay

users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/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.

Comparison between GC/MS and Lay Person Results for Amphetamine Cup Format

% of cut off	Number of samples	d-Amphetamine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results (%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	248	0	20	100%
-50% cut off	20	492	0	20	100%
-25% cut off	20	741	2	18	90%
+25% cut off	20	1262	20	0	100%
+50% cut off	20	1506	20	0	100%
+75% cut off	20	1744	20	0	100%

Comparison between GC/MS and Lay Person Results for Amphetamine Split Key Cup Format

% of cut off	Number of samples	d-Amphetamine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results (%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	248	0	20	100%
-50% cut off	20	492	0	20	100%
-25% cut off	20	741	2	18	90%

+25% cut off	20	1262	20	0	100%
+50% cut off	20	1506	20	0	100%
+75% cut off	20	1744	20	0	100%

Comparison between GC/MS and Lay Person Results for Cocaine Cup

% of cut off	Number of samples	Cocaine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	62	0	20	100%
-50% cut off	20	135	0	20	100%
-25% cut off	20	212	1	19	95%
+25% cut off	20	365	20	0	100%
+50% cut off	20	444	20	0	100%
+75% cut off	20	533	20	0	100%

Comparison between GC/MS and Lay Person Results for Cocaine Split Key Cup

% of cut off	Number of samples	Cocaine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	62	0	20	100%
-50% cut off	20	135	0	20	100%
-25% cut off	20	212	1	19	95%

+25% cut off	20	365	19	1	95%
+50% cut off	20	444	20	0	100%
+75% cut off	20	533	20	0	100%

Comparison between GC/MS and Lay Person Results for Oxazepam Cup

% of cut off	Number of samples	Oxazepam Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	64	0	20	100%
-50% cut off	20	141	0	20	100%
-25% cut off	20	221	1	19	95%
+25% cut off	20	362	18	2	90%
+50% cut off	20	440	20	0	100%
+75% cut off	20	530	20	0	100%

Comparison between GC/MS and Lay Person Results for Oxazepam Split Key Cup

% of cut off	Number of samples	Oxazepam Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	64	0	20	100%

-50% cut off	20	141	0	20	100%
-25% cut off	20	221	0	20	100%
+25% cut off	20	362	18	2	90%
+50% cut off	20	440	20	0	100%
+75% cut off	20	530	20	0	100%

Comparison between GC/MS and Lay Person Results for Methamphetamine Cup Format

% of cut off	Number of samples	d-Methamphetamine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results (%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	248	0	20	100%
-50% cut off	20	489	0	20	100%
-25% cut off	20	734	0	20	100%
+25% cut off	20	1284	18	2	90%
+50% cut off	20	1535	20	0	100%
+75% cut off	20	1783	20	0	100%

Comparison between GC/MS and Lay Person Results for Methamphetamine Split Key Cup Format

% of cut off	Number of samples	d-Methamphetamine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results (%)
-100% cut off	20	0	0	20	100%

-75% cut off	20	248	0	20	100%
-50% cut off	20	489	0	20	100%
-25% cut off	20	734	0	20	100%
+25% cut off	20	1284	20	0	100%
+50% cut off	20	1535	20	0	100%
+75% cut off	20	1783	20	0	100%

Comparison between GC/MS and Lay Person Results for Morphine Cup

% of cut off	Number of samples	Morphine Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	70	0	20	100%
-50% cut off	20	136	0	20	100%
-25% cut off	20	228	2	18	90%
+25% cut off	20	378	20	0	100%
+50% cut off	20	445	20	0	100%
+75% cut off	20	510	20	0	100%

Comparison between GC/MS and Lay Person Results for Morphine Split Key Cup

% of cut off	Number of samples	Morphine Concentration by	Number of Positive	Number of Negative	Percentage of Correct Results(%)

		GC/MS(ng/mL)			
-100% cut off	20	0	0	20	100%
-75% cut off	20	70	0	20	100%
-50% cut off	20	136	0	20	100%
-25% cut off	20	228	1	19	95%
+25% cut off	20	378	20	0	100%
+50% cut off	20	445	20	0	100%
+75% cut off	20	510	20	0	100%

Comparison between GC/MS and Lay Person Results for Marijuana Cup Format

% of cut off	Number of samples	Marijuana Concentration by GC/MS(ng/mL)	Number of Positive	Number of Negative	Percentage of Correct Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	10	0	20	100%
-50% cut off	20	24	0	20	100%
-25% cut off	20	36	0	20	100%
+25% cut off	20	60	19	1	95%
+50% cut off	20	73	20	0	100%
+75% cut off	20	82	20	0	100%

Comparison between GC/MS and Lay Person Results for Marijuana Split Key Cup Format

% of cut off	Number of samples	Marijuana Concentration by	Number of Positive	Number of Negative	Percentage of Correct

		GC/MS(ng/mL)			Results(%)
-100% cut off	20	0	0	20	100%
-75% cut off	20	10	0	20	100%
-50% cut off	20	24	0	20	100%
-25% cut off	20	36	0	20	100%
+25% cut off	20	60	20	0	100%
+50% cut off	20	73	20	0	100%
+75% cut off	20	82	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 Study

Not applicable.

5.9 Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, Based on the information provided in this premarket notification, SHANGHAI VENTURE BIO-TECH CO., LTD has demonstrated that proposed device BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use, BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use, BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use are substantially equivalent to the predicate.