

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k180879

B. Purpose for Submission:

New device

C. Measurand:

d-Amphetamine, Oxazepam, Cocaine, Methamphetamine, Morphine, and Marijuana

D. Type of Test:

Qualitative, lateral flow immunochromatographic assay

E. Applicant:

SHANGHAI VENTURE BIO-TECH CO., LTD.

F. Proprietary and Established Names:

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

G. Regulatory Information:

Product Codes	Class	Regulation Section	Regulation Name	Panel
DKZ, NFT	II	862.3100	Amphetamine Test System	Toxicology (91)
DIO, NFY	II	862.3250	Cocaine and cocaine metabolites test system	
JXM, NFV	II	862.3170	Benzodiazepine test system	
DJC, NGG	II	862.3610	Methamphetamine Test System	
DNK, NGI	II	862.3640	Morphine Test System	
LDJ, NFW	II	862.3870	Cannabinoid test system	

H. Intended Use:

1. Intended use(s):

Refer to Indication for Use

2. Indication(s) 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, Benzoyllecgonine, 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)	Benzoyllecgonine	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, Benzoyllecgonine, 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)	Benzoyllecgonine	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.

3. Special conditions for use statement(s):

The BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use and BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use are intended for over the counter use.

The BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use and BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use are intended for prescription use.

4. Special instrument requirements:

Not applicable.

I. 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, and BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Amphetamine, Oxazepam, Benzoylcegonine, d-Methamphetamine, Morphine and 11-Nor- Δ^9 -Tetrahydrocannabinol-9- COOH (target analytes) in human urine. The BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use and BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use devices consist of a cup that may be configured as single drug tests or multiple drug tests in any combination of the drug analytes up to a maximum of 6 analytes , and the BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use and the BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use devices consist of a split key cup that may be configured as a single drug test or multiple drug tests in any combination of the drug analytes up to 6 total. 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.

J. Substantial Equivalence Information:1. Predicate device name(s):

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

2. Predicate 510(k) number(s):

k173303

3. Comparison with predicate:

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

Similarities		
Item	Device	Predicate
Intended Use	Same	For the qualitative determination of drugs of abuse in human urine.
Methodology	Same	Lateral flow immunochromatographic assays
Test Type	Same	Qualitative
Specimen Type	Same	Urine
Intended Users	Same	OTC Use

Differences		
Item	Device	Predicate
Configurations	Easy Cup and Split Key Cup	Cup
Analytes	d-Amphetamine, Oxazepam, Benzoylcegonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH	d-Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Benzoylcegonine, d-Methamphetamine, Methadone, Phencyclidine, Nortriptyline, 11-nor- Δ^9 -THC-9-COOH, Methylenedioxy-methamphetamine, Morphine, Oxycodone

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

Similarities		
Item	Device	Predicate
Intended Use	Same	For the qualitative determination of drugs of abuse in human urine.
Methodology	Same	Lateral flow immunochromatographic assays
Test Type	Same	Qualitative
Specimen Type	Same	Urine
Intended Users	Same	Rx Use

Differences		
Item	Device	Predicate
Configurations	Easy Cup and Split Key Cup	Cup
Analytes	d-Amphetamine, Oxazepam, Benzoyllecgonine, d-Methamphetamine, Morphine and Delta-9-THC-COOH	d-Amphetamine, Secobarbital, Buprenorphine, Oxazepam, Benzoyllecgonine, d-Methamphetamine, Methadone, Phencyclidine, Nortriptyline, 11-nor- Δ^9 -THC-9-COOH, Methylenedioxy-methamphetamine, Morphine, Oxycodone

K. Standard/Guidance Document Referenced (if applicable):

None referenced

L. 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 and BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for Rx Use are rapid tests for the qualitative detection of d-Amphetamine, Benzoyllecgonine, Oxazepam, Methamphetamine, Morphine, and 11-Nor- Δ^9 -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.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use and BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use are identical physical devices but the BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use has different labeling appropriate for OTC users. Similarly, the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for OTC Use and the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for Rx Use are identical physical devices but the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for OTC Use has different labeling appropriate for OTC users. The precision testing is from one BIO-VENTURE Rapid Multi-Drug Test Easy Cup device and one BIO-VENTURE Rapid Multi-drug Test Split Key Cup but represents expected performance from both the Rx and OTC devices.

Precision was evaluated by analyzing spiked urine samples at concentrations of -100%, -75%, -50%, -25%, cutoff, +25%, +50%, +75%, and +100%. Three lots were evaluated and the results were read by six operators. Results were as follows:

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

AMP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% % cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

COC	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	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+	22-/28+	50+/0-	50+/0-	50+/0-	50+/0-

OXA Z	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
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+	23-/27+	50+/0-	50+/0-	50+/0-	50+/0-

MET	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	12-/38+	50+/0-	50+/0-	50+/0-	50+/0-

MOP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	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-

THC	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	36-/14+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	38-/12+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	35-/15+	50+/0-	50+/0-	50+/0-	50+/0-

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

AMP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	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+	24-/26+	50+/0-	50+/0-	50+/0-	50+/0-

COC	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	24-/26+	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+	25-/25+	50+/0-	50+/0-	50+/0-	50+/0-

OXAZ	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

MET	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	11-/39+	50+/0-	50+/0-	50+/0-	50+/0-

MOP	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	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-

THC	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cutoff
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	36-/14+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	38-/12+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	35-/15+	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity/assay reportable range:

Not applicable. These devices are intended for qualitative use only.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

This device has internal process controls. A control line appears in the control region confirming that sufficient sample volume has been applied to the test strip and that the sample has migrated correctly on the test strip. Users are informed that the test is invalid if the colored line does not appear in the control region. There are no external controls supplied with the device.

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

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Cross-reactivity

Cross-reactivity was evaluated by spiking in potential cross-reactants and titrating potential cross-reactants to find the lowest concentration of cross-reactant that produced a positive result with each device. The percent cross-reactivity was calculated as:

$$(\text{cutoff concentration} / \text{lowest concentration causing a positive result}) \times 100$$

The results are summarized below for BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use are representative of all formats.

AMP

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
D-Amphetamine	1000	100.0
D/L-Amphetamine	1500	66.7
Hydroxyamphetamine	10,000	10.0
Phentermine	3000	33.3
MDA	10,000	10.0
MDMA	> 100,000	<1
MDE	> 100,000	<1
Ephedrine	> 100,000	<1
Pseudoephedrine	> 100,000	<1
D/L-Methamphetamine	> 100,000	<1
D-Methamphetamine	> 100,000	<1
L- Amphetamine	3000	33.3
L-Methamphetamine	> 100,000	<1

COC

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Cocaine HCl	5000	6
Norcocaine	25,000	1.2
Ecgonine HCl	50,000	0.6
Benzoyllecgonine	300	< 0.3
Cocaethylene	> 100,000	100

Oxazepam

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
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
Oxazepam	300	100
Clorazepate dipotassium	>100,000	0.3
Desalkylflurazepam	>100,000	0.3
Norchlordiazepoxide	>100,000	0.3

MET

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
p-Hydroxyamphetamine	50000	2
(+)-3,4-Methylenedioxyamphetamine(MDA)	20000	5
(+)-3,4-Methylenedioxymethamphetamine(MDMA)	3000	33.3
(+)-3,4-methylenedioxy-n-ethylamphetamine(MDEA)	5000	20
D/L-Amphetamine	>100000	<1
D-Amphetamine	>100000	<1
D/L- Methamphetamine	3000	33.3
D- Methamphetamine	1000	100
L-Amphetamine	>100000	10

MOR

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Acetylmorphine	6000	5
Hydromorphone	3000	10
Hydrocodone	50000	.6
Levorphanol	1500	20
Oxycodone	50000	.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

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
(-)-11-Nor- Δ 9- Tetrahydrocannabinol-9-COOH	50	100
11-Hydroxy- Δ 9- Tetrahydrocannabinol	10000	0.5
11- Nor- Δ 8- Tetrahydrocannabinol-9-COOH	2500	2
Cannabinol	5000	1
11-Nor- Δ 9-THC-carboxy glucuronide	5000	1
(-)-11-nor-9-carboxy- Δ 9-THC	10000	<0.5
Δ 8- Tetrahydrocannabinol	>50000	<0.1
Δ 9- Tetrahydrocannabinol	>50000	<0.1
Cannabidiol	>50000	<0.1

Interferences

Interference was evaluated by spiking the potential interferents below into urine samples having test drug analytes at $\pm 25\%$ of the cutoff for each assay.

All potential interferents were tested at a concentration of 100 $\mu\text{g/mL}$, except for Ethanol which was tested at a final concentration of 1%. There were no deviations from the expected results for any of the devices.

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
Benzoyllecgonine	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
Benzoyllecgonine	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
Benzoyllecgonine	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 Hydrochloride	Ranitidine	Tramadol
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			

Endogenous Interferents:

The effect of pH was evaluated by preparing samples with test drug analytes at $\pm 25\%$ of the cutoff for all devices and adjusting the pH to 4.00 to 9.00, in increments of 1 pH unit. There were no deviations from the expected results.

The effect of specific gravity was evaluated by preparing samples with test drug analytes at $\pm 25\%$ of the cutoff for all devices and adjusting the specific gravity from 1.002 – 1.033. There were no deviations from the expected results.

f. Assay cut-off:

For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

The BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use and BIO-VENTURE Rapid Multi-Drug Test Easy Cup for Rx Use are identical physical devices but the BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use has different labeling appropriate for OTC users. Similarly, the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for OTC Use and the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for Rx Use are identical physical devices but the BIO-VENTURE Rapid Multi-drug Test Split Key Cup for OTC Use has different labeling appropriate for OTC users. The method comparison testing is from one BIO-VENTURE Rapid Multi-Drug Test Easy Cup device and one BIO-VENTURE Rapid Multi-drug Test Split Key Cup but represents expected performance from both the Rx and OTC devices.

Unaltered, remnant clinical samples were obtained to test amphetamines, cocaine and oxazepam, morphine and THC. Three operators tested each sample, and each sample was also tested by GC-MS for comparison.

Amphetamine – Easy Cup Format (87 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

Amphetamine – Split Key Cup Format (87 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

Oxazepam – Easy Cup Format (80 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

Operator	GC/MS Result (ng/mL)	Candidate Device Result
1	333	Negative
3	298	Positive

Oxazepam –Split Key Cup Format (80 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

COC – Easy Cup Format (80 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

COC – Split Key Cup Format (80 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

MET – Easy Cup Format (81 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

MET – Split Key Cup Format (81 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

MOR– Easy Cup Format (81 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
Operator 1	Negative	19	9	12	0	0
	Positive	0	0	1	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

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

Operator	GC/MS Result (ng/mL)	Candidate Device Result
3	293	Positive

MOR–Split Key Cup Format (81 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

THC– Easy Cup Format (81 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

THC– Split Key Cup Format (82 samples total)		Negative Urine	(less than -50% by LC/MS)	Near Cutoff Negative by LC/MS (Between -50% and cut-off)	Near Cutoff Positive by LC/MS (Between the cut-off and +50%)	High Positive by LC/MS (greater than +50%)
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

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

b. Matrix comparison:

Not applicable.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable.

b. Clinical specificity:

Not applicable.

- c. Other clinical supportive data (when a. and b. are not applicable):

Lay user studies

A lay user study was performed by 140 lay persons for each format for the BIO-VENTURE Rapid Multi-Drug Test Easy Cup for OTC Use and the BIO-VENTURE Rapid Multi-Drug Test Split Key Cup for OTC Use (280 lay persons total). The lay users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared with test drug analytes 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.

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (AMP)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results (%)
			Positive	Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	248	0	20	100
-50% Cutoff	20	492	0	20	100
-25% Cutoff	20	741	2	18	90
+25% Cutoff	20	1262	20	0	100
+50% Cutoff	20	1506	20	0	100
+75% Cutoff	40	1744	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (Oxazepam)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	64	0	20	100
-50% Cutoff	40	141	0	20	100
-25% Cutoff	40	221	1	19	95
+25% Cutoff	40	362	18	2	90
+50% Cutoff	40	440	20	0	100
+75% Cutoff	40	530	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (COC)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	62	0	20	100
-50% Cutoff	40	135	0	20	100
-25% Cutoff	40	212	1	19	95
+25% Cutoff	40	365	20	0	100
+50% Cutoff	40	444	0	0	100
+75% Cutoff	40	533	40	0	100

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (MET)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	248	0	20	100
-50% Cutoff	40	489	0	20	100
-25% Cutoff	40	734	0	20	100
+25% Cutoff	40	1284	18	2	90
+50% Cutoff	40	1535	20	0	100
+75% Cutoff	40	1783	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (MOP)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	70	0	20	100
-50% Cutoff	40	136	0	20	100
-25% Cutoff	40	228	2	18	90
+25% Cutoff	40	378	20	0	100
+50% Cutoff	40	445	20	0	100
+75% Cutoff	40	510	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Easy Cup (THC)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	10	0	20	100
-50% Cutoff	40	24	0	20	100
-25% Cutoff	40	36	0	20	100
+25% Cutoff	40	60	19	1	95
+50% Cutoff	40	73	20	0	100
+75% Cutoff	40	82	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (AMP)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	248	0	20	100
-50% Cutoff	40	492	0	20	100
-25% Cutoff	40	741	2	18	90
+25% Cutoff	40	1262	20	0	100
+50% Cutoff	40	1506	20	0	100
+75% Cutoff	40	1744	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (Oxazepam)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	64	0	20	100
-50% Cutoff	40	141	0	20	100
-25% Cutoff	40	221	0	20	100
+25% Cutoff	40	362	18	2	90
+50% Cutoff	40	440	20	0	100
+75% Cutoff	40	530	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (COC)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	62	0	20	100
-50% Cutoff	40	135	0	20	100
-25% Cutoff	40	212	1	19	95
+25% Cutoff	40	365	19	1	95
+50% Cutoff	40	444	20	0	100
+75% Cutoff	40	533	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (MET)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	248	0	20	100
-50% Cutoff	40	489	0	20	100
-25% Cutoff	40	734	0	20	100
+25% Cutoff	40	1284	20	0	100
+50% Cutoff	40	1535	20	0	100
+75% Cutoff	40	1783	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (MOP)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	70	0	20	100
-50% Cutoff	40	136	0	20	100
-25% Cutoff	40	228	1	19	95
+25% Cutoff	40	378	20	0	100
+50% Cutoff	40	445	20	0	100
+75% Cutoff	40	510	20	0	100

BIO-VENTURE Rapid Multi-Drug Test Split Key Cup (THC)

% of Cutoff	Number of samples	Concentration by GC/MS (ng/mL)	Lay person results		Percentage of correct results
			Positive	Negative	
-100% Cutoff	40	0	0	20	100
-75% Cutoff	40	10	0	20	100
-50% Cutoff	40	24	0	20	100
-25% Cutoff	40	36	0	20	100
+25% Cutoff	40	60	20	0	100
+50% Cutoff	40	73	20	0	100
+75% Cutoff	40	82	20	0	100

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.