

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

A. 510(k) Number:

k180878

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Oxazepam, Cocaine, Marijuana, Methamphetamine, Morphine

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 Amphetamine Test Cassette for OTC Use
BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use
BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use
BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use
BIO-VENTURE Rapid Morphine Test Cassette for OTC Use
BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use

BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use
BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use
BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use
BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use
BIO-VENTURE Rapid Morphine Test Cassette for Rx Use
BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use

G. Regulatory Information:

Product Codes		Regulation Section	Regulation Name	Panel
DKZ, NFT	Class II	862.3100	Amphetamine Test System	Toxicology (91)
DIO, NFY		862.3250	Cocaine and Cocaine metabolites test system	
JXM, NFV		862.3170	Benzodiazepine test system	
DJC, NGG		862.3610	Methamphetamine Test System	
DNK, NGI		862.3640	Morphine Test System	
LDJ, NFW		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 Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette 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:

Drug Identifier	Cut-off Level
Amphetamine(AMP)	1000ng/mL
Oxazepam	300 ng/mL
Cocaine(COC)	300 ng/mL
Marijuana(THC)	50 ng/mL
Methamphetamine(MET)	1000 ng/mL
Morphine	300 ng/mL

The cassette test may be configured as single drug test in any drug analytes listed in the table. 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.

BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, BIO-VENTURE Rapid Marijuana Test Cassette 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:

Drug Identifier	Cut-off Level
Amphetamine(AMP)	1000ng/mL
Oxazepam	300 ng/mL
Cocaine(COC)	300 ng/mL
Marijuana(THC)	50 ng/mL
Methamphetamine(MET)	1000 ng/mL
Morphine	300 ng/mL

The cassette test may be configured as single drug test in any drug analytes listed in the table. 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.

3. Special conditions for use statement(s):

The BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use are for prescription use.

The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use are for over the counter use.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use and the BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use differ in intended use (prescription use or over the counter use), but share the same test cassette, with each cassette housing only one of 6 different drug test strips (for the qualitative detection of d-Methamphetamine, Morphine, 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH, d-Amphetamine, Cocaine or Oxazepam in human urine).

The BIO-VENTURE test cassettes (noted in the above paragraph) are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-Methamphetamine, Morphine, 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH, d-Amphetamine, Cocaine and Oxazepam in human urine. The tests are available in single drug test cassette formats. BIO-VENTURE test cassettes are coated with mouse monoclonal antibodies, each raised against specific drug analytes (deposited on the test line), and a anti-IgG polyclonal antibody (deposited on the control line). The cassettes are provided in individual aluminum foil bags.

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:

Similarities		
Item	Candidate Devices	Predicate – k173303
Intended Use	Same	For the qualitative determination of drugs of abuse in human urine.
Methodology	Same	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody

Similarities		
Item	Candidate Devices	Predicate – k173303
		immunochemistry.
Specimen type	Same	Urine

Differences		
Item	Candidate Device	Predicate – k173303
Formats	Cassette	Cup

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

None referenced.

L. Test Principle:

The BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use and the BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use are rapid tests for the qualitative detection of Methamphetamine, Morphine, 11-Nor- Δ^9 -Tetrahydrocannabinol-9-COOH, d-Amphetamine, Benzoylcegonine and Oxazepam in urine samples. The tests are lateral flow chromatographic immunoassays. During testing, a urine specimen migrates across the test strip by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, they will not saturate the binding sites of specific anti-target drug monoclonal mouse antibodies coated on gold-conjugated nanoparticles, allowing the antibody-coated nanoparticles to be captured by immobilized drug-conjugate on the test line, and a visible colored line will show up in the test line region. The colored line in the test line region will not form if the target drug level exceeds its cutoff concentration because it will saturate all the binding sites of the antibody-coated nanoparticles, thus competing for binding to the test line region.

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 sample has migrated past the test and control line regions.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use are identical physical devices to the BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use, but have different labeling appropriate for OTC users. Precision testing was conducted using the The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use devices, 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, each operator performs 9 samples for 25 days in a randomized order. Results were as follows:

Methamphetamine:

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+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	9-/41+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	10-/40+	50+/0-	50+/0-	50+/0-	50+/0-

Morphine:

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+	17-/33+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	19-/31+	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	15-/35+	50+/0-	50+/0-	50+/0-	50+/0-

Marijuana:

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-

Amphetamine:

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+	28-/22+	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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine:

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+	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+	26-/24+	50+/0-	50+/0-	50+/0-	50+/0-

Oxazepam:

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+	28-/22+	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+	28-/22+	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:

The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use are identical physical devices to the BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use, but have different labeling appropriate for OTC users. Cross reactivity and interference testing was conducted using the The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use devices, but represents expected cross-reactivity and interference performance from both the Rx and OTC devices.

Cross-reactivity:

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

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

Results are summarized below.

Methamphetamine

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
D-Amphetamine	100,000	1

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
L-Amphetamine	100,000	1
D/L-Amphetamine	100,000	1
p-Hydroxyamphetamine	50,000	2
MDA	20,000	5
MDMA	3000	33.3
MDEA	5000	20
D/L-Methamphetamine	3000	33.3
D-Methamphetamine	1000	100
L-Methamphetamine	10,000	10

Morphine

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Acetylmorphine	6000	5
Hydromorphone	3000	10
Dimethylmorphine	3000	10
Hydrocodone	50,000	0.6
Oxycodone	50,000	0.6
Levorphanol	1500	20
Morphine-3- Glucuronide	>100,000	<0.3
Morphine	300	100
Codeine	300	100
Heroin	300	100
O ⁶ - Monoacetylmorphine	300	100
Ethylmorphine	>100,000	<0.3

Marijuana

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	10,000	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	10,0000	0.5

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
Δ^8 - Tetrahydrocannabinol	>50,000	0.1
Δ^9 - Tetrahydrocannabinol	>50,000	0.1
Cannabidiol	>50,000	0.1

Amphetamine

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

Cocaine

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

Potential cross-reactant	Lowest Concentration producing a positive result (ng/ml)	% Cross Reactivity
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

Interferences:

Interference was evaluated by spiking the potential interferents below into urine samples at $\pm 25\%$ of the cut-off for the AMP, COC, BNZ, MET, MOP, and THC assays.

All potential interferents were tested at a concentration of 100 $\mu\text{g/mL}$ except for THC which was tested at 10 $\mu\text{g/mL}$ and 1% Ethanol. There were no deviations from the expected results for any of the the three formats.

Methamphetamine

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	$\Delta 9$ -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	

Morphine

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
Benzoyllecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Amphetamine	MDMA	Ethanol

THC

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
Benzoyllecgonine	Secobarbital	Angiotensin	Adrenaline
Oxazepam	Uric Acid	Triglyceride	Oxalic Acid
Prednisolone acetate	Cholesterol	Hydrocortisone	Oxycodone
Ethanol			

AMP

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

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

Cocaine

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

The effect of pH was evaluated by preparing samples at $\pm 25\%$ of the cutoff for the MET, MOR, THC, AMP, COC, and OXAZ assays 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 at $\pm 25\%$ of

the cutoff for the MET, MOR, THC, AMP, COC, and OXAZ assays and adjusting the specific gravity to 1.002, 1.016, 1.018, 1.023, 1.033, and 1.036. 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 Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use are identical physical devices to the BIO-VENTURE Rapid Amphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Oxazepam Test Cassette for Rx Use, BIO-VENTURE Rapid Cocaine Test Cassette for Rx Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for Rx Use, BIO-VENTURE Rapid Morphine Test Cassette for Rx Use, BIO-VENTURE Rapid Marijuana Test Cassette for Rx Use, but have different labeling appropriate for OTC users. Method comparison testing was conducted using the The BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use devices, but represents expected performance from both the Rx and OTC devices.

Method comparison studies for the BIO-VENTURE Rapid Single Drug Test Cassettes for Amphetamine, Oxazepam, Cocaine and Cocaine metabolites, Marijuana, Methamphetamine, Morphine 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 and 82 samples for Marijuana. The samples were blind-labeled and compared to results obtained by GC/MS. The results are presented in the tables below:

Methamphetamine – Cassette		Negative	(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	7	0	0
	Positive	0	0	1	11	29
Operator 2	Negative	17	16	8	3	0
	Positive	0	0	0	8	29
Operator 3	Negative	17	16	7	0	0
	Positive	0	0	1	11	29

Discordant results

Drug in urine	Operator	Cut-off (ng/mL)	GC/MS results(ng/mL)	Test results
Methamphetamine	2	1000	1025	-
	2		1033	-
	1		984	+
	3		984	+
	2		1055	-

Morphine – Cassette		Negative	(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	3	0
	Positive	0	0	0	12	25
Operator 3	Negative	19	9	12	0	0
	Positive	0	0	1	15	25

Discordant results

Drug in urine	Operator	Cut-off (ng/mL)	GC/MS results(ng/mL)	Test results
Morphine	2	300	323	-
	2		325	-
	2		335	-
	1		293	+
	3		293	+

THC Cassette		Negative	<-50% cut off	-50% cut off~cut off	Cut off~+50% cut off	>+50% cut off
Operator 1	Negative	18	11	13	4	0
	Positive	0	0	0	12	24
Operator 2	Negative	18	11	13	0	0
	Positive	0	0	0	16	24
Operator 3	Negative	18	11	13	1	0
	Positive	0	0	0	15	24

Discordant results

Drug in urine	Operator	Cutoff(ng/mL)	GC/MS Results (ng/mL)	Test Results
Marijuana	1	50	61	-
	1		59	-
	3		59	-
	1		61	-
	1		59	-

Amphetamine- cassette		Negative	(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	Positive	19	16	11	1	0
	Negative	0	0	0	13	27
Operator 2	Positive	19	16	10	1	0
	Negative	0	0	1	13	27
Operator 3	Positive	19	16	10	0	0

Amphetamine- cassette		Negative	(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%)
	Negative	0	0	1	14	27

Discordant results

Drug in urine	Operator	Cut-off (ng/mL)	GC/MS results(ng/mL)	Test results
Amphetamine	2	1000	989	+
	3		989	+
	2		1035	-
	1		1062	-

Oxazepam - cassette		Negative	(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	Positive	15	10	15	0	0
	Negative	0	0	0	20	20
Operator 2	Positive	15	10	13	0	0
	Negative	0	0	2	20	20
Operator 3	Positive	15	10	13	0	0
	Negative	0	0	2	20	20

Discordant results

Drug in urine	Operator	Cut-off (ng/mL)	GC/MS results(ng/mL)	Test results
Oxazepam	2	300	283	+
	2		288	+
	3		288	+
	3		298	+

Cocaine - cassette		Negative	(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	Positive	18	13	11	0	0
	Negative	0	0	0	17	21
Operator 2	Positive	18	13	9	0	0
	Negative	0	0	2	17	21
Operator 3	Positive	18	13	9	0	0
	Negative	0	0	2	17	21

Discordant results

Drug in urine	Operator	Cut-off (ng/mL)	GC/MS results(ng/mL)	Test results
Cocaine	2	300	278	+
	3		278	+
	2		285	+
	3		285	+

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):

A lay user study was conducted to assess the BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use, BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use, BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use, BIO-VENTURE Rapid Morphine Test Cassette for OTC Use, and BIO-

VENTURE Rapid Marijuana Test Cassette for OTC Use devices with 840 lay persons with diverse educational and professional backgrounds and ranging 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, and the results provided below are from each lay user, who tested only one device at one test concentration. Lay-users were also given surveys on the ease of understanding the package insert instructions (Flesch-Kincaid reading analysis revealed a reading Grade Level of 7 for the device labeling). All lay users indicated that the device instructions could be easily followed.

BIO-VENTURE Rapid Amphetamine Test Cassette for OTC Use

% 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	19	1	95%
+50% cut off	20	1506	20	0	100%
+75% cutoff	20	1744	20	0	100%

BIO-VENTURE Rapid Cocaine Test Cassette for OTC Use

% 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	2	18	90%
+25% cut off	20	365	20	0	100%
+50% cut off	20	444	20	0	100%
+75% cut off	20	533	20	0	100%

BIO-VENTURE Rapid Oxazepam Test Cassette for OTC Use

% 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	20	0	100%
+50% cut off	20	440	20	0	100%
+75% cut off	20	530	20	0	100%

BIO-VENTURE Rapid Methamphetamine Test Cassette for OTC Use

% 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	2	18	90%
+25% cut off	20	1284	20	0	100%
+50% cut off	20	1535	20	0	100%
+75% cut off	20	1783	20	0	100%

BIO-VENTURE Rapid Morphine Test Cassette for OTC Use

% 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%

BIO-VENTURE Rapid Marijuana Test Cassette for OTC Use

% 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	20	0	100%
+50% cut off	20	73	20	0	100%
+75% cut off	20	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.