

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

A. 510(k) Number:

k061617

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine, Methamphetamine, Benzodiazepine, Barbiturates, Benzoylcegonine, Morphine, Tetrahydrocannabinol (THC), Phencyclidine (PCP), Methadone, Oxycodone, Tricyclic Antidepressant (TCA), and Propoxyphene in urine.

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Tianjin New Bay Bioresearch Co., Ltd.

F. Proprietary and Established Names:

Forsure One Step Dip & Read Drug Screen Test

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3100, Amphetamine Test System
21 CFR 862.3150, Barbiturate Test System
21 CFR 862.3170, Benzodiazepine Test System
21 CFR 862.3250, Cocaine and Cocaine Metabolite Test System
21 CFR 862.3610, Methamphetamine Test System
21 CFR 862.3620, Methadone Test System
21 CFR 862.3650, Opiates and Test System
21 CFR 862.3700, Propoxyphene Test System
21 CFR 862.3870, Cannabinoids Test System
21 CFR 862.3910, Tricyclic Antidepressant
21 CFR 862.3200, Clinical Toxicology Calibrator
21 CFR 862.3280, Clinical Toxicology Control Material
Unclassified, Phencyclidine

2. Classification:

Class II

3. Product code:

DKZ, DIS, JXM, DIO, DJC, DJR, DJG, JXN, LDJ, LFG, and LCM

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to the Indications for use.

2. Indication(s) for use:

Forsure One Step Dip & Read Drug Screen Test is a prescription assay intended for professional use in central laboratories only. It provides qualitative screening results for Amphetamine (AMP), Methamphetamine (MET), Benzodiazepine (BZD), Barbiturate (BAR), Cocaine (COC), Cannabinoids (THC), Opiates (OPI), Phencyclidine (PCP), Methadone (MTD), Oxycodone (OXY), Tricyclic Antidepressant (TCA) and Propoxyphene (PPX) in human urine at the following cutoff levels:

<u>Test</u>	<u>Calibrator</u>	<u>Cutoff</u>
Amphetamine	D-Amphetamine	1000 ng/mL
Methamphetamine	D-Methamphetamine	1000 ng/mL
Benzodiazepine	Oxazepam	300 ng/mL
Barbiturate	Secobarbital	300 ng/mL
Cocaine	Benzoyllecgonine	300 ng/mL
Cannabinoids	11-nor Δ 9-THC-9 COOH	50 ng/mL
Opiates	Morphine	2000 ng/mL
Phencyclidine	Phencyclidine	25 ng/mL
Methadone	Methadone	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
Tricyclic Antidepressant	Nortriptyline	1000 ng/mL
Propoxyphene	Propoxyphene	300 ng/mL

The assay provides only preliminary analytical test results. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.

3. Special conditions for use statement(s):

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly in evaluating a preliminary positive. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

For prescription use only.

4. Special instrument requirements:

Not applicable; the device is a visually-read single-use device.

I. Device Description:

Forsure One Step Dip & Read Drug Screen Test contains up to twelve individual chromatographic absorbent strips in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane support for the limited antibody sites. The method employs unique monoclonal and polyclonal antibodies to selectively identify the drug or drug metabolite in the sample. The membrane on the strip is coated with goat anti-mouse antibody and a specific drug-protein conjugate. The sample pad contains a colloidal gold labeled mouse monoclonal anti specific drug antibody. The device is for single-use and is visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Forsure Rapid One Step Multiple (X) Abuse Drug Screen Test Cup Device

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

k052882

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended use	Qualitative determination of drugs in human urine	Same
Matrix	Human Urine	Same
Test Principle	Immunochromatographic, lateral flow	Same

Similarities		
Item	Device	Predicate
Analytes	Amphetamine Methamphetamine Benzodiazepine, Barbiturate, Cocaine, Cannibinoids , Opiates PCP, Methadone, Oxycodone, TCA and Propoxyphene	Same

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

None referenced

L. Test Principle:

The test employs lateral flow immunochromatographic technology. Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a preliminary positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed using in house drug standards. The standard was diluted in drug-free urine to give drug concentrations at the following levels: 0, 50%, 75%, 100%, 125% and 150% of the cutoff. A total of 15 determinations were made at each concentration for each analyte. Testing was performed on one day by one operator. All samples at 0 and -50% yielded negative results and all samples 150% yielded positive results. Within lot precision study data for 75%, 100% and 125% is summarized below:

75% Cutoff	AMP	MET	MOR	BEG	BAR	BZD	THC	PCP	MAD	OXY	TCA	PPX
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/ml)	750	750	1500	150	225	225	37.5	18.75	225	75	750	225
#NEG/#POS	12/3	12/3	13/2	12/3	14/1	13/2	12/3	11/4	13/2	10/5	11/4	12/3
Precision	80%	80%	87%	80%	93%	87%	80%	73%	87%	67%	73%	80%

100% Cutoff	AMP	MET	MOR	BEG	BAR	BZD	THC	PCP	MAD	OXY	TCA	PPX
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/mL)	1000	1000	2000	300	300	300	50	25	300	100	1000	300
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15
Precision	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

125% Cutoff	AMP	MET	MOR	BEG	BAR	BZD	THC	PCP	MAD	OXY	TCA	PPX
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
Concentration (ng/mL)	1250	1250	2500	375	375	375	62.5	31.25	375	125	1250	375
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15
Precision	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Inter Lot Reproducibility

To test inter lot precision, drug-free urine was spiked with commercially available drug standard to the following levels: 0, 50%, 75%, 100%, 125% and 150% of cutoff. Testing was performed using three different lot numbers, 15 samples of each lot were run at each of the concentrations for each drug over 20 days. All samples tested at 0, -50% yielded negative results and all samples at 150% yielded positive results. Inter lot Precision Study data for 75%, 100% and 125% of cutoff is summarized below:

75% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	14/1	13/2	13/2	93%	87%	87%	89%
MET	15	15	15	11/4	14/1	11/4	73%	93%	73%	80%
MOR	15	15	15	14/1	12/3	12/3	93%	80%	80%	84%
BEG	15	15	15	13/2	14/1	14/1	87%	93%	93%	91%
BAR	15	15	15	14/1	13/2	14/1	93%	87%	93%	91%
BZD	15	15	15	12/3	13/2	11/4	80%	87%	73%	80%

75% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
THC	15	15	15	13/2	14/1	14/1	87%	93%	93%	91%
PCP	15	15	15	14/1	14/1	13/2	93%	93%	87%	91%
MTD	15	15	15	14/1	14/1	13/2	93%	93%	87%	91%
OXY	15	15	15	11/4	11/4	12/3	73%	73%	80%	75%
TCA	15	15	15	13/2	11/4	12/3	87%	73%	80%	80%
PPX	15	15	15	11/4	10/5	11/4	73%	67%	73%	71%

100% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MET	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MOR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BEG	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BAR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BZD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
THC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PCP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MTD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OXY	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
TCA	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PPX	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%

125% Cutoff	Total # determination			# Negative/# Positive			inter Lot Precision (%)			Average Lot
	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Lot 1	Lot 2	Lot 3	Precision
AMP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MET	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MOR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BEG	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BAR	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
BZD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
THC	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PCP	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
MTD	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
OXY	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
TCA	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%
PPX	15	15	15	15/0	15/0	15/0	100%	100%	100%	100%

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

The device has an internal procedural control. A magenta line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume and adequate membrane wicking.

External control materials are not supplied with these tests; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. User should follow local, state and federal guidelines for testing QC material.

Stability

Real time and accelerated studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 2 – 30°C product is good until expiration date which is 18 months.

d. *Detection limit:*

A drug-free urine pool was spiked with specific drug at the following concentrations: 25% and 50% below the cutoff, cutoff and 25% above the cutoff. The results are presented in the table below:

	AMP	MET	BZD	BAR	BEG	THC	MOR	PCP	MAD	OXY	TCA	PPX
Total # determinations	15	15	15	15	15	15	15	15	15	15	15	15
-50% of cutoff/ concentration ng/mL	500	500	150	150	150	25	1000	12.5	150	50	500	150
#NEG/#POS	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0	15/0
-25% of cutoff/ concentration ng/mL	750	750	225	225	750	225	1500	75	18.75	225	750	37.5
#NEG/#POS	12/3	11/4	11/4	11/4	11/4	9/6	12/3	11/4	10/5	10/5	13/2	10/5
Cutoff/ concentration ng/mL	1000	300	300	300	1000	300	2000	100	25	300	1000	50
NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15

+25% of cutoff/ concentration ng/mL	1250	375	375	375	1250	375	2500	125	31.25	375	1250	62.5
#NEG/#POS	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15	0/15

e. *Analytical specificity:*

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into normal human urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the tables below:

Amphetamine	
Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	1000
l-amphetamine	25,000
d-l-amphetamine	10,000
B-Phenylethylamine	180,000
Tyramin	100000
(±)3,4-Methylenedioxyamphetamine ((±)3,4-MDA)	1200
(±)3,4-Methylenedioxyethylamphetamine ((±)3,4-MDA)	100000

Methamphetamine	
Drug Compound	Response equivalent to cutoff in ng/mL
d-Amphetamine	200000
l-Amphetamine	200,000
d-Methamphetamine	1000
(±)3,4-Methylenedioxyamphetamine ((±)3,4-MDA)	1000
(±)3,4-Methylenedioxyethylamphetamine ((±)3,4-MDA)	500

Morphine	
Drug compound	Response equivalent to cutoff in ng/mL
Morphine	2000

Morphine	
Drug compound	Response equivalent to cutoff in ng/mL
Morphine-3-β-D glucuronide	2000
Codeine	2000
Heroin	2000
Levorphanol	4000
6-Monoacetylmorphine	50
Hydromorphone	5000
Hydrocodone	20000
Oxycodone	60000
Ethylmorphine	50

Cocaine	
Compound	Response equivalent to cutoff in ng/mL
Benzoylcegonine	300
Cocaine	300
Cocaethylene	50

Cannabinoids (THC)	
Compound	Response equivalent to cutoff in ng/mL
Cannabinol	10000
11-Nor-Δ ⁸ -Tetrahydrocannabinol carboxylic acid	50
11-Nor-Δ ⁹ -Tetrahydrocannabinol carboxylic acid	50
Δ ⁸ -Tetrahydrocannabinol	7500
Δ ⁹ -Tetrahydrocannabinol	10000
11-hydroxy-Δ ⁹ -Tetrahydrocannabinol	2500

Phencyclidine	
Compound	Response equivalent to cutoff in ng/mL
Tenocyclidine	2000
Phencyclidine	25
4-Hydroxyphencyclidine	1000
Phencyclidine Morphine	5

Barbiturates	
Compound	Response equivalent to cutoff in ng/mL
Secobarbital	300
Allobarbital	600
Amobarbital	600
Barbital	300
Butobarbital	300
Butalbital	300
Pentobarbital	300
Phenobarbital	300

Benzodiazepines	
Compound	Response equivalent to cutoff in ng/mL
Alprazolam	600
Chlordiazepoxide	300
Diazepam	300
Oxazepam	300
Clonazepam	300
Flunitrazepam	300
Nitrazepam	250
Bromazepam	100
Clobazam	300
Estazolam	300
Flurazepam	150
Lorazepam	500
Lormetazepam	500
Clorazepate	200
Nordiazepam	150
Prazepam	1500
Temazepam	150
Delorazepam	3000
Triazolam	200

Methadone	
Compound	Response equivalent to cutoff in ng/mL
Methadone	300
Doxylamine	50000

Methadone	
Compound	Response equivalent to cutoff in ng/mL
EDDP	100000
Methadol	25000
Perphenazine	75000
Protriptyline	2000
Trimipramine	10000

Propoxyphene	
Compound	Response equivalent to cutoff in ng/mL
Propoxyphene	300
Norpropoxphene	1000
Methadone	1350000
2-ethyl-1,5-dimethyl 3,3-diphenylpyrroline	200000

Oxycodone	
Compound	Response equivalent to cutoff in ng/mL
Oxycodone-HCL	100
Morphine-Sulfate	7000
Codeine	700
Morphine 3-β-D glucuronide	40000
Hydromorphone	1500
Norcodeine	40000
Oxymorphone	300
Hydrocodone	500

Tricyclic Antidepressant (TCA)	
Compound	Response equivalent to cutoff in ng/mL
Amitriptyline	1000
Cyclobenzaprine	1500
Clomipramine	5000
Desipramine	600
Doxepin	1000
Imipramine	600

Tricyclic Antidepressant (TCA)	
Compound	Response equivalent to cutoff in ng/mL
Nortriptyline	1000
Nordoxepin	1000

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor added potentially interfering compounds to drug-free urine (to test for positive interference) and to urine samples at the cutoff concentration (to test for negative interference). All potential interferents were added at a concentration of 100 µg/mL. There were no deviations from the expected results.

Common Substances		
Acetaminophen	Diphenhydramine	(+/-) Naproxen
Acetone	5,5-Diphenylhydantoin	Nicotine
Acetylsalicylic Acid	Dopamine	Nor-Bupreorphine
Amikacin	EDDP	Noscapine Hydrochloride
Amitriptyline	+ Ephedrine	Oxalic Acid
Ampicillin	- Ephedrine	Omega-3-fatty acid
l-Ascorbic Acid	+/- Epinephrine	Penicillin-G
Aspartame	Erythromycin	Phenazine
Aspirin	Ethanol	l-Phenylephrine
Atropine	Fentanyl	(+/-) Phenylpropanolamine
Benzocaine	Fluoxetine	Promethazine
Benzoic Acid	Furosemide	Pseudoephedrine
Buprenorphine-3-β-D-glucuronide	Glucosamine	Quinine
(+)-Brompheniramine	Guaiacol Glyceryl Ether	Quinidine

Buprenorphine	Hydrochlorothiazide	Salicylic Acid
Caffeine	Hydrocodone	Sustiva
(+)-Chlorpheniramine	Ibuprofen	Sulindac
(+/-)- Chlorpheniramine	Ketamine	Theophylline
Chlorpromazine	Lidocaine	Thioridazine
Cortisone	Maprotiline	Tramadol
(-)-Cotinine	Meperidine	d(+)-Trehalose
Creatinine	Methanol	Trifluoperazine
Dextromethorphan	Methylphenidate	
4-Dimethylaminoantipyrine	Naltrexone	

The following endogenous compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor added potentially interfering compounds to drug-free urine (to test for positive interference) and to urine samples at the cutoff concentration plus 25% (to test for negative interference). There were no deviations from the expected results.

Substances	
Bilirubin	1.0 mg/dL
Creatinine	500 mg/dL
Glucose	1500 mg/dL
Hemoglobin	300 mg/dL
Potassium	110 mEq/dL
Human Serum Albumin	500 mg/dL
Globulin	1500 mg/dL
Sodium chloride	6000 mg/dL
Uric Acid	23 mg/dL
Cholesterol	500 mg/dL

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

Specific Gravity

Two drug free urine samples, one with a specific gravity of 1.030 and the other 1.003 were prepared. The samples were divided into two and one was spiked with drug concentration at 25% above the cutoff for all the analytes. Each sample was run in duplicate. The results demonstrate that a specific gravity range of 1.003 – 1.030 did not affect the expected or accuracy of the results.

pH

The pH of an aliquot negative urine pool was adjusted to a pH range of 4 to 9 in 1 pH increments for a total of six samples. Each of the samples was split into two samples to form a pair for each pH level. One of the paired samples from each set was spiked with drug concentration at 25% above the cutoff for all the analytes. Each sample was run on the device and the results demonstrate that varying ranges of pH dose not interfere with the performance of the test.

f. Assay cut-off:

The identified cutoff concentrations for amphetamine, cocaine, methamphetamine, opiates 2000, Phencyclidine and THC are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA has not recommended a cutoff concentration for Barbiturate, Benzodiazepine, Oxycodone, Propoxyphene and Tricyclic Antidepressant (TCA).

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision and detection sections above.

2. Comparison studies:

a. *Method comparison with predicate device:*

93-110 unaltered clinical urine samples, depending on the drug type, were evaluated. Specimens obtained from a reference laboratory were tested using the Forsure One Step Dip & Read Drug Screen Test and Gas Chromatography/Mass Spectrometry (GC/MS). Approximately 10% of samples had drug concentration between 50% below the cutoff and the cutoff concentration, another 10% of samples had drug concentration between the cutoff and 50% above the cutoff concentration.

	Candidate Device Results	Negative by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	% Agreement (among positives and negatives)
AMP	Positive	0	2	5	42	100%
	Negative	58	3	0	0	96.8%
MET	Positive	0	1	10	31	100%
	Negative	55	4	0	0	98.3%
BEG	Positive	0	1	17	25	100%
	Negative	49	4	0	0	98.1%
THC	Positive	0	1	6	36	100%
	Negative	50	3	0	0	98%
MOR	Positive	0	1	17	24	100%
	Negative	50	4	0	0	98%
PCP	Positive	0	4	16	24	100%
	Negative	50	3	0	0	93%
BZD	Positive	0	0	15	28	100%
	Negative	49	4	0	0	100%
MAD	Positive	0	0	9	33	100%
	Negative	48	4	0	0	100%
OXY	Positive	0	1	5	50	100%
	Negative	39	4	0	0	98%
TCA	Positive	0	1	18	23	100%
	Negative	38	4	0	0	98%
BAR	Positive	0	2	19	20	100%
	Negative	49	3	0	0	96%

	Candidate Device Results	Negative by GC/MS	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)	% Agreement (among positives and negatives)
PPX	Positive	0	2	19	24	100%
	Negative	53	2	0	0	96.3%

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):

Not applicable

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 Part 809.10.

O. Conclusion:

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