

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

A. 510(k) Number:

k071489

B. Purpose for Submission:

Previously cleared prescription use device expanding for over-the-counter (OTC) use

C. Measurand:

methamphetamine, amphetamine, opiates, cocaine, tetrahydrocannabinol, phen-
cyclidine, barbiturates, benzodiazepines, oxycodone, tricyclic antidepressants,
methadone

D. Type of Test:

qualitative, immunoassay, lateral flow

E. Applicant:

Tianjin, New Bay Bioresearch Company Limited

F. Proprietary and Established Names:

HomeCheck™ Multiple Drug Cup Test

G. Regulatory Information:

1. Regulation section:

862.3100, Amphetamine Test System
862.3150, Barbiturate Test System
862.3170, Benzodiazepine Test System
862.3870, Cannabinoids Test System
862.3250, Cocaine and Cocaine Metabolite Test System
862.3620, Methadone Test System
862.3610, Methamphetamine Test System
862.3650, Opiates and Oxycodone Test System
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product code:
DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM, LFH

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

HomeCheck™ Multiple Drug cup test device for Amphetamine (cutoff at 1000ng/ml), Methamphetamine (cutoff at 1000ng/ml), Benzoyllecgonine (cutoff at 300ng/ml), Benzodiazepine (cutoff at 300ng/ml for Oxazepam), Marijuana (cutoff at 50ng/ml), Morphine (cutoff at 2000ng/ml), Phencyclidine (cutoff at 25ng/ml), Methadone (cutoff at 300ng/ml), Oxycodone (cutoff at 100ng/ml), Tricyclic Antidepressant (cutoff at 1000 ng/ml for Nortriptyline HCl), and Barbiturates (cutoff at 300ng/ml for Secobarbital).

2. Indication(s) for use:

The assay provides a simple and rapid analytical screening procedure to detect single or multiple different abused drugs (Amphetamine, Methamphetamine, Benzoyllecgonine, Benzodiazepine, Marijuana, Morphine, Phencyclidine, Methadone, Oxycodone, Tricyclic Antidepressant, and Barbiturates in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS) is the preferred confirmatory method. HPLC is preferred confirmatory method for Tricyclic Antidepressant.

3. Special conditions for use statement(s):

This test is intended for over the counter (OTC) consumer use as the first step in a 2-step process to provide consumers with information concerning the presence or absence of the above stated drugs in a urine sample. Information regarding the confirmatory testing - the second step in the process-, along with materials for shipping the urine specimen to the laboratory is included with the test. There are no uniformly recognized levels for Benzodiazepine, Oxycodone, Tricyclic Antidepressant, and Barbiturates. The test is not intended to screen individuals who are prescribed these drugs by a physician; the test may yield positive results for individuals taking such drugs, as prescribed.

4. Special instrument requirements:

None

I. Device Description:

The test consists of chromatographic absorbent strips inserted within a sample collection cup and home use labeling with supplies and instructions for obtaining laboratory confirmation for preliminary positive results (at no additional cost).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Tianjin New Bay Forsure Rapid One Step Multiple(X) Abuse Drug Screen Test

2. Predicate K number(s):

k052882

3. Comparison with predicate:

The new device is for home use; the predicate device is for prescription use. Therefore, the new device provides users with additional instructions and supplies for obtaining confirmation. The physical device is the same as the predicate except that the home use device does not include propoxyphene, which is present on the professional use device.

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

None were referenced.

L. Test Principle:

As the test sample flows through the absorbent strip, the colloidal gold labeled antibody-conjugate binds to the free drug in the specimen forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the Test reaction zone, with the result that no color band is produced if there is drug in the sample above the detection levels (stated in the intended use). In addition, unbound colloidal gold-labeled antibody conjugate binds to the reagent in the negative control zone, producing a color band, to indicate that sufficient sample was added.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

All analytical performance characteristics were reviewed previously under k(052882). See <http://www.fda.gov/cdrh/reviews/k052882.pdf>. Therefore this current 510(k) submission includes the lay user study only. See 3.c. "other

clinical supportive data”, below, for results of the lay-user study.

a. Precision/Reproducibility:

b. Linearity/assay reportable range:

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

d. Detection limit:

e. Analytical specificity:

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). The SAMHSA has not recommended a cutoff concentration for Barbiturate, Benzodiazepine, Oxycodone, and Tricyclic Antidepressant (TCA). Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision and detection limit sections for the predicate (k052882). See <http://www.fda.gov/cdrh/reviews/k052882.pdf>

2. Comparison studies:

a. Method comparison with predicate device:

See 3.c., below

b. Matrix comparison:

Not applicable. The test is only for urine specimens.

3. Clinical studies:

a. Clinical Sensitivity:

Not typically reviewed for this device type.

b. Clinical specificity:

Not typically reviewed for this device type.

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

The HomeCheck One Step Drug Cup Screen test was performed and interpreted by 103 lay users using spiked, masked, urine samples.

Volunteers were selected as they presented themselves at the participating U.S. site. Participants represented diversity in age (20-72), gender (75% male), education (7% non-high school graduates; 69% high school graduates; 21% some college education; 6% post-graduate or technical) and occupation.

Each participant performed one multiple drug cup test using a spiked masked urine sample. Each sample contained a combination of drugs (4-6 drugs) at varying concentrations above and below the cutoff concentration. Drug concentrations in the samples included low negative, 50% below the cutoff, 25% below the cutoff, 25% above, 50% above, and high positive for each drug. Each participant performed the test independently using the proposed labeling, with no additional instructions, and recorded results for all 11 drugs in the test. After testing, the participants also answered questions to help evaluate whether the tests could be performed and interpreted by lay users. Test results are tabulated below compared to results of GCMS (and HPLC for TCA) for each drug.

Results for amphetamines:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
AMP	Positive	0	0	2	6	13	13	13	96.6	100
	Negative	29	15	12	0	0	0	0		

Results for barbiturates

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
BAR	Positive	0	0	2	12	13	14	15	95.8	98.2
	Negative	29	6	11	1	0	0	0		

Results for benzodiazepine :

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
BZD	Positive	0	0	1	14	15	14	6	98.1	98
	Negative	26	13	13	1	0	0	0		

Results for benzoylecgonine:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
COC	Positive	0	0	2	6	13	13	13	96.6	100
	Negative	29	15	12	0	0	0	0		

Results for methadone

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
MAD	Positive	0	0	2	13	6	13	13	96.5	97.8
	Negative	27	15	15	1	0	0	0		

Results for methamphetamine:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
MET	Positive	0	0	2	13	14	6	13	96.4	100
	Negative	26	14	15	0	0	0	0		

Results for morphine:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
OPI	Positive	0	0	2	13	6	13	13	96.5	97.8
	Negative	27	15	15	1	0	0	0		

Results for oxycodone:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
OXY	Positive	0	0	1	14	15	15	14	97.8	100
	Negative	19	13	12	0	0	0	0		

Results for phencyclidine:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
PCP	Positive	0	0	0	13	13	13	14	100	100
	Negative	30	14	6	0	0	0	0		

Results for tricyclic antidepressants:

HomeCheck Test Results By Lay User		HPLC Test Results							% Agreement with HPLC	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
TCA	Positive	0	0	3	13	14	15	15	96.4	100
	Negative	20	13	10	0	0	0	0		

Results for THC:

HomeCheck Test Results By Lay User		GC/MS Test Results							% Agreement with GC/ Mass	
		Low Negative	50% below Cutoff	25% Below Cutoff	Cutoff	25 % Above Cutoff	50 % Above Cutoff	High Positive	Negative	Positive
THC	Positive	0	0	2	15	14	6	13	96.3	100
	Negative	26	14	13	0	0	0	0		

Participant Procedure Questionnaire:

After testing, participants responded to surveys with questions to help determine whether participants understood test instructions.

These included questions to the participant on whether they had any difficulty running the test, reading it at the appropriate time, seeing the test line, and whether there was anything in the labeling that they found confusing. Participants were given the opportunity to rate various features of the labeling (clarity, illustration, directions) on a scale of 1-5. Responses indicated that 99-100% of participants felt the test was not difficult to run, read, or interpret, and that labeling was understandable.

Additional questions were included to address test interpretation issues such as test line darkness/faintness, importance of confirmation testing, and possibility for false positives from certain foods or drugs, as well as issues concerning testing and confirmation of prescription drugs. Participant

responses support that lay user participants generally understood how to run and interpret the screening test, including the importance of confirmation, and some of the issues concerning testing for prescription drugs.

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.