

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

A. 510(k) Number:

k130275

B. Purpose for Submission:

New device

C. Measurand:

3,4 Methylene-dioxy-methamphetamine (MDMA) & Opiates

D. Type of Test:

Qualitative lateral flow immunochromatographic competitive binding assay

E. Applicant:

Tianjin New Bay Bioresearch

F. Proprietary and Established Names:

QuikScreen Multi (MDMA and OPI) Drug Cup Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DJG	Class II	21CFR862.3650, Opiate test system	91-Toxicology
LAF	Class II	21CFR862.3610, Methamphetamine test system	91-Toxicology

H. Intended Use:

1. Intended use(s):

See Indications for Use

2. Indication(s) for use:

The QuikScreen™ Multi (MDMA and OPI) Drug Cup Test consists of competitive binding , lateral flow immunochromatographic assays and provides

a simple and rapid analytical screening procedure to simultaneously detect the drugs of abuse MDMA at or above the cutoff level of 500 ng/ml and OPI at or above the cutoff level of 300 ng/ml in human urine. The device is intended for prescription use and Over-The-Counter settings.

<u>Test</u>	<u>Calibrator</u>	<u>Cutoff</u>
Opiate	Morphine	300 ng/ml
MDMA	(+/-)-3,4Methylene-dioxymethamphetamine	500 ng/ml

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method. Clinical and professional judgment should be exercised with any drug of abuse test result, particularly when preliminary results are used. The assay does not distinguish whether OPI or MDMA is being taken therapeutically or abused.

3. Special conditions for use statement(s):

For Over-The-Counter (OTC) and prescription use
For in vitro diagnostic (IVD) use only.

4. Special instrument requirements:

Not applicable

I. Device Description:

The QuikScreen Multi (MDMA and OPI) Drug Cup Test is a device consisting of a specimen collection cup with a built-in strip holder which is able to hold MDMA and OPI test strips. The membrane of the drug test strip is coated with goat anti-mouse antibody and drug-bovine serum albumin conjugate. The sample pad of test strip contains a colloidal gold-labeled mouse monoclonal anti-drug (OPI or MDMA) antibody.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Wondfo Multi-Drug Urine Test Cup
Wondfo Multi-Drug Urine Test Panel

2. Predicate K number(s):

k121166

3. Comparison with predicate:

	Candidate QuikScreen Multi (MDMA and OPI) Drug Cup Test	Predicate Wondfo Multi- Drug Urine Test Cup and Test Panel(k121166)
Indications for Use	Same	Guanzhou Wondfo Biotech Co Multi-Drug Urine Test Cup and Test Panel are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of drugs of abuse in human urine
Sample Type	Same.	Urine
Type of Test	Same	Qualitative lateral flow immunochromatographic competitive binding assay
Test Format	Cup	Cup and Panel
Analyte and Cut-off	Same for MDMA and OPI	Multiple drugs of abuse analytes including MDMA (300 ng/mL) and OPI (500 ng/mL)

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

None

L. Test Principle:

The assay is based on lateral flow immunochromatographic technology. Drug (OPI or MDMA) in the urine sample competes with the colloidal gold labeled goat anti-mouse monoclonal antibody -conjugated for binding to drug protein conjugate in the test zone area.

If drug (OPI or MDMA) is present in the sample, the test sample flows through the absorbent device, and the colloidal gold labeled antibody-conjugate binds to the free drug in the specimen forming an antibody-conjugate in the test reaction zone

and will not produce a magenta color band when the drug is above the detection level (positive result). In the absence of drug (OPI or MDMA) in the sample, the drug-protein conjugate binds to labeled antibody and produces a magenta band in the test zone area (negative result).

The device also has an internal process control which indicates that adequate volume of sample has been added and that the immune-chromatographic device is intact. A goat anti-mouse antibody is also employed in the control line system. A negative specimen produces two distinct color bands in both the test line and control area. A positive specimen produces only one color band in the control area.

The absence or presence of a line is determined visually by the user. The tester will obtain a result in five minutes.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision (within lot) of the QuikScreen Multi (MDMA and OPI) Drug Cup Test was tested with one lot of the test device by one operator on one day. This consists of (90) replicates for each level of each drug standard (negative), -75% cutoff, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% of cutoff concentrations.

Within –lot precision for MDMA

MDMA Level (ng/mL)	Cut-off level	N	Expected	Percent Correct (%)
0	Neg	30	Negative	100
125	-75%	30	Negative	100
250	-50%	30	Negative	100
375	-25%	30	Negative	86.6
500	Cut-off	30	Positive	100
625	+25%	30	Positive	100
750	+50%	30	Positive	100
875	+75%	30	Positive	100
1000	+100%	30	Positive	100

Within lot precision for OPI

OPI Level ng/ml	Cut-off level	N	Expected	Percent Correct (%)
0	Neg	30	Negative	100
75	-75%	30	Negative	100
150	-50%	30	Negative	100
225	-25%	30	Negative	90
300	Cut-off	30	Positive	100
375	+25%	30	Positive	100
450	+50%	30	Positive	100
525	+75%	30	Positive	100
600	+100%	30	Positive	100

An inter lot precision test was performed on the three different lots of QuikScreen Multi (MDMA and OPI) Drug Cup Test Devices. Three lots of test devices were used by three different operators on 3 different days. This consists of (30) replicates of each level of of each drug standards (0, -75% cutoff , -50% cutoff , -25% cutoff, cutoff , +25 % cutoff ,+50% cutoff, +75 % cutoff and +100% cutoff) and performed by 3 operators at multiple day period.

Inter lot study for MDMA:

MDMA Conc.	Lot1				Lot 2				Lot 3			
	N	+	-	Correct %	N	+	-	Correct %	N	+	-	Correct %
0 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
125 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
250 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
375 ng/ml	30	4	26	86.6	30	4	26	86.6	30	2	28	93.3
500 ng/ml (Cut-off)	30	29	1	96.6	30	29	1	96.6	30	28	2	93.3
625 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
750 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
875 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
1000 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100

Inter- lot study for OPI

OPI Conc	Lot1				Lot 2				Lot 3			
	N	+	-	Correct %	N	+	-	Correct %	N	+	-	Correct %
0 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
75 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
150 ng/ml	30	0	30	100	30	0	30	100	30	0	30	100
225 ng/ml	30	3	27	90.0	30	4	26	86.6	30	1	29	96.6
300 ng/ml (Cut-off)	30	30	0	100	30	30	0	100	30	29	1	96.6
375 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
450 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
525 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100
600 ng/ml	30	30	0	100	30	30	0	100	30	30	0	100

b. *Linearity/assay reportable range:*

Not applicable, the device is intended for qualitative use

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

Stability protocols and acceptance criteria for the test device were reviewed and found acceptable. The sponsor demonstrated the MDMA and OPI drug cup device is stable for 24 months at 2-8 °C and 37 °C using accelerated and real time studies.

Commercially available quality controls are recommended for use in the labeling.

d. *Detection limit:*

Not applicable.

e. *Analytical specificity:*

Cross-reactivity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds is presented below:

Concentration of Opiate-related compounds that yield positive

results approximately equivalent to the Opiate 300 cutoff set for the test.

Minimum Concentration of Opiate Related Compounds Require to yield the positive result as cut off concentration	Test Result After Add drug related compounds to Drug free Urine	% of Cross reactivity
Morphine	300 ng/ml	100%
6-Acetylmorphine	300 ng/ml	100%
Codeine	300 ng/ml	100%
Ethylmorphine	5000 ng/ml	0.06%
Hydromorphone	6000 ng/ml	0.05%
Hydrocodone	6000 ng/ml	0.05%

Concentration of MDMA-related compounds that yield positive results approximately equivalent to the MDMA 500 cutoff set for the test.

Minimum Concentration of Opiate Related Compounds Require to Yield the Positive Result as Cut Off Concentration	Test Result After Add drug Related Compounds to Drug free Urine ng/ml	% of Cross Reactivity
3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
D-Amphetamine	1×10^6	0.005%
(D)-Methamphetamine	5×10^5	0.01%
L-Methamphetamine	5×10^5	0.01%
3,4-Mthylenedioxyethylamphetamine(MDEA)	5000	0.005%
3,4-Methylenedioxyamphetamine(MDA)	5000	0.005%
p-Methoxyamphetamine (PMA)	5×10^5	0.01%

In order to examine potential naturally occurring interfering substances in urine, drug negative urine (-25 % cutoff) and drug positive urine (+25 % cutoff) were spiked with various potentially interfering substances. Both aliquots were tested with QuikScreen™ Multi (MDMA and OPI) Drug Cup Test Device. There was no interference from the following substances at the concentration listed in Table below:

The effect on OPI and MDMA test device with natural occurring endogenous substances

Interfering Substances	Final Concentration	OPI		MDMA	
		225 ng/ml Results	375 ng/ml Result	375 ng/ml Results	625 ng/ml Result
Ascorbic Acid	300 mg/dl	-	+	-	+
Bilirubin	1.0 mg/dl	-	+	-	+
Creatine	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	-	+	-	+

A study was conducted with QuikScreen™ Multi (MDMA and OPI) drug cup 1 to determine the cross-reactivity of non-drug related compounds with the test at concentrations much higher than normally found in the urine of people using or abusing drugs. Non-drug related compounds (100µg/ml) were spiked into the urine containing -25 % cutoff of drug (negative) and +25 % cutoff of drug (positive). No cross reactivity with MDMA or OPI test device were detected with the substances spiked in the either negative or positive urine in the table below:

Compounds tested and found not to cross react with the test at a 100µg/ml concentration in urine:

Acetaminophen	Methylphenidate	Phenylpropanolamine
Acetylsalicylic Acid	Histamine	l-Phenylephrine
Amikacin	*2-Ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine.	Pentobarbital
Amitriptyline	Hydrochlorothiazide	d-Propoxyphene

Ampicillin	Methadone	l-Propanol
Arterenol	Methaqualone	Quinine
Aspartame	Nalorphine	Phendimetrazine
Benzoic Acid	Naloxone	Penicillin G
Benzoyllecgonine .HCl	Naltrexone	Pentobarbital
Caffeine	Noroxycodone	d-Propoxyphene
Chlorpheniramine	Noroxymorphone	l-Propanol
Chlorpromazine .HCl	Lansoprazol	Phencyclidine
Cimetidine	Oxazepam	Phenobarbital
Deoxyephedrine	Oxymorphone	Phentermine
Dextromethorphan	Oxycodone	Phenylpropanolamine
Diazepam	Phendimetrazine	l-Phenylephrine
Diethylpropion	Penicillin G	Quinine
5,5Dihydrocodeine	Pentobarbital	Sodium Salicylate
Doxylamine	d-Propoxyphene	Sulindac
Ecgonine .HCl	l-Propanol	Tryptophan

The sponsor provided studies to show that the QuikScreen™ Multi (MDMA and OPI) Drug Cup Test device performance at the cutoff level is not affected by any urine samples with a pH ranging from 4.0 to 8.5 and specific gravity ranging from 1.005 to 1.030. The protocols and data were reviewed and found to be acceptable.

f. Assay cut-off:

The assay cutoff characterization study was performed by using QuikScreen Multi (MDMA and OPI) Drug Cup Test. The study samples were made by using OPI or MDMA stock solution confirmed by GC/MS and diluting in drug-free urine. Results are shown in the tables below:

OPI (ng/ml)	QuikScreen OPI Drug Cup Test Results	
	No. of positive /Total sample	% Positive Urine
0	0/15	0.0 %
75 (-75 %)	0/15	0.0 %
150(-50 %)	0/15	0.0%
225(-25%)	2/15	13.3%
270 (-10 %)	7/15	46.6 %
300 (Cutoff)	15/15	100 %
330 (+10 %)	15/15	100%
375 (+25 %)	15/15	100 %
450 (+50%)	15/15	100 %
525 (+75%)	15/15	100 %
600 (+100%)	15/15	100 %

MDMA (ng/ml)	QuikScreen MDMA Drug Cup Test Results	
	No. of positive /Total sample	% Positive Urine
0	0/15	0.0 %
125 (-75 %)	0/15	0.0 %
250(-50 %)	0/15	0.0%
375(-25%)	1/15	6.6%
450(-10 %)	8/15	53.3%
500 (Cutoff)	15/15	100 %
550 (+10 %)	15/15	100%
625 (+25 %)	15/15	100 %
750 (+50%)	15/15	100 %
875 (+75%)	15/15	100 %
1000 (+100%)	15/15	100 %

2. Comparison studies:

a. Method comparison with predicate device:

A method comparison study was performed using positive and negative unaltered clinical urine specimens. Samples were collected from 80 negative drug free urine specimens, 80 OPI positive patient's urine specimens, and 130 MDMA positive specimens. Each urine specimen was tested with the QuikScreen Multi (MDMA and OPI) Drug Cup Test and the reference method (GC-MS or LC-MS). The results are summarized as follows:

Agreement between QuikScreen™ One Step OPI Drug Cup Test Results to Reference Methods Results are shown in the table below:

Drug Test		Drug free patient Urine Negative	Negative To <-50%	Near cutoff Negative. (-50% to Cutoff	Near cutoff Positive (+50% to Cutoff)	Positive (>+50% Cutoff	% Agreement with Reference Methods	
		0 ng/ml	0 to 150 ng/ml	150 – 300 ng/ml	300 – 450 ng/ml	>450 ng/ml	Negative (-)	Positive (+)
QuikScreen OPI Drug Cup test	Positive (+)	0	0	5	17	43	96.3 %	100%
	Negative (-)	80	10	15	0	0		

Discordant Patient Specimens of Morphine Drug test from QuikScreen (MDMA and Morphine) Cup test is summarized as follows:

Patients ID #	Morphine Reference value ng/ml	QuikScreen Cup test Result Positive/Negative Cutoff Value 300 ng/ml	
		Expected	Observed
Patient 104 (M4)	261 ng/ml	Negative	Positive
Patient 105 (M15)	265 ng/ml	Negative	Positive
Patient 106 (M27)	267 ng/ml	Negative	Positive
Patient 107 (M30)	273 ng/ml	Negative	Positive
Patient 168	293 ng/ml	Negative	Positive

Agreement between QuikScreen™ One Step MDMA Drug Cup Test Results to reference methods Results are shown in the table below:

Drug Test		Drug Free Patient Urine Negative	Negative To <-50%	Near cutoff Negative. (-50% to Cutoff)	Near cutoff Positive (+50% to Cutoff)	Positive (>+50% Cutoff)	%Agreement With Reference Methods	
		0 ng/ml	0 to 250 ng/ml	250 – 500 ng/ml	500 – 750 ng/ml	>750 ng/ml	Negative (-)	Positive (+)
QuikScreen MDMA Drug Cup test	Positive (+)	0	0	6	10	43	96.1 %	98.1%
	Negative (-)	80	51	19	1	0		

Discordant Patient Specimens of MDMA Drug test from QuikScreen (MDMA and Morphine) Cup test is summarized as follows:

Patients ID #	MDMA Reference Test Results ng/ml	QuikScreen Cup test Result Positive/Negative Cutoff Value 500 ng/ml	
		Expected	Observed
Patient 150 (AA021)	422.8 ng/ml	Negative	Positive
Patient 153 (AA020)	441.4 ng/ml	Negative	Positive
Patient 154 (AA033)	445.4 ng/ml	Negative	Positive
Patient 155 (AA034)	470.8 ng/ml	Negative	Positive
Patient 156 (AA028)	472.5 ng/ml	Negative	Positive
Patient 157 (AA036)	478.7 ng/ml	Negative	Positive
Patient 158 (AA038)	510.5 ng/ml	Positive	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):

A lay user study was performed with 104 lay persons. Participants in the study (65 females and 39 Males) tested the MDMA and Opiate samples. They had diverse educational and professional backgrounds and ranged in age from 26 to 66. Urine samples were prepared at the following concentrations; negative, +/-

75%, +/-50%, and +/-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 aliquotted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample, and a device. The results are summarized below.

Drug	Concentration	Number of samples	OTC user		%Agreement With Reference Test
			Negative	Positive	
MDMA	Negative	104	104	0	100 %
	-75 %	104	104	0	100 %
	-50%	104	104	0	100 %
	-25%	104	93	11	89.4 %
	Cutoff	104	4	100	96.1 %
	+25%	104	0	104	100 %
	+50%	104	0	104	100 %
	+75%	104	0	104	100 %
	+100%	104	0	104	100 %

Drug	Concentration	Number of samples	OTC user		%Agreement With Reference Test
			Negative	Positive	
OPI	Negative	104	104	0	100 %
	-75 %	104	104	0	100 %
	-50%	104	104	0	100 %
	-25%	104	93	11	89.4 %
	Cutoff	104	1	103	99 %
	+25%	104	0	104	100 %
	+50%	104	0	104	100 %
	+75%	104	0	104	100 %
	+100%	104	0	104	100 %

The labeling is rated at 8.3 grade reading level per Flesch-Kincaid methodology. All participants(100%) indicated on the questionnaire that the instructions are clear and that they do not find the QuikScreen™ Multi (MDMA and OPI) Drug Cup Test difficult to operate.

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.