

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

**A. 510(k) Number:**

k112236

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Methylenedioxyamphetamine (MDMA), Morphine

**D. Type of Test:**

Qualitative lateral flow chromatographic Immunoassay

**E. Applicant:**

Guangzhou Wondfo Biotech Co., Ltd.

**F. Proprietary and Established Names:**

Wondfo Methylenedioxyamphetamine Urine Test

Wondfo Morphine Urine Test

**G. Regulatory Information:**

<b>Product Code</b>	<b>Classification</b>	<b>Regulation Section</b>	<b>Panel</b>
LAF	Class II	21 CFR §862.3610: Methamphetamine test system	Toxicology (91)
DJG	Class II	21 CFR §862.3650: Opiate test system	Toxicology (91)

**H. Intended Use:**

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

Wondfo Methylenedioxyamphetamine Urine Test:

Wondfo Methylenedioxyamphetamine Urine Test is an immunochromatographic assay for the qualitative determination of MDMA in human urine at a cutoff concentration of 500 ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS 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.

Wondfo Morphine Urine Test:

Wondfo Morphine Urine Test is an immunochromatographic assay for the qualitative determination of MDMA in human urine at a cutoff concentration of 300 ng/mL. The test is available in a dip card format and a cup format. It is intended for prescription use and over the counter use.

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a conformed analytical result. GC/MS 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.

3. Special conditions for use statement(s):

For prescription and over the counter use.

4. Special instrument requirements:

Not applicable, as the devices are visually-read single-use devices.

**I. Device Description:**

Wondfo Methylenedioxyamphetamine Urine Test:

Two Different Formats:

- 1) Urine cups with built in test device and reaction activation key
- 2) Urine cups with dip card

Wondfo Morphine Urine Test:

Two Different Formats:

- 1) Urine cups with built in test device and reaction activation key
- 2) Urine cups with dip card

Wondfo® Methylenedioxymethamphetamine and morphine urine DOA test kits contain 25 tests (urine cups with built in test device, reaction activation key/ urine cups with dip card) per kit. Each kit contains 25 security sealed labels and a leaflet with instructions for use. For over the counter test kits, the following are contained with each kit: 25 labeled vials for shipping a “preliminary” sample to be confirmed by a lab, 25 plastic transportation bags, 25 mailing boxes, and 25 personal identification numbers.

Material Required but not provided: Timer, external urine controls

**J. Substantial Equivalence Information:**

1. Predicate Device Name:

Acon Laboratories, Inc. One Step Drug Screen Test

Acon Laboratories, Inc. MDMA One Step Ecstasy Test

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

k020771, k022589

3. Comparison with predicate:

<b>Similarities and Differences</b>		
	<b>Candidate Device:</b>	<b>Predicate Devices:</b>
Intended Use/ Indications for Use	Qualitative detection of drugs-of-abuse in urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on the principle of antigen antibody immunochemistry	Same
Type of Test	Immunoassay	Same

Device Design/ Performance	Positive Result	A rose-pink band in the control region	Same
	Negative result	A rose-pink band visible in the control region and the test region	Same
	Detection reagent	Ovalbumin Conjugate	Same
Accuracy Assessment	Anti-mouse IgG Polyclonal antibody (control line reagent)	Same	
Results		Qualitative	Same
Cut-off		Morphine 300 ng/mL Methylenedioxymethamphetamine 500 ng/mL	Same
Configurations		Cup, dip card	Card, dip card with an integrated cup for Morphine  Strip, device for MDMA

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

None were referenced.

**L. Test Principle:**

Wondfo Methylenedioxymethamphetamine and Morphine Urine Tests are a one-step lateral flow immunoassay containing a conjugate pad with colloidal gold with anti-drug antibodies, a nitrocellulose membrane, with a test line (T) and a control line (C). The T line is coated with drug antigen bound to duck egg protein and the C line is coated with goat anti-mouse IgG polyclonal antibodies. The test is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of sample is applied, the sample migrates through the test device by capillary action. If the concentration of drug is below the cutoff level, the anti-drug antibodies in the colloidal gold particles will bind to the drug antigens coated in the

test zone producing a band which indicates a negative result. If the drug concentration is at the cutoff level or higher no band will form in the test zone (test line T) indicating a preliminary positive. A band should form in the control region regardless of the presence of drug or metabolite in the sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision study was conducted by three operators. Three different lots were tested for morphine and methamphetamine using 12 devices/ lot at each control level of negative, -75%, -50%, -25%, cut-off, +25%, +50%, and +75% of the cut-off. Samples were prepared, concentrations of each sample confirmed by GC/MS, and then each sample was divided into 300 aliquots. The 300 sample aliquots were divided into 12 sets of 25 for each test format (cup/dipcard). The study was conducted over a 25 day period and ran 3 batches of each test format (cup/dipcard) in 2 runs/day. Each device was tested and interpreted by the same operator. Summaries are presented in the following tables:

Methylenedioxymethamphetamine (MDMA):

**A. Cup Format**

Result MDMA	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	Cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LOT W1260901CU	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1260902CU	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1260903CU	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

**B. Dip card Format**

Result MDMA	- 100% cut off	-75% Cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% Cut off	+100% cut off
LOT W1260901P	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1260902P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1260903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Morphine:

**A. Cup Format**

<b>Result</b> <b>MOP</b>	<b>-100% cut off</b>	<b>-75% cut off</b>	<b>-50% cut off</b>	<b>-25% Cut off</b>	<b>cut off</b>	<b>+25% cut off</b>	<b>+50% cut off</b>	<b>+75% cut off</b>	<b>+100% cut off</b>
<b>LOT W1460901CU</b>	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
<b>LOT W1460902CU</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
<b>LOT W1460903CU</b>	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

**B. Dip card Format**

<b>Result</b> <b>MOP</b>	<b>- 100% cut off</b>	<b>-75% cut off</b>	<b>-50% cut off</b>	<b>-25% cut off</b>	<b>Cut off</b>	<b>+25% Cut off</b>	<b>+50% cut off</b>	<b>+75% cut off</b>	<b>+100% cut off</b>
<b>LOT W1460901P</b>	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
<b>LOT W1460902P</b>	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
<b>LOT W1460903P</b>	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

*b. Linearity/assay reportable range:*

Not applicable, the assay is intended for qualitative use.

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

This device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Control standards are not supplied with this device; however it is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

*Stability:*

Accelerated stability and real time stability tests were performed on three batches of cups and dip card strips for the Wondfo Methylenedioxymethamphetamine (MDMA) and Morphine Urine tests. Accelerated stability was performed at 50°C and the data submitted supports an 18 month shelf life. Real time studies were performed by storing three lots

of cups and dip card strips at 4°C and 30°C. Performance tests were completed at defined intervals and the results support a 24 month shelf life at 4°C for both MDMA and morphine urine tests and a shelf life of 23 months when stored at 30°C.

*d. Detection limit:*

Analytical performance of the device around the cutoff is described in Section f. (Assay cut-off) below.

*e. Analytical specificity:*

To evaluate specificity of the urine Methylenedioxymethamphetamine (MDMA) and morphine urine devices, three batches of urine samples were tested by taking 30 negative urine samples and spiking these samples with three different analyte concentration levels. Two different groups of operators were assigned to test blinded urine samples (three operators tested the cup format and three operators tested the dip stick format). Percent cross reactivity of a compound was calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result and multiplying by 100%. Summary of the results are as follows:

**MDMA**

<b>Methylenedioxymethamphetamine (MDMA) (3,4- Methylenedioxymethamphetamine HCl, Cutoff =500 ng/mL)</b>	<b>Result Positive at 500 ng/mL</b>	<b>% Cross- Reactivity 100%</b>
3,4- Methylenedioxymethamphetamine HCl (MDA)	Positive at 3,000 ng/mL	16.7%
3,4- Methylenedioxymethamphetamine	Positive at 300 ng/mL	166.7%

**MOP:**

<b>MOP(Morphine) (Morphine, Cutoff=300 ng/mL)</b>	<b>Result Positive at 300 ng/mL</b>	<b>% Cross- Reactivity 100%</b>
Codeine	Positive at 300 ng/mL	100%
Ethyl Morphine	Positive at 300 ng/mL	100%
Hydrocodone	Positive at 5,000 ng/mL	6%
Hydromorphone	Positive at 5,000 ng/mL	6%
Morphine – 3 – β – d - glucuronide	Positive at 1,000 ng/mL	30%
Thebaine	Positive at 30,000 ng/mL	1%

**Interference Studies:**

Interference studies were performed using the cup and dipcard tests using urine controls at +/-25% of each analyte cut-off concentration. Potential interferences to the Wondfo Methylenedioxymethamphetamine (MDMA) and morphine urine cup and dipcard tests were evaluated by adding various drugs, drug metabolites, and other compounds (structurally unrelated and

endogenous compounds) that are commonly found in the urine which may interfere with testing results. The following compounds were found not to cross react when tested at concentrations of 100 µg/mL.

MDMA:

4-Acetamidophenol	(L) – Epinephrine	Perphenazine
Acetophenetidin	Erythromycin	Phencyclidine
N-Acetylprocainamide	β-Estradiol	Phenelzine
Acetylsalicylic acid	Estrone-3-sulfate	Phenobarbital
Aminopyrine	Ethyl-p-aminobenzoate	Phentermine
Amitriptyline	Fenoprofen	Trans-2-phenylcyclopropylamine hydrochloride
Amobarbital	Furosemide	L-Phenylephrine
Amoxicillin	Gentisic acid	β-Phenylethylamine
Ampicillin	Hemoglobin	Phenylpropanolamine
L-Ascorbic acid	Hydralazine	Prednisolone
Apomorphine	Hydrochlorothiazide	Prednisone
Aspartame	Hydrocodone	Procaine
Atropine	(±) – Isoproterenol	Promazine
Benzilic acid	Hydrocortisone	Promethazine
Benzoic acid	O-Hydroxyhippuric acid	DL-Propranolol
Benzoyllecgonine	3-Hydroxytyramine	D-Propoxyphene
Bilirubin	Ibuprofen	D-Pseudoephedrine
(±) - Brompheniramine	Imipramine	Quinacrine
Buspiron	Iproniazid	Quinidine
Caffeine	Isoxsuprine	Quinine
Cannabidiol	Ketamine	Ranitidine
Cannabinol	Ketoprofen	Salicylic acid
Chloralhydrate	Labetalol	Secobarbital
Chloramphenicol	Levorphanol	Serotonin (5-Hydroxytyramine)
Chlordiazepoxide	Loperamide	Sulfamethazine
Chlorothiazide	Maprotiline	Sulindac
(±) - Chlorpheniramine	Meperidine	Sustiva
Chlorpromazine	Meprobamate	Temazepam
Chlorquine Methylphenidate	Methadone	Tetracycline
Cholesterol	Morphine-3-β-Dglucuronide	Tetrahydrocortisone, 3-acetate
Clomipramine	Morphine sulfate	Tetrahydrocortisone 3-

		(β-Dglucuronide)
Clonidine	Nalidixic acid	Tetrahydrozoline
Cocaethylene	Naloxone	Thebaine
Cocaine hydrochloride	Naltrexone	Theophylline
Codeine	Naproxen	Thiamine
Cortisone	Niacinamide	Thioridazine
(-) Cotinine	Nifedipine	Tolbutamide
Creatinine	Nimesulidate	Trans-2-phenylcyclopropylamine
Deoxycorticosterone	Norcodein	Trazodone
Dextromethorphan	Norethindrone	Triamterene
Diclofenac	D-Norpropoxyphene	DL-Tyrosine
Diazepam	Noscapine	Trifluoperazine
Diflunisal	D,L-Octopamine	Trimethoprim
Digoxin	Oxalic acid	Trimipramine
Dicylomine	Oxazepam	Tryptamine
Diphenhydramine	Oxolinic acid	D L-Tryptophan
5,5 – Diphenylhydantoin	Oxycodone	Tyramine
Doxylamine	Oxymetazoline	Uric acid
Ecgonine hydrochloride	Papaverine	Verapamil
Ecgonine methylester	Penicillin-G	Zomepirac
(-) – Ψ-Ephedrine	Pentazocinehydrochloride	
[1R,2S](-) Ephedrine	Pentobarbital	

#### Morphine

4-Acetamidophenol	Ecaonine dydrochloride	Perphenazine
Acetophenetidin	Ecqonine methylester	Phencyclidine
N-Acetyprocainamide	(-)-Ψ-Ephedrine	Phenelzine
Acetylsalicylic acid	Fenoprofen	Phenobarbital
Aminopyrine	Furosemide	Phentermine
Amityptvline	Gentisic acid	L-Phenylephrine
Amorbarbital	Hemoglobin	β-Phenylethylamine
Amoxicillin	Hydrocortisone	Phenylpropanotamine
Ampicillin	O-Hydroxyhippuric acid	Prednisone
l-Ascorbic Acid	p-Hydroxy-methamphetamine	D.L-Propranolol

D.L-Amphetamine	3-Hydroxytyramine	D-Propoxyphene
Apomorphine	Ibuprofen	D-Pseudoephedrine
Aspartame	Imipramine	Quinine
Atropine	Iproniazid	Ranitidine
Benzillic acid	(±)Isoproterenol	Salicylic acid
Benzoic acid	Isoxsuprine	Secobarbital
Benzoylcaonine	Ketamine	Serotonin (5-Hydroxytyramine)
Benzphetamine	Ketoprofen	Sulfamethazine
Bilirubin	Labetalol	Sulindac
Caffeine	Loperamide	Temazepam
Cannabidiol	Maprotiline	Tetrahydrocortisone,3 Acetate
Chloralhydrate	Meperidine	Tetrahydrocortisone,(β-D glucuronide)
Chloramphenicol	Meprobamate	Tetrahydrozoline
Chlordiazepoxide	Methadone	Thiamine
Chlorothiazide	Methoxyphenamine	Thioridazine
(±)Chlorpheniramine	(-) 3,4-Methylenedioxy-amphetamine	D.L-Tyrosine
Chlorpromazine	(-)3,4-Methylenedioxy-methamphetamine	Tolbutamide
Chlorquine	Nalidixic acid	Triamterene
Cholesterol	Nalorphine	Trifluoperazine
Clomipramine	Naloxone	Trimethoprim
Clonidine	Naltrexone	Triyptamine
Cocaine hydrochloride	Naproxen	D.L-Tryptophan
Cortisone	Niacinamide	Yramine
(-)cotinine	Nifedipine	Uric acid
Creatinine	Norethindrone	Verapamil
Dextromethlorphan	D-Norpropoxyphene	Zomepirac
Diazepam	Noscapine	
Diclofenac	D.L-Octopamine	
Diflunisal	Oxalic acid	
Diaoxin	Oxazepam	
Diphenhydramine	Oxolinic acid	
Doxylamine	Pentobarbital	

pH:

The pH of an aliquoted negative urine pool was adjusted to pH 4, pH 5, pH 6, pH 7, pH 8, or pH 9 was spiked with +/- 25% of the cut-off concentration of MDMA and Morphine. Each was individually tested using three batches of

strips and three batches of the cup format. The spiked, pH-adjusted urine was tested in triplicate. Varying the pH did not affect the accuracy of each test format (dipcard and cup).

**Specific Gravity:**

Twelve drug-free urine samples with specific gravities (1.000-1.035) and spiked with +/- 25% of the cut-off concentration of MDMA and Morphine using three batches of strips and three batches of the cup format. The spiked urine samples were tested in triplicate. The results show that varying the specific gravity does not affect the accuracy of each test format (dipcard and cup).

*f. Assay cut-off:*

The assay cut off established by collecting 25 clinical urine samples containing +/- 50% of the morphine cutoff of 300 ng/ml and 25 clinical urine samples containing +/- 50% of the Methylenedioxymethamphetamine (MDMA) cutoff of 500 ng/mL. Additionally, 125 drug-free clinical urine samples spiked with cocaine and 125 drug-free clinical urine samples spiked with methamphetamine were both diluted from the International Drug Standard (Sigma) to concentrations: -50%, -25%, cutoff, +25%, and +50% of the morphine cutoff 300 ng/mL and Methylenedioxymethamphetamine (MDMA) cutoff 500 ng/mL. The clinical urine samples were collected from the Shenzhen Drug Addiction Recovery Center and drug concentrations were confirmed by GC/MS. Results were read by three laboratory assistants with relevant experience. There cutoff studies were performed by two separate groups of operators (one for the dipcard format and one for the cup format). Three operators in each group performed the readings and they were blinded to the samples. Each result was confirmed by two other assistants. The results of the study are as follows:

**a. Cup Format: MDMA**

Concentration (ng/mL)	Cut-off range	n	Batch1		Batch2		Batch3		Total	
			-	+	-	+	-	+	-	+
250	-50% cutoff	30	30	0	30	0	30	0	90	0
375	-25% cutoff	30	30	0	30	0	30	0	90	0
500	Cutoff	30	5	25	5	25	2	28	12	78
625	+25% cutoff	30	0	30	0	30	0	30	0	90
750	+50%	30	0	30	0	30	0	30	0	90

b. DipCard

MDMA

Concentration (ng/mL)	Cut-off range	n	Batch1		Batch2		Batch3		Total	
			-	+	-	+	-	+	-	+
250	-50% cutoff	30	30	0	30	0	30	0	90	0
375	-25% cutoff	30	30	0	30	0	30	0	90	0
500	Cutoff	30	4	26	4	26	3	27	11	79
625	+25% cutoff	30	0	30	0	30	0	30	0	90
750	+50%	30	0	30	0	30	0	30	0	90

a. Cup Format

Morphine

Concentration (ng/mL)	Cut-off range	n	Batch1		Batch2		Batch3		Total	
			-	+	-	+	-	+	-	+
150	-50% cutoff	30	30	0	30	0	30	0	90	0
225	-25% cutoff	30	30	0	30	0	30	0	90	0
300	Cutoff	30	4	26	4	26	3	27	11	79
375	+25% cutoff	30	0	30	0	30	0	30	0	90
450	+50%	30	0	30	0	30	0	30	0	90

b. DipCard

Morphine

Concentration (ng/mL)	Cut-off range	n	Batch1		Batch2		Batch3		Total	
			-	+	-	+	-	+	-	+
150	-50% cutoff	30	30	0	30	0	30	0	90	0
225	-25% cutoff	30	30	0	30	0	30	0	90	0
300	Cutoff	30	2	28	4	26	5	25	11	79
375	+25% cutoff	30	0	30	0	30	0	30	0	90

450	+50%	30	0	30	0	30	0	30	0	90
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The cut-off values were determined to be:

Test	Calibrator	Cut-off (ng/mL)
Methylenedioxyamphetamine (MDMA)	3,4 - Methylenedioxyamphetamine HCl	500
Morphine (MOP)	Morphine	300

## 2. Comparison studies:

### a. *Method comparison with predicate device:*

Performance of the Wondfo Methylenedioxyamphetamine (MDMA) and Morphine Urine Tests (dipcard and cup formats) were established by comparing 80 samples (40 positive and 40 negative) of each analyte against GC/MS. Ten of the 80 samples came from drug-free urine samples. Each result was read by three laboratory assistants and a lay person. All urine samples were collected at the Shenzhen Drug Addiction Recovery Center. A summary of results comparing the results of the lay person to the experienced person are as follows:

### MDMA:

Cup Format:

Wondfo Device Result		Drug-Free urine	<-50% of the cut-off	Near cutoff (Between -50% and cutoff)	Cut-off to +50% of the cut-off	>+ 50% of the cut-off
Viewer A	+	0	0	2	20	20
	-	10	10	18	0	0
Viewer B	+	0	0	2	20	20
	-	10	10	18	0	0
Viewer C	+	0	0	1	20	20
	-	10	10	19	0	0
Lay Person	+	0	0	3	20	20
	-	10	10	17	0	0

Dipcard:

Wondfo Device Result		Drug-Free urine	<-50% of the cut-off	Near cutoff (Between	Cut-off to +50% of the cut-off	>+ 50% of the cut-off

				-50% and cutoff)		
Viewer A	+	0	0	2	20	20
	-	10	10	18	0	0
Viewer B	+	0	0	2	20	20
	-	10	10	18	0	0
Viewer C	+	0	0	2	20	20
	-	10	10	18	0	0
Lay Person	+	0	0	3	20	20
	-	10	10	17	0	0

**Morphine:**

Cup Format:

Wondfo Device Result		Drug-Free urine	<-50% of the cut-off	Near cutoff (Between -50% and cutoff)	Cut-off to +50% of the cut-off	>+ 50% of the cut-off
Viewer A	+	0	0	1	20	20
	-	10	19	10	0	0
Viewer B	+	0	0	2	20	20
	-	10	19	9	0	0
Viewer C	+	0	0	1	20	20
	-	10	19	10	0	0
Lay Person	+	0	0	3	20	20
	-	10	19	8	0	0

Dipcard:

Wondfo Device Result		Drug-Free urine	<-50% of the cut-off	Near cutoff (Between -50% and cutoff)	Cut-off to +50% of the cut-off	>+ 50% of the cut-off
Viewer A	+	0	0	2	20	20
	-	10	19	9	0	0
Viewer B	+	0	0	2	20	20
	-	10	19	9	0	0
Viewer C	+	0	0	1	20	20
	-	10	19	10	0	0
Lay Person	+	0	0	2	20	20
	-	10	19	9	0	0

A summary of discordant results are as follows:

**MDMA:**

Cup Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	MDMAC33	405	+
Viewer A	MDMAC63	497	+
Viewer B	MDMAC63	497	+
Viewer B	MDMA 218	402	+
Viewer C	MDMAC33	405	+
Lay person	MDMAC33	405	+
Lay person	MDMAC63	497	+
Lay person	MDMA 218	402	+

Dipcard:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	MDMAC33	405	+
Viewer A	MDMA 218	402	+
Viewer B	MDMAC33	405	+
Viewer B	MDMA 218	402	+
Viewer C	MDMAC33	405	+
Viewer C	MDMAC63	497	+
Lay person	MDMAC33	405	+
Lay person	MDMAC61	490	+
Lay person	MDMA 218	402	+

**Morphine:**

Cup Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	MOPC32	227	+
Viewer B	MOPC64	292	+
Viewer B	MOPC65	285	+
Viewer C	MOPC65	285	+
Lay person	MOPC32	227	+
Lay person	MOPC64	292	+
Lay person	MOPC65	285	+

Dipcard:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	MOPC64	292	+
Viewer A	MOPC65	285	+

Viewer B	MOPC32	227	+
Viewer B	MOPC64	292	+
Viewer C	MOPC32	227	+
Lay person	MOPC32	227	+
Lay person	MOPC64	292	+

The results indicate a similar positive, negative, and overall agreement rates for both morphine and methamphetamine using the cup and dipcard formats.

The overall agreement between the Wondfo devices and GC/MS is represented in the following table:

The agreement between Wondfo devices and GC/MS method

% Agreement	MDMA(cup)	MDMA (Dipcard)	MOP (Cup)	MOP (Dipcard)
Positive	100%	100%	100%	100%
Negative	95.8%	95.0%	96.7%	95.8%
Total	97.9%	97.5%	98.4%	97.9%

The agreement between lay person and experience viewer:

% Agreement	MDMA (cup)	MDMA (Dipcard)	MOP (Cup)	MOP (Dipcard)
Positive	100%	100%	100%	100%
Negative	96.6%	97.4%	95.6%	99.2%
Total	98.3%	98.7%	97.8%	99.6%

*b. Lay-User Study:*

A lay-user study was performed to assess the suitability of the device for home use. Six drug-free urine sample pools were spiked with +75%, +50%, +25%, -25%, -50%, and -75% of the cutoff for MDMA and morphine. Additionally, a negative urine pool with no drug was tested. The six spiked urine samples and the negative urine pool concentrations were confirmed by GC/MS and aliquoted into 40 individual containers per concentration (n=280 aliquots, 20 aliquots per concentration per test format). Testing was performed at three sites by 140 blinded consumers divided between three sites (140 lay-users for the cup format and 140 lay-users for the dipcard format). The lay users were chosen from likely intended users at the Shenzhen Drug Addiction Recovery Center, Baiyun Drug Addiction Recovery Voluntary Center, and Guangdong Provincial No. 2 People's Hospital. Each participant received the package insert, 1 blinded sample, and either a cup or dipcard test format. The lay persons test result was compared to the GC/MS result to demonstrate accuracy by lay-users. The following are the results of the lay-user study:

**MDMA:**

Comparison between GC/MS and lay person results for Cup format

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	149.5	0	20	100
-50% Cutoff	20	237.9	0	20	100
-25% Cutoff	20	408.6	3	17	85.0
+25% Cutoff	20	608.8	19	1	95.0
+50% Cutoff	20	786.7	20	0	100
+75% Cutoff	20	911.8	20	0	100

Comparison between GC/MS and lay person results for Dip card format

% of Cutoff	Number of samples	MDMA Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	149.5	0	20	100
-50% Cutoff	20	237.9	0	20	100
-25% Cutoff	20	408.6	2	18	90.0
+25% Cutoff	20	608.8	19	1	95.0
+50% Cutoff	20	786.7	20	0	100
+75% Cutoff	20	911.8	20	0	100

**Morphine:**

Comparison between GC/MS and lay person results for Cup format

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	80.7	0	20	100
-50% Cutoff	20	169.5	0	20	100
-25% Cutoff	20	236.4	3	17	85.0
+25% Cutoff	20	390.7	18	2	90.0
+50% Cutoff	20	439.8	20	0	100
+75% Cutoff	20	548.6	20	0	100

Comparison between GC/MS and lay person results for Dip card format

% of Cutoff	Number of samples	Morphine Concentration by GC/MS (ng/mL)	Lay person results		The percentage of correct results (%)
			No. of Positive	No. of Negative	
-100% Cutoff	20	0	0	20	100
-75% Cutoff	20	80.7	0	20	100
-50% Cutoff	20	169.5	0	20	100
-25% Cutoff	20	236.4	2	18	90.0
+25% Cutoff	20	390.7	19	1	95.0
+50% Cutoff	20	439.8	20	0	100
+75% Cutoff	20	548.6	20	0	100

The overall percent agreement between the Lay person and the GC/MS method:

% Agreement	MDMA (cup)	MDMA(dipcard)	MOP (cup)	MOP (dipcard)
Total	97.1%	97.8%	96.4%	97.8%

c. Lay-User Questionnaire:

Cup Format:

**Morphine:**

The participant's ages ranged from 21 to 63, and there were slightly more females than males. There was a variety of occupational and educational backgrounds and three of the lay-users had used a drug kit before. All participants understood the storage and expiration of the device and that the test could not be reused. They all understood that they could not insert and rotate the key until they were ready to test. They all read the test results at 5 minutes (none after 5 minutes) and all understood how to interpret the results.

Clarity of the package insert

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for use	60	79	1	0
Interpretation of results	71	69	0	0

Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	51	89	0	0

None of the participants responded that the test was not easy to do.

**MDMA:**

The participant's ages ranged from 22 to 63, and there were more males than females. There was a variety of occupational and educational backgrounds and one of the lay-users had used a drug kit before. All participants understood the storage and expiration of the device and that the test could not be reused. They all understood that they could not insert and rotate the key until they were ready to test. They all read the test results at 5 minutes (none after 5 minutes) and all understood how to interpret the results.

## Clarity of the package insert

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for use	77	63	0	0
Interpretation of results	81	59	0	0

## Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	80	58	2	0

Two of the participants responded that the test was not easy to do.

## ii. Dipcard Format:

**Morphine:**

The participant's ages ranged from 24 to 60, and there were slightly more males than females. There was a variety of occupational and educational backgrounds and one of the lay-users had used a drug kit before. All participants understood the storage and expiration of the device and that the test could not be reused. They all understood that the dipcard couldn't be immersed in urine above the marker line and understood the storage and expiration of the device and that the test could not be reused. They all read the test results at 5 minutes (none after 5 minutes) and all understood how to interpret the results.

## Clarity of the package insert

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for use	60	80	0	0
Interpretation of results	79	61	0	0

## Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	64	75	1	0

Only one of them responded that the test was not easy to do.

## MDMA:

The participant's ages ranged from 23 to 61, and there were slightly more males than females. There was a variety of occupational and educational backgrounds and none of the lay-users had used a drug kit before. All participants understood the storage and expiration of the device and that the test could not be reused. They all understood that the dipcard couldn't be immersed in urine above the marker line and understood the storage and expiration of the device and that the test could not be reused. They all read the test results at 5 minutes (none after 5 minutes) and all understood how to interpret the results.

### Clarity of the package insert

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for use	77	63	0	0
Interpretation of results	82	58	0	0

### Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	64	75	1	0

Only one of them responded that the test was not easy to do.

Additionally, a Flesch-Kincaid reading analysis revealed that both package inserts had a reading grade level of 7.

*c. Matrix comparison:*

Not applicable; these devices are for use with urine only.

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.