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

A. 510(k) Number:

k112071

B. Purpose for Submission:

New Device

C. Measurand:

Cocaine, Methamphetamine

D. Type of Test:

Qualitative lateral flow chromatographic Immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Cocaine Urine Test

Wondfo Methamphetamine Urine Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIO	Class II	21 CFR §862.3250: Cocaine and Cocaine Metabolites Test System	Toxicology (91)
LAF	Class II	21 CFR §862.3610: Methamphetamine Test System	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

Wondfo Cocaine Urine Test:

Wondfo Cocaine Urine Test is an immunochromatographic assay for the qualitative determination of Benzolecgonine 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.

Wondfo Methamphetamine Urine Test:

Wondfo Methamphetamine Urine Test is an immunochromatographic assay for the qualitative determination of D(+)-Methamphetamine in human urine at a cutoff concentration of 1000 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 Cocaine Urine Test:

Two Different Formats:

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

Wondfo Methamphetamine Urine Test:

Two Different Formats:

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

Wondfo Cocaine and methamphetamine 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.

Materials required but not provided: Timer, external urine controls

J. Substantial Equivalence Information:

1. Predicate Device Name: Acon Laboratories, Inc. One Step Drug Screen Test

2. Predicate 510(k) Number(s): k020771

Similarities and Differences			
		Candidate Devices: Wondfo Cocaine Urine Test and Wondfo Methamphetamine Urine Test (k112071)	**Predicate Devices:** Acon Laboratories, Inc. One Step Drug Screen Test (k020771)
Indication for use/ Intended Use		Qualitative detection of drugs-of- abuse in urine	Same
Intended Users		Prescription and Over the Counter Use.	Prescription Use
Specimen		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

		A rose-pink band visible in the control region and the test region	Same
	Negative result		
	Detection reagent	Ovalbumin Conjugate	Same
	Accuracy Assessment	Anti-mouse IgG Polyclonal antibody (control line reagent)	Same
Results		Qualitative	Same
Cut-off		Cocaine 300 ng/mL Methamphetamine 1000 ng/mL	Same
Configurations		Cup, dip card	Card, dip card with an integrated cup
Read time		5 minutes	Same
Storage		4 – 30°C	Same

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

None were referenced.

L. Test Principle:

Wondfo Methamphetamine and Cocaine Urine Tests are one-step lateral flow immunoassays 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. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

The precision study was conducted by three operators. Three different lots were tested for cocaine and methamphetamine using 12 devices/ lot at each control level of negative, -75%, -50%, -25%, cut-off, +25%, +50%, +75%, and +100% 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:

The results summary is below:

Cocaine:

A. Cup Format

Result / COC	-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 W1060901CU	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1060902CU	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1060903CU	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

B. Dip card Format

Result / COC	-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 W1060901P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1060902P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1060903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

Methamphetamine:

A. Cup Format

Result / MET	-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 W1160901CU	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

Result / MET	-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 W1160902CU	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**45+/5-**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
LOT W1160903CU	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**45+/5-**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**

B. Dip card Format

Result / MET	-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 W1160901P	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**45+/5-**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
LOT W1160902P	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**44+/6-**	**50+/0-**	**50+/0-**	**50+/0-**	**50+/0-**
LOT W1160903P	**50-/0+**	**50-/0+**	**50-/0+**	**50-/0+**	**46+/4-**	**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 Methamphetamine and Cocaine Urine tests. Accelerated stability and real time stability studies were performed and the results support Wondfo's claimed shelf life of 23 months at 4°C and 30ºC for the cocaine urine tests and a shelf life of 24 months at 4ºC and 30ºC for the methamphetamine urine tests.

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 cocaine and methamphetamine 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:

Cocaine

COC(Cocaine) (Benzoylecgonine, Cutoff=300ng/mL)	**Result Positive at 300 ng/mL**	**% Cross-Reactivity 100%**
Cocaine HCl	Positive at 750 ng/mL	40%
Cocaethylene	Positive at 12,500 ng/mL	2.4%
Ecgonine	Positive at 32,000 ng/mL	<1%

Met:

MET(Methamphetamine) (D(+)-Methamphetamine, Cutoff=1000 ng/mL)	**Result** Positive at 1,000 ng/mL	**% Cross-Reactivity** 100%
D-Amphetamine	Positive at 50,000 ng/mL	2%
Chloroquine	Positive at 50,000 ng/mL	2%
(+/-)-Ephedrine	Positive at 50,000 ng/mL	2%
(-)-Methamphetamine	Positive at 25,000 ng/mL	4%
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	Positive at 2,000 ng/mL	50%
β-Phenylethylamine	Positive at 50,000 ng/mL	2%
Trimethobenzamide	Positive at 10,000 ng/mL	10%

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 cocaine and methamphetamine 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.

Cocaine:

Cortisone	Methadone	Quinidine	
(-) Cotinine	Methoxyphenamine	Quinine	
Acetominophen	Digoxin	Naltrexone	Temazepam
Acetophenetidin	(±)-3,4-Methylene dioxyamphetamine	Naproxen	Tetracycline
N-Acetylprocainamide	Diphenhydramine hydrochloride	Nicotinamide	Tetrahydrocortisone, 3-Acetate
Deoxycorticosterone	(±)-3,4-Methylene dioxymethamphetamine hydrochloride	Niacinamide	Tetrahydrocortisone 3-(β-D glucuronide)
Acetylsalicylic acid	Doxylamine	Salicylic acid	Tetrahydrozoline
Adenosine	Ergonine methylester	Nifedipine	Thebaine
Dextromethorphan	Morphine-3-β-D glucuronide	Norcodeine	Thiamine
Amitryptyline	(-) - Ψ-Ephedrine	Secobarbital	Thioridazine
Diazepam	Erythromycin	Norethindrone	DL-Tyrosine
Amobarbital	Morphine Sulfate	Serotonin	Tolbutamide
Diclofenac	β-Estradiol	D-Norpropoxyphene	Triamterene
Amoxicillin	Nalidixic acid	Sulfamethazine	Trifluoperazine
Diflunisal	Estrone-3-sulfate	Noscapine	Trimethoprim
Ampicillin	Naloxone	Sulindac	Trimipramine
L-Ascorbic acid	Ethyl-p-aminobenzoate	DL-Octopamine	Tryptamine
DL-Amphetamine Sulfate	Furosemide	Oxalic acid	DL-Tryptophan
Apomorphine	Gentisic acid	Oxazepam	Tyramine
Aspartame	Hemoglobin	Oxolinic acid	Uric acid
Atropine	Hydralazine	Oxycodone	Verapamil
Benzilic acid	Hydrochlorothiazide	Oxymetazoline	Zomepirac
Benzoic acid	Hydrocodone	Papaverine	
Benzphetamine	Hydrocortisone	Penicillin-G	
Bilirubin	O-Hydroxyhippuric acid	Pentobarbital	
(±) - Brompheniramine	p-Hydroxymethamphetamine	Perphenazine	
Caffeine	3-Hydroxytyramine	Phencyclidine	
Cannabidiol	Ibuprofen	Phenelzine	
Cannabinol	Imipramine	Phenobarbital	
Chloralhydrate	Iproniazid	Phentermine	
Chloramphenicol	(±) – Isoproterenol	L-Phenylephrine	
Chlordiazepoxide	Isoxsuprine	β-Phenylethylamine	
Chlorothiazide	Ketamine	Phenylpropanolamine	
(±) - Chlorpheniramine	Ketoprofen	Prednisolone	
Chlorpromazine	Labetalol	Prednisone	
Chlorquine	Levorphanol	Procaine	
Cholesterol	Loperamide	Promazine	
Clomipramine	Maprotiline	Promethazine	
Clonidine	Meperidine	DL-Propranolol	
Codeine	Meprobamate	D-Propoxyphene	
		D-Pseudoephedrine	

Methamphetamine

Acetamidophen	Estrone-3-sulfate	Noroxymorphone	Thioridazine
Acetophenetidin	Ethyl-p-aminobenzoate	D-Norpropoxyphene	Tolbutamine
N-Acetylprocainamide	Fenoprofen	Noscapine	Triamterene
Acetylsalicylate	Furosemide	Nylidrin	Trifluoperazine
Aminopyrine	Gentisic acid	D,L-Octopamine	Trimethoprim
Amitryptyline	Glucuronide	Oxalic acid	Trimipramine
Amobarbital	Glutethimide	Oxazepam	D, L-Tryptophan
Amoxicillin	Guaifenesin	Oxolinic acid	Tyramine
Ampicillin	Hippuric acid	Oxycodone	D, L-Tyrosine
Apomorphine	Hydralazine	Oxymetazoline	Uric acid
Aspartame	Hydrochlorothiazide	Papaverine	Verapamil
Atropine	Hydrocodone	Penicillin-G	Zomepirac
Benzilic acid	Hydrocortisone	Pentazocine	
Benzoic acid	O-Hydroxyhippuric acid	Pentobarbital	
Benzoylecgonine	3-Hydroxytyramine	Perphenazine	
Butabartital	Ibuprofen	Phencyclidine	
Cannabidiol	Imipramine	Phenelzine	
Chloralhydrate	(-) Isoproterenol	Phenobarbital	
Chloramphenicol	Isoxsuprine	Prednisolone	
Chlordiazepoxide	Ketamine	Phenylpropanolamine	
Chlorothiazide	Ketoprofen	Prednisone	
Chlorpromazine	Labetalol	Procaine	
Cholesterol	Levorphanol	Promazine	
Clomipramine	Loperamide	Promethazine	
Clonidine	Loxapine succinate	D,L-Propanolol	
Cocaine hydrochloride	Maprotiline	D-Propoxyphene	
Codeine	Meperidine	D-Pseudoephedrine	
Cortisone	Meprobamate	Quinidine	
(-) Cotinine	Methadone	Quinine	
Creatinine	Methaqualone	Ranitidine	
Deoxycorticosterone	Methylphenidal	Salicylic acid	
Dextromethorphan	Methyprylon	Secobarbital	
Diazepam	Morphine-3-β-Dglucuronide	Serotonin (5-Hydroxytyramine)	
Diclofenac	Nalidixic acid	Sulfamethazine	
Diflunisal	Nalorphine	Sulindac	

Digoxin	Naloxone	Temazepam	
Diphenhydramine	Naltrexone	Tetracycline	
Doxylamine	Naproxen	Tetrahydrocortisone, 3-Acetate	
Ecgonine hydrochloride	Niacinamide	Tetrahydrocortisone 3 (β-D glucuronide)	
Ecgonine methyl ester	Nifedipine	Tetrahydrozoline	
Erythromycin	Norcodein	Thebaine	
β-Estradiol	Norethindrone	Thiamine	

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 benzoylecgonine and D(+) – Methamphetamine. 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 benzoylecgonine and D (+) – Methamphetamine 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 cocaine cutoff of 300 ng/ml and 25 clinical urine samples containing +/- 50% of the methamphetamine cutoff of 1000 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 cocaine cutoff 300 ng/mL and methamphetamine cutoff 1000ng/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:

Cocaine

a. Cup Format:

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	3	27	2	28	3	27	8	82
375	+25% cutoff	30	0	30	0	30	0	30	0	90
450	+50% cutoff	30	0	30	0	30	0	30	0	90

b. DipCard Format

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	3	27	3	27	3	27	9	81
375	+25% cutoff	30	0	30	0	30	0	30	0	90
450	+50% cutoff	30	0	30	0	30	0	30	0	90

Methamphetamine

a. Cup Format

Concentration (ng/mL)	Cut-off range	n	Batch1		Batch2		Batch3		Total	
			-	+	-	+	-	+	-	+
500	-50% cutoff	30	30	0	30	0	30	0	90	0
750	-25% cutoff	30	30	0	30	0	30	0	90	0
1000	Cutoff	30	3	27	3	27	2	28	8	82
1250	+25% cutoff	30	0	30	0	30	0	30	0	90

1500	+50% cutoff	30	0	30	0	30	0	30	0	90

b. DipCard Format

Concentration (ng/mL)	**Cut-off range**	**n**	**Batch1**		**Batch2**		**Batch3**		**Total**	
			-	+	-	+	-	+	-	+
500	-50% cutoff	30	30	0	30	0	30	0	90	0
750	-25% cutoff	30	30	0	30	0	30	0	90	0
1000	Cutoff	30	4	26	5	25	2	28	11	79
1250	+25% cutoff	30	0	30	0	30	0	30	0	90
1500	+50% cutoff	30	0	30	0	30	0	30	0	90

The cut-off values were determined to be:

Test	Calibrator	Cut-off (ng/mL)
Cocaine	Benzoylecgonine	300
Methamphetamine	D-Methamphetamine	1,000

2. Comparison studies:

a. *Method comparison with predicate device:*

Performance of the Wondfo Cocaine and Methamphetamine 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:

Cocaine:

Cup Format:

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

				cutoff)		
Viewer A	+	0	0	1	11	29
	-	10	10	19	0	0
Viewer B	+	0	0	2	11	29
	-	10	10	18	0	0
Viewer C	+	0	0	2	11	29
	-	10	10	18	0	0
Lay Person	+	0	0	2	11	29
	-	10	10	18	0	0

Dipcard 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	11	29
	-	10	10	18	0	0
Viewer B	+	0	0	1	11	29
	-	10	10	19	0	0
Viewer C	+	0	0	2	11	29
	-	10	10	18	0	0
Lay Person	+	0	0	3	11	29
	-	10	10	17	0	0

Methamphetamine:

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	16	13	0	0
Viewer B	+	0	0	2	20	20
	-	10	16	12	0	0
Viewer C	+	0	0	1	20	20
	-	10	16	13	0	0
Lay Person	+	0	0	3	20	20
	-	10	16	11	0	0

Dipcard 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	16	13	0	0
Viewer B	+	0	0	2	20	20
	-	10	16	12	0	0
Viewer C	+	0	0	2	20	20
	-	10	16	12	0	0
Lay Person	+	0	0	2	20	20
	-	10	16	12	0	0

A summary of discordant results are as follows:

Cocaine:

Cup Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	COC 209	212	+
Viewer B	COC C35	222	+
Viewer B	COC 219	241	+
Viewer C	COC 210	292	+
Viewer C	COC 219	241	+
Lay person	COCC35	222	+
Lay person	COC 219	241	+

Dipcard Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	COC 209	212	+
Viewer A	COC C35	222	+
Viewer B	COC 210	292	+
Viewer C	COC 219	241	+
Viewer C	COC C35	222	+
Lay person	COC C35	222	+
Lay person	COC 210	292	+
Lay person	COC 219	241	+

Methamphetamine:

Cup Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	METC92	914	+
Viewer B	METC34	819	+
Viewer B	METC92	914	+
Viewer C	METC34	819	+
Lay person	METC34	819	+
Lay person	METC92	914	+
Lay person	METC94	986	+

Dipcard Format:

Viewer	Sample Number	GC/MS result	Viewer Result
Viewer A	METC34	819	+
Viewer B	METC34	819	+
Viewer B	METC92	914	+
Viewer C	METC92	914	+
Viewer C	METC94	986	+
Lay person	METC92	914	+
Lay person	METC94	986	+

The results indicate a similar positive, negative, and overall agreement rates for both cocaine 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	COC (cup)	COC (Dipcard)	MET (Cup)	MET (Dipcard)
Positive	100%	100%	100%	100%
Negative	95.8%	95.8%	96.7%	95.8%
Total	97.9%	97.9%	98.4%	97.9%

The agreement between lay person and experience viewer:

% Agreement	COC (cup)	COC (Dipcard)	MET (Cup)	MET (Dipcard)
Positive	100%	100%	100%	100%
Negative	99.2%	96.6%	95.6%	99.2%
Total	99.6%	98.3%	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 cocaine and

methamphetamine. 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, Guangzhou Red Cross Hospital, and Guangzhou Mental 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:

Cocaine:

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

% of Cutoff	Number of samples	Benzoylecgonine 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	71.5	0	20	100
-50% Cutoff	20	169.4	0	20	100
-25% Cutoff	20	208.5	2	18	90.0
+25% Cutoff	20	398.6	19	1	95.0
+50% Cutoff	20	475.6	20	0	100
+75% Cutoff	20	508.3	20	0	100

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

% of Cutoff	Number of samples	Benzoylecgonine 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	71.5	0	20	100
-50% Cutoff	20	169.4	0	20	100
-25% Cutoff	20	208.5	2	18	90.0
+25% Cutoff	20	398.6	18	2	90.0
+50% Cutoff	20	475.6	20	0	100
+75% Cutoff	20	508.3	20	0	100

Methamphetamine:

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

% of Cutoff	Number of samples	D(+)-Methamphetamine 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	269.5	0	20	100
-50% Cutoff	20	542.6	0	20	100
-25% Cutoff	20	700.1	2	18	90.0
+25% Cutoff	20	1280.8	17	3	85.0
+50% Cutoff	20	1582.4	20	0	100
+75% Cutoff	20	1828.2	20	0	100

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

% of Cutoff	Number of samples	D(+)-Methamphetamine 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	269.5	0	20	100
-50% Cutoff	20	542.6	0	20	100
-25% Cutoff	20	700.1	2	18	90.0
+25% Cutoff	20	1280.8	19	1	95.0
+50% Cutoff	20	1582.4	20	0	100
+75% Cutoff	20	1828.2	20	0	100

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

% Agreement	COC (cup)	COC(dipcard)	MET (cup)	MET (dipcard)
Total	97.8%	97.1%	96.4%	97.8%

c. Lay-User Questionnaires:

i. Cup Format:

Cocaine:

The participant's ages ranged from 23 to 62, and there were slightly more females than

males. There was a variety of occupational and educational backgrounds and two of the lay-users had used a home 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	64	76	0	0
Interpretation of results	80	60	0	0

Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	86	52	2	0

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

Methamphetamine:

The participant's ages ranged from 23 to 61, and there were slightly more females than males. There was a variety of occupational and educational backgrounds and two of the lay-users had used a home 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	69	71	0	0
Interpretation of results	86	54	0	0

Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	92	48	0	0

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

ii. Dipcard Format:

Cocaine:

The participant's ages ranged from 22 to 60, 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 home 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	74	66	0	0

Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	70	69	1	0

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

Methamphetamine:

The participant's ages ranged from 22 to 67, 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 home 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	67	73	0	0
Interpretation of results	80	60	0	0

Clarity of test simplicity

Remarks	Very easy	Easy	Difficult	Very difficult
Number	69	69	2	0

Only two 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 8.

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.