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

A. 510(k) Number:

k161214

B. Purpose for Submission:

New Device

C. Measurand:

Amphetamine, Cocaine and Methamphetamine

D. Type of Test:

Qualitative Lateral Flow chromatographic immunoassay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Amphetamine Urine Test AMP 500 (Cup, DipCard)
Wondfo Cocaine Urine Test COC 150 (Cup, DipCard)
Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIO	Class II	21 CFR, 862.3250 Cocaine Test System	Toxicology (91)
DKZ	Class II	21 CFR, 862.3100 Amphetamine Test System	Toxicology (91)
DJC	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 Amphetamine Urine Test AMP 500 Cup is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

   Wondfo Amphetamine Urine Test AMP 500 DipCard is an immunochromatographic assay for the qualitative determination of Amphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Amphetamine (calibrator).

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

   Wondfo Cocaine Urine Test COC 150 Cup is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 150 ng/mL. This test is calibrated to Benzoylecgonine (calibrator).

   The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their

metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Cocaine Urine Test COC 150 DipCard is an immunochromatographic assay for the qualitative determination of Benzoylecgonine in human urine at a Cut-Off concentration of 150 ng/mL. This test is calibrated to Benzoylecgonine (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Methamphetamine Urine Test MET 500 Cup is an immunochromatographic assay for the qualitative determination of Methamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

Wondfo Amphetamine Urine Test MET 500 DipCard is an immunochromatographic assay for the qualitative determination of Methamphetamine in human urine at a Cut-Off concentration of 500 ng/mL. This test is calibrated to d-Methamphetamine (calibrator).

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed 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. For in vitro diagnostic use only. This test is intended for over-the-counter (OTC) consumer use as the first step in a two-step process to provide consumers with information concerning the presence or absence of the above stated drugs or their metabolites in a urine sample. Information regarding confirmatory testing- the second step in the process, is provided in the package labeling.

3. Special conditions for use statement(s):

   For in vitro diagnostic use only, for over-the-counter use.

4. Special instrument requirements:

   Not applicable. The devices are visually read single-use devices.

I. Device Description:

Wondfo Amphetamine Urine Tests, Wondfo Cocaine Urine Tests and Wondfo Methamphetamine Urine Tests are immunochromatographic assays that use a lateral flow system for the qualitative detection of d-amphetamine, Benzoylecgonine or d-methamphetamine (target analyte) in human urine. It is a single-use visually read in vitro diagnostic device, which comes in the format of DipCard or Cup. The product contains a Test Device (in one of the two formats), a package insert and a urine cup. Each test and format is available separately. Each test device is sealed with a desiccant in an aluminum pouch.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Advin Multi-Drug Screen Test

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

   k122809

3. Comparison with predicate:

Similarities		
Item	Candidate Device k161214 Wondfo Amphetamine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Calibrator	d-Amphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same

Similarities		
Item	Candidate Device k161214 Wondfo Amphetamine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL	Same
Intended Use	For over-the-counter use.	Same

Differences		
Item	Candidate Device k161214 Wondfo Amphetamine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Indication(s) for Use	For the qualitative determination of d-amphetamine in human urine.	For the qualitative determination of multiple drugs in human urine.
Configurations	Cup and Dip Card	Cup, Dip Card, Cassette

Similarities		
Item	Candidate Device k161214 Wondfo Cocaine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Calibrator	Benzoylecgonine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	150 ng/mL	Same
Intended Use	For over-the-counter use.	Same

Differences		
Item	Candidate Device k161214 Wondfo Cocaine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Indication(s) for Use	For the qualitative determination of Benzoylecgonine in human urine.	For the qualitative determination of multiple drugs in human urine.
Configurations	Cup and Dip Card	Cup, Dip Card, Cassette

Similarities		
Item	Candidate Device k161214 Wondfo Methamphetamine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Calibrator	d-methamphetamine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen antibody immunochemistry.	Same
Type of Test	Qualitative	Same
Specimen Type	Human Urine	Same
Cut-Off Values	500 ng/mL	Same
Intended Use	For over-the-counter use.	Same

Differences		
Item	Candidate Device k161214 Wondfo Methamphetamine Urine Test	Predicate device k122809 Advin Multi-Drug Screen Test
Indication(s) for Use	For the qualitative determination of d-methamphetamine in human urine.	For the qualitative determination of multiple drugs in human urine.
Configurations	Cup and Dip Card	Cup, Dip Card, Cassette

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

In Vitro Diagnostic Devices; Guidance for the Preparation of 510(k) Submission, HHS Publication FDA 97-4224.

Premarket Submission and labeling Recommendations for Drugs of Abuse Screening Tests, Draft Guidance, December 2, 2003.

L. Test Principle:

Wondfo Amphetamine Urine Tests, Wondfo Cocaine Urine Tests and Wondfo Methamphetamine Urine Tests use a lateral flow, one step system for the qualitative detection of d-Amphetamine, Benzoylecgonine or d-Methamphetamine in human urine. Each assay uses a monoclonal antibody-dye conjugate against drugs with gold chloride and fixed drug-protein conjugates and anti-mouse IgG polyclonal antibody in membranes.

When the absorb end is immersed into the urine specimen, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target Cut-Off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target Cut-Off, the free drug in the sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly because of the antibody-dye conjugate binding to anti-mouse IgG immobilized in the Control Region(C) of the device.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Precision studies were carried out for Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests using samples with concentrations of -100% cut off, -75% cut off, -50% cut off, -25% cut off, +25% cut off, +50% cut off , +75% cut off and +100% cut off. These samples were prepared by spiking drug in negative samples. Each drug concentration was confirmed by GC/MS. All sample aliquots were blindly labeled and randomized. For each concentration, tests were performed by six operators in two runs per day for 25 days per device. The results obtained are summarized in the following tables:

Amphetamine (AMP) Dip Card Format

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

Amphetamine (AMP) Cup Format

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine (COC) Dip Card Format

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

Cocaine (COC) Cup Format

Lot Number	-100% cut off	-75% cut off	-50% cut off	-25% cutoff	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) precision performance data are found in k122961.

b. Linearity/assay reportable range:

Not applicable.

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

Device stability for Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests has been evaluated through accelerated and real-time studies. A transport simulation study was performed to test extreme shipping temperatures. Protocols and acceptance criteria were reviewed and found to be acceptable. The manufacturer claims that the devices are stable at 4-30 °C

(39-86°F) for 24 months.

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) stability performance data are found in k122961. The manufacturer claims that the devices are stable at 4-30 °C (39-86°F) for 18 months.

This device has internal process controls. A colored line appearing in the control region confirms that sufficient sample volume and that the correct technique has been used. Users are instructed that the test is invalid if a colored line failed to appear in the control region. External control materials are not supplied with these devices; however the labeling provides information on how to obtain quality control materials.

d. Detection limit:

Not applicable.

e. Analytical specificity:

To test specificity of Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests, drug metabolites and other components that are likely to interfere in urine samples were tested by three operators using three lots of each device. The lowest concentration that caused a positive result for each compound device are listed below. There were no differences observed for the cup and dipcard test formats.

Amphetamine

Compound	**Concentration (ng/mL)**	**% Cross-reactivity**
d- Amphetamine	500	100%
l - Amphetamine	25000	2%
d,l - Amphetamine	1500	33%
Phentermine	1500	33%
Hydroxyamphetamine	8000	6%
Methylenedioxyamphetamine (MDA)	2500	20%
d-Methamphetamine	Negative at 100000	<1%
1-Methamphetamine	Negative at 100000	<1%
ephedrine	Negative at 100000	<1%
Methylenedioxyethylamphetamine (MDEA)	Negative at 100000	<1%
3,4-methylenedioxy-methamphetamine (MDMA)	Negative at 100000	<1%

Cocaine

Compound	Concentration (ng/mL)	% Cross-reactivity
Benzoylecogonine	150	100%
Cocaine HCl	375	40%
Cocaethylene	6250	2.4%
Ecgonine	16000	0.9%
Norcocaine	Positive at 50000	0.3%

Methamphetamine

Compound	Concentration (ng/mL)	% Cross-reactivity
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	500	100%
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	500	100%
d/l-Methamphetamine	500	100%
l-Methamphetamine	10,000	5%
l-Amphetamine	37,500	1.3%

Additional cross reactivity performance data forWondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) are found in k122961.

For Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 25% below and 25% above Cut-Off levels. These urine samples were tested by three operators using three lots of each device. Compounds that showed no interference at a concentration of 100μg/mL are summarized in the following tables. There were no differences observed for the cup and dipcard test formats.

Amphetamine

4-Acetamidophenol	L-Ephedrine	Oxycodone
Acetophenetidin	(-) Y Ephedrine	Oxymetazoline
N-Acetylprocainamide	Erythromycin	Papaverine
Acetylsalicylic acid	β-Estradiol	Penicillin-G
Aminopyrine	Estrone-3-sulfate	Pentazocaine
Amitryptyline	Ethyl aminobenzoate	Pentobarbital
Amobarbital	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine

Ascorbic acid	Gentisic acid	Phenobarbital
Aspartame	Hemoglobin	Phetoin
Atropine	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	Phenylpropanolamine
Benzoic acid	Hydrocodone	Prednisolone
Benzoylecgonine	Hydrocortisone	Prednisone
Bilirubin	O-Hydroxyhippuric acid	Procaine
Brompheniramine	3-Hydroxytyramine	Promazine
Caffeine	Ibuprofen	Promethazine
Cannabidiol	Imipramine	D,L-Propanolol
Cannabinol	(-) Isoproterenol	D-Propoxyphene
Chloralhydrate	Isoxsuprine	Quinidine
Chloramphenicol	Ketamine	Quinine
Chlordiazepoxide	Ketoprofen	Ranitidine
Chlorothiazide	Labetalol	Salicylic acid
(±) Chlorpheniramine	Levorphanol	Secobarbital
Chlorpromazine	Loperamide	Sulfamethazine
Chloroquine	Maprotiline	Sulindac
Cholesterol	Meperidine	Temazepam
Clomipramine	Meprobamate	Tetracycline
Clonidine	Methadone	Tetrahydrocortisone
Cocaine hydrochloride	Methylphenidate	Tetrahydrozoline
Codeine	Morphine-3-D-glucuronide	Δ9-THC-COOH
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	D,L-Octopamine	D, L-Tyrosine
Ecgonine hydrochloride	Oxalic acid	Uric acid
Ecgonine methylester	Oxazepam	Verapamil
(IR,2S)-(-)-Ephedrine	Oxolinic acid	Zomepirac

Cocaine

Acetaminophen	Estrone-3-sulfate	Oxymetazoline
Acetophenetidin	Ethyl-p-aminobenzoate	Papaverine
N-Acetylprocainamide	Fenoprofen	Penicillin-G
Acetylsalicylic acid	Furosemide	Pentobarbital
Aminopyrine	Gentisic acid	Perphenazine
Amitryptyline	Hemoglobin	Phencyclidine
Amobarbital	Hydralazine	Phenelzine
Amoxicillin	Hydrochlorothiazide	Phenobarbital
Ampicillin	Hydrocodone	Phentermine
L-Ascorbic acid	Hydrocortisone	L-Phenylephrine
DL-Amphetamine Sulfate	O-Hydroxyhippuric acid	β-Phenylethylamine
Apomorphine	p-Hydroxymethamphetamine	Phenylpropanolamine
Aspartame	3-Hydroxytyramine	Prednisolone
Atropine	Ibuprofen	Prednisone
Benzilic acid	Imipramine	Procaine
Benzoic acid	Iproniazid	Promazine
Benzphetamine	(±) - Isoproterenol	Promethazine
(±) -Brompheniramine	Isoxsuprine	DL-Propranolol
Caffeine	Ketamine	D-Propoxyphene
Cannabidiol	Ketoprofen	D-Pseudoephedrine
Cannabinol	Labetalol	Quinidine
Chloralhydrate	Levorphanol	Quinine
Chloramphenicol	Loperamide	Ranitidine
Chlordiazepoxide	Maprotiline	Salicylic acid
Chlorothiazide	Meperidine	Secobarbital
(±) -Chlorpheniramine	Meprobamate	Serotonin
Chlorpromazine	Methadone	Sulfamethazine
Chloroquine	Methoxyphenamine	Sulindac
Cholesterol	(±) -3,4-Methylene dioxyamphetamine	Temazepam
Clomipramine	Methylene-dioxymethamphetamine	Tetracycline
Clonidine	Morphine-3-β-D glucuronide	Tetrahydrocortisone 3-(β-D glucuronide)
Codeine	Morphine Sulfate	Tetrahydrozoline
Cortisone	Nalidixic acid	Thebaine
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine

Deoxycorticosterone	Naproxen	DL-Tyrosine
Dextromethorphan	Niacinamide	Tolbutamide
Diazepam	Nifedipine	Triamterene
Diclofenac	Norcodein	Trifluoperazine
Diflunisal	Norethindrone	Trimethoprim
Digoxin	D-Norpropoxyphene	Trimipramine
Diphenhydramine	Noscapine	Tryptamine
Doxylamine	DL-Octopamine	DL-Tryptophan
Ecgonine methylester	Oxalic acid	Tyramine
(-) - Ψ-Ephedrine	Oxazepam	Uric acid
Erythromycin	Oxolinic acid	Verapamil
β-Estradiol	Oxycodone	Zomepirac

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) interference performance data are found in k122961.

Effect of Urine Specific Gravity and Urine pH:

To investigate the effect of urine specific gravity and urine pH, urine samples for Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests, with 1.000 to 1.035 specific gravity (1.000, 1.003, 1.008, 1.014, 1.018, 1.020, 1.022, 1.025, 1.028, 1.030, 1.032, and 1.035) and urine samples with pH 4 to 9 (4.0, 5.0, 6.0, 7.0, 8.0, and 9.0) were spiked with target drugs at 25% below and 25% above Cut-Off levels. These samples were tested using three lots of each device. Results were all positive for samples at and above +25% Cut-Off and all negative for samples at and below -25% Cut-Off. There were no differences observed for the cup and dipcard test formats and the sponsor claims that pH and specific gravity do not affect urine testing results around each analyte cut-off.

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) Urine Specific Gravity and Urine pH performance data are found in k122961.

f. Assay cut-off:

Cutoff studies were performed for Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests using a combination of clinical and spiked samples for each drug (n=150 per drug). The testing protocol was identical for each drug. 25 clinical samples were collected for each drug. Concentrations of amphetamine and cocaine in the samples were determined by GC/MS. An additional 125 drug free negative samples were obtained for each drug and spiked with either amphetamine or cocaine at -50% cutoff, -25% cutoff, cutoff, +25% cutoff, and +50 % cutoff. 30 samples were tested at each concentration for each drug in replicates of 30 using three lots and 3 operators (n=270).

Results are summarized below:

Amphetamine

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	11/79	12/78
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90
Lot 2	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	12/78	11/79
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90
Lot 3	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	11/79	12/78
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90

Cocaine

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	12/78	12/78
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90
Lot 2	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	12/78	12/78
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90
Lot 3	-50% cutoff	90	90/0	90/0
	-25% cutoff	90	90/0	90/0
	Cutoff	90	12/78	12/78
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) cut off performance data are found in k122961.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison studies for Wondfo Amphetamine Urine Tests and Wondfo Cocaine Urine Tests were performed in-house with three different laboratory assistants for each format of the device. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples for each drug. The samples were blind labeled and compared to GC/MS results. The results are presented in the tables below:

Amphetamine (AMP) Dip Card

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer C	Positive	0	0	1	29	10
	Negative	10	17	12	0	0

Discordant Results of AMP Dip Card

Viewer	Sample Number	GC/MS Result	Dipcard Format Viewer Results
Viewer A	AMP5062	480	Positive
Viewer A	AMP5065	481	Positive
Viewer B	AMP5062	480	Positive
Viewer C	AMP5062	480	Positive
Viewer B	AMP5218	365	Positive

Amphetamine (AMP) Cup

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	1	30	10
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	17	11	0	0

Discordant Results of AMP Cup

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Results
Viewer A	AMP5062	480	Positive
Viewer A	AMP5065	481	Positive
Viewer B	AMP5062	480	Positive
Viewer C	AMP5062	480	Positive
Viewer C	AMP5065	481	Positive

Cocaine (COC) Dip Card

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	18	11	0	0

Discordant Results of COC DipCard

Viewer	Sample Number	GC/MS Result (ng/mL)	DipCard Format Viewer Results
Viewer A	COC1215	145	Positive
Viewer A	COC1217	146	Positive
Viewer B	COC1215	145	Positive
Viewer B	COC1217	146	Positive
Viewer C	COC1217	146	Positive

Cocaine (COC) Cup

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cut-off)	Near Cutoff Positive by GC/MS (Between the cut-off and +50%)	High Positive by GC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	1	30	10
	Negative	10	18	11	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	18	10	0	0

Discordant Results of COC Cup

Viewer	Sample Number	GC/MS Result (ng/mL)	Cup Format Viewer Results
Viewer A	COC1215	145	Positive
Viewer B	COC1215	145	Positive
Viewer C	COC1215	145	Positive
Viewer C	COC1217	146	Positive
Viewer A	COC1217	146	Negative

The Wondfo Methamphetamine Urine Test MET 500 (Cup, DipCard) method comparison performance data are found in k122961.

b. *Matrix comparison:*

Not applicable. This device is for use with urine samples 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):

Consumer / lay person study:

A lay user study was performed by a total of 840 lay users at three intended user sites: two hospitals and one drug addiction recovery center in P.R. China. The Wondfo Amphetamine Urine Test devices were tested by 280 lay persons, the Wondfo Cocaine Urine Test devices were tested by 280 lay persons and the Wondfo Methamphetamine Urine Test devices were tested by 280 lay persons. The participants had diverse educational and professional backgrounds and ranged in age from 21 to 63 years.

Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device (cup or dipcard). Lay-users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions could be easily followed. The lay user study was performed using English only labeling. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7. The results are summarized below:

Comparison between GC/MS and Amphetamine Cup

% of Cutoff	Number of samples	d-Amphetamine 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	126.3	0	20	100
-50% Cutoff	20	248.6	0	20	100
-25% Cutoff	20	377.1	1	19	95.0
+25% Cutoff	20	625.8	18	2	90.0
+50% Cutoff	20	753.2	20	0	100
+75% Cutoff	20	874.3	20	0	100

Comparison between GC/MS and Amphetamine Dip Card

% of Cutoff	Number of samples	d-Amphetamine 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	126.3	0	20	100
-50% Cutoff	20	248.6	0	20	100
-25% Cutoff	20	377.1	2	18	90.0
+25% Cutoff	20	625.8	18	2	90.0
+50% Cutoff	20	753.2	20	0	100
+75% Cutoff	20	874.3	20	0	100

Comparison between GC/MS and Cocaine Cup

% 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	38.1	0	20	100
-50% Cutoff	20	75.6	0	20	100
-25% Cutoff	20	113.4	2	18	90.0
+25% Cutoff	20	186.7	18	2	90.0
+50% Cutoff	20	226.3	20	0	100
+75% Cutoff	20	259.8	20	0	100

Comparison between GC/MS and Cocaine Dip Card

% 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	38.1	0	20	100
-50% Cutoff	20	75.6	0	20	100
-25% Cutoff	20	113.4	2	18	90.0
+25% Cutoff	20	186.7	18	2	90.0
+50% Cutoff	20	226.3	20	0	100
+75% Cutoff	20	259.8	20	0	100

Comparison between GC/MS and Methamphetamine Cup

% of Cutoff	Number of samples	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	124.8	0	20	100
-50% Cutoff	20	251.3	0	20	100
-25% Cutoff	20	377.6	2	18	90.0
+25% Cutoff	20	625.9	18	2	90.0
+50% Cutoff	20	748.3	20	0	100
+75% Cutoff	20	878.1	20	0	100

Comparison between GC/MS and Methamphetamine Dip Card

% of Cutoff	Number of samples	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	124.8	0	20	100
-50% Cutoff	20	251.3	0	20	100
-25% Cutoff	20	377.6	2	18	90.0
+25% Cutoff	20	625.9	18	2	90.0
+50% Cutoff	20	748.3	20	0	100
+75% Cutoff	20	878.1	20	0	100

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.