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

A. 510(k) Number:

k112395

B. Purpose for Submission:

New device

C. Measurand:

Phencyclidine and Nortriptyline

D. Type of Test:

Qualitative immunochromatographic

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Phencyclidine Urine Test
Wondfo Nortriptyline Urine Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LCM	unclassified	Enzyme Immunoassay Phencyclidine	91, Toxicology
LFG	II	21 CFR 862.3910 -Tricyclic antidepressant drug test system	91, Toxicology

H. Intended Use:

1. Intended use(s):

   See indication for use below

2. Indication(s) for use:

Wondfo Phencyclidine Urine Test

Wondfo Phencyclidine Urine Test is an immunochromatographic assay for the qualitative determination of Phencyclidine in human urine at a cutoff concentration of 25 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 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.

Wondfo Nortriptyline Urine Test

Wondfo Nortriptyline Urine Test is an immunochromatographic assay for the qualitative determination of Nortriptyline (major metabolite of Tricyclic Antidepressants) 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 tests will yield preliminary positive results when the prescription drug Nortriptyline is ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for Nortriptyline in urine. 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.

3. Special conditions for use statement(s):

For prescription and over the counter use

4. Special instrument requirements:

Not applicable, as the device is a visually-read single-use device

I. Device Description:

The devices are for use in human urine in dip card and cup formats. The Dip Card and Cup Tests are single-test test strips. The Dip Card and Cup Tests contain test cassettes or cup and package insert (instructions for use). Both devices are single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   ACON One Step Drug Screen Test Card, Acon Laboratories
   ACON TCA One Step Tricyclic Antidepressant Test Strip and Device, Acon Laboratories

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

   k020771 and k021526 respectively

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicates
Intended/Indications for Use	For the qualitative determination of Phencyclidine, Tricyclic antidepressant in individual human urine.	Same
Methodology	Competitive binding, lateral flow immunochromatographic assays based on the principle of antigen-antibody immunochemistry	Same
Type of Test	Immunoassay principles that rely on antigen-antibody interactions to indicate positive or negative result	Same
Results	Qualitative	Same
Specimen Type	Human Urine	Same
Cut Off Value	Phencyclidine: 25 ng/ml Tricyclic antidepressant: 1000 ng/ml	Same
Configurations	Cup, Dip Card	Card, dip card with integrated cup (same)
Intended Use	OTC Use & Prescription Use	Prescription Use

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

None were referenced

L. Test Principle:

The Wondfo Phencyclidine Urine Test and Wondfo Nortriptyline Urine Test are immunochromatographic assay for Phencyclidine and Nortriptyline Urine test using a lateral flow, one step system for the qualitative detection of Phencyclidine and Nortriptyline (target analyte) in human urine. Each assay uses a mouse monoclonal antibody-dye conjugate against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed using drug free urine spiked to the following concentrations: 0, +100%, +/-75% of cutoff, +/- 50% of cutoff, +/-25% of cutoff and the cutoff for each analyte and each device. The samples were aliquots, coded, randomized and blinded. Testing was performed twice a day for twenty-five days by three operators. Three different lot numbers for each device were used for the study. A total of 50 determinations were made at each concentration and each lot. Sample concentrations were confirmed by GC/MS. The results are displayed in the tables below:

Phencyclidine

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	0 (negative)	50	50/0	50/0
	6.25 (-75%)	50	50/0	50/0
	12.5 (-50%)	50	50/0	50/0
	18.75 (-25%)	50	50/0	50/0
	25 (cutoff)	50	6/44	4/45
	31.25 (+25%)	50	0/50	0/50
	37.5(+50%)	50	0/50	0/50
	43.75 (+75%)	50	0/50	0/50
	50 (+100%)	50	0/50	0/50
Lot 2	0 (negative)	50	50/0	50/0
	6.25 (-75%)	50	50/0	50/0
	12.5 (-50%)	50	50/0	50/0
	18.75 (-25%)	50	50/0	50/0
	25 (cutoff)	50	4/46	4/46
	31.25 (+25%)	50	0/50	0/50
	37.5(+50%)	50	0/50	0/50
	43.75 (+75%)	50	0/50	0/50
	50 (+100%)	50	0/50	0/50
Lot 3	0 (negative)	50	50/0	50/0

	6.25 (-75%)	50	50/0	50/0
	12.5 (-50%)	50	50/0	50/0
	18.75 (-25%)	50	50/0	50/0
	25 (cutoff)	50	5/45	5/45
	31.25 (+25%)	50	0/50	0/50
	37.5(+50%)	50	0/50	0/50
	43.75 (+75%)	50	0/50	0/50
	50 (+100%)	50	0/50	0/50

Nortriptyline

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	0 (negative)	50	50/0	50/0
	250 (-75%)	50	50/0	50/0
	500(-50%)	50	50/0	50/0
	750(-25%)	50	50/0	50/0
	1000(cutoff)	50	6/44	5/45
	1250(+25%)	50	0/50	0/50
	1500(+50%)	50	0/50	0/50
	1750(+75%)	50	0/50	0/50
	2000(+100%)	50	0/50	0/50
Lot 2	0 (negative)	50	50/0	50/0
	250 (-75%)	50	50/0	50/0
	500(-50%)	50	50/0	50/0
	750(-25%)	50	50/0	50/0
	1000(cutoff)	50	5/45	6/44
	1250(+25%)	50	0/50	0/50
	1500(+50%)	50	0/50	0/50
	1750(+75%)	50	0/50	0/50
	2000(+100%)	50	0/50	0/50
Lot 3	0 (negative)	50	50/0	50/0
	250 (-75%)	50	50/0	50/0
	500(-50%)	50	50/0	50/0
	750(-25%)	50	50/0	50/0
	1000(cutoff)	50	4/46	5/45
	1250(+25%)	50	0/50	0/50
	1500(+50%)	50	0/50	0/50
	1750(+75%)	50	0/50	0/50
	2000(+100%)	50	0/50	0/50

b. Linearity/assay reportable range:

Not applicable, the devices are intended for qualitative use.

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

External control materials are not supplied with this device; however, the device has internal process controls. A colored line appearing in the control region indicates 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.

Stability

Accelerated and real time studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date: The Wondfo Phencyclidine Urine Test and Wondfo Nortriptyline Urine Test unopened stability is 18 months for both formats (cup and dip card).

d. *Detection limit:*

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

e. *Analytical specificity:*

Cross-reactivity was established by spiking similarly structured compounds into drug free urine at various concentrations. These solutions were tested using 3 lots/device (dip card and cup). Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. Both devices produced similar results. The percent cross-reactivity of those compounds are presented below:

Compound	Tested Concentration (ng/mL)	% Cross-reactivity
Phencyclidine	25	100%
4-Hydroxphencyclidine	12500	0.2%

Compound	Tested Concentration (ng/mL)	% Cross-reactivity
Nortriptyline	1,000	100%
Nordoxepine	1,000	100%
Trimipramiine	3,000	33.3%
Amitriptyline	1,500	66.7%
Promazine	1,500	66.7%

Desipramine	200	500%
Imipramine	400	250%
Clomipramine	12,500	8%
Doxepine	2,000	50%
Maprotiline	2,000	50%
Promethazine	25,000	4%

Structurally un-related
The following unrelated compounds were found not to cross-react when tested spiked (100 μg/mL) into drug-free urine, as well as into urine spiked with ± 25% of the cut-off concentration of phencyclidine or Tricyclic antidepressant individually:

Acetophenetidin	Furosemide	Penicillin-G
N-acetylprocainamide	Gentisic acid	Pentazocine hydrochloride
Acetylsalicylic acid	Hemoglobin	Pentobarbital
Aminopyrine	Hydralazine	Perphenazine
Amobarbital	Hydrochlorothiazide	Phenelzine
Amoxicillin	Hydrocodone	Phenobarbital
Ampicillin	Hydrocortisone	Phentermine
Aspartame	O-Hydroxyhippuric	L-Phenylephrine
Atropine	p-Hydroxymethamphetamine	Prednisolone
Benzilic acid	3-Hydroxytyramine	Prednisone
Benzoic acid	Ibuprofen	Procaine
Benzoylecgonine	Iproniazid	D,L- Propranolol
Benzphetamine	(+/-)-Isoproterenol	D-Propoxyphene
Bilirubin	Isoxsuprine	D-Pseudoephedrine
Caffeine	Ketamine	Quinidine
Cannabidiol	Ketoprofen	Quinine
Cannabinol	Labetalol	Ranitidine
Chloralhydrate	Loperamide	Salicylic Acid
Chloramphenicol	Meperidine	Secobarbital
Chlorothiazide	Meprobamate	Serotonin (5-Hydroxytyramine)
(±) Chlolrpheniramine	Methadone	Sulfamethazine
Chlorpromazine	Methoxyphenamine	Sulindac
Chlorquine	(+) 3,4 Methylenedioxy-amphetamine	Temazepam
Cholesterol	(+) 3,4 Methylenedioxy-methamphetamine	Tetracycline
Clonidine	Morphine-3- β-D glucuronide	Tetrahydrocortisone, 3acetate
Cocaine hydrochloride	Morphine salt	Tetrahydrocortisone3 (β -Dglucuronide)
Codeine	Nalidixic Acid	Tetrahydrozoline

Cortisone	Naloxone	Thiamine
(-) Cotinine	Naltrexone	Thioridazine
Creatinine	Naproxen	D, L-Tyrosine
Deoxycorticosterone	Niacinamide	Tolbutamide
Diclofenac	Nifedipine	Triamterene
Diflunisal	Norcodein	Trifluoperazine
Digoxin	Norethindrone	Trimethoprim
Diphenhydramine	D -Norpropoxyphene	Trimipramine
Doxylamine	Noscapine	Tryptamine
Ecgonine hydrochloride	D,L- Octopamine	D,L-Tryptophan
Ecgonine methylester	Oxalic Acid	Tyramine
Erythromycin	Oxazepam	Uric Acid
β-Estradiol	Oxolinic acid	Verapamil
Estrone-3-sulfate	Oxycodone	Zomepirac
Ethyl-p-aminobenzoate	"Oxymetazoline	
Fenoprofen	Papaverine	

The following compounds were tested for interference with PCP at a concentration of 100 µg/mL into urine samples containing drug at +/-25% of the respective drug cutoff concentrations. Testing was performed on 3 lots/device (dip card and cup). The following compounds showed no interference when tested at the +/-25% drug concentration; Acetaminophen, Amitriptyline, Ascorbic acid. D,L-Amphetamine, Apomorphine acid, Brompheniramine, chlordiazepoxide, clomipramine, Dextromethorphan, Diazepam, (-) Y Ephedrine, Imipramine, Maprotiline, D,L-Octopamine, β-Phenylethylamine, Phenylpropanolamine, Promazine, Promethazine and Temazepam.

The following compounds were tested for interference with Nortriptyline at a concentration of 100 µg/mL into urine samples containing drug at +/-25% of the respective drug cutoff concentrations. Testing was performed on 3 lots/device (dip card and cup). The following compounds showed no interference when tested at the +/-25% drug concentration; 4-Acetamidophenol, L-ascorbic acid, DL-Amphetamine sulfate, Apomorphine, (±)-Brompheniramine, Cocaethylene, (-)-ψ-Ephedrine, [1R,2S] (-) Ephedrine, p-Hydroxyamphetamine, (L) Methamphetamine, Phencyclidine, Trans-2-phenylcyclopropylamine hydrochloride and Quinacrine

Evaluation of SG and pH on test results:

To evaluate the effect of pH value on the test results, a negative urine sample were adjusted to pH levels 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0.The samples were then spiked with drug at +/-25% of the cutoff values. Testing was performed on 3 lots/device (dip card and cup).

To evaluate the effect of specific gravity, 12 having specific gravities of 1.000, 1.003, 1.007, 1.008, 1.017, 1.019, 1.020, 1.025, and 1.030, 1.031, 1.033 and 1.035 were spiked with drug at +/-25% of the cut-off values. Testing was performed on 3 lots/device (dip card and cup).

The testing results demonstrate that varying pH's and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Cutoff studies were performed for phencyclidine and Nortriptyline 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 phencyclidine and Nortriptyline in the samples were determined by GC/MS. An additional 125 drug free negative samples were obtained for each drug and spiked with either phencyclidine or nortriptyline at -50% cutoff, -25% cutoff, cutoff, +25% cutoff, and +50 % cutoff. 5 clinical samples and 25 spiked 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:

Phencyclidine

	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	10/80
	+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	14/76	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	13/77	9/81
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90

Nortriptyline

	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	13/77
	+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	10/80
	+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	10/80	11/79
	+25%cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90

2. Comparison studies:

   a. *Method comparison with predicate device:*
   The method comparison for the Wondfo Phencyclidine Urine Test and Wondfo Nortriptyline Urine Test was performed in-house with three laboratory assistants with relevant experience and a lay person with no experience other than reading the instructions for use. Operators ran 80 (40 negative and 40 positive) unaltered clinical samples. The samples were blind labeled and compared to GC/MS results. The results are presented in the table below:

Phencyclidine

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Viewer A	Positive	0	0	2	18	22	100%
	Negative	10	13	15	0	0	95%
Viewer B	Positive	0	0	2	18	22	100%
	Negative	10	13	15	0	0	95%
Viewer C	Positive	0	0	2	18	22	100%
	Negative	10	13	15	0	0	95%
Lay Person	Positive	0	0	3	18	22	100%
	Negative	10	13	14	0	0	95%

Phencyclidine

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Viewer A	Positive	0	0	1	18	22	100%
	Negative	10	13	16	0	0	97.5%
Viewer B	Positive	0	0	2	18	22	100%
	Negative	10	13	15	0	0	95%
Viewer C	Positive	0	0	1	18	22	100%
	Negative	10	13	16	0	0	97.5%
Lay Person	Positive	0	0	2	18	22	100%
	Negative	10	13	15	0	0	92.5%

Discordant table:

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	PCP 213	20	positive
Viewer A	PCP 218	24	positive
Viewer B	PCP 214	20	positive
Viewer B	PCP 218	24	positive
Viewer C	PCP 213	20	positive
Viewer C	PCP 214	20	positive
Lay person	PCP 213	20	positive
Lay person	PCP 214	20	positive
Lay person	PCP 218	24	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	PCP218	24	positive
Viewer B	PCP213	20	positive
Viewer B	PCP218	24	positive
Viewer C	PCP214	20	positive
Lay person	PCP214	20	positive
Lay person	PCP218	24	positive

Nortriptyline

Cup format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Viewer A	Positive	0	0	1	10	30	100%
	Negative	10	19	10	0	0	97.5%
Viewer B	Positive	0	0	1	10	30	100%
	Negative	10	19	10	0	0	97.5%
Viewer C	Positive	0	0	1	10	30	100%
	Negative	10	19	10	0	0	97.5%
Lay Person	Positive	0	0	2	10	30	100%
	Negative	10	19	8	0	0	95%

	Negative	10	19	9	0	0	95%

Dip Card format		Negative	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and cutoff)	Near Cutoff Positive by GC/MS (Between the cutoff and +50%)	High Positive by GC/MS (greater than +50%)	% Agreement
Viewer A	Positive	0	0	1	10	30	100%
	Negative	10	19	10	0	0	97.5%
Viewer B	Positive	0	0	2	10	30	100%
	Negative	10	19	9	0	0	95%
Viewer C	Positive	0	0	1	10	30	100%
	Negative	10	19	10	0	0	97.5%
Lay	Positive	0	0	2	10	30	100%

Nortriptyline

Discordant result

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	NOR61	906	positive
Viewer B	NOR63	944	positive
Viewer C	NOR61	906	positive
Lay person	NOR61	906	positive
Lay person	NOR63	944	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	NOR63	944	positive
Viewer B	NOR61	906	positive
Viewer B	NOR63	944	positive
Viewer C	NOR63	944	positive
Lay person	NOR61	906	positive
Lay person	NOR63	944	positive

Test Cup format:
A lay user study was performed with 140 lay persons/drug from three locations: Guangzhou No. 8 People's Hospital, Guangzhou Mental Hospital, and Guangdong Provincial No. 2 People's Hospital. Participants in the study were 61 females and 79 males tested the PCP samples and 58 females and 82 males tested the Nortriptyline samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The results are summarized below.

Cup format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
PCP	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%

	125%	20	2	18	90%
	150%	20	0	20	100%
	175%	20	0	20	100%
Nortriptyline	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	125%	20	1	19	95%
	150%	20	0	20	100%
	175%	20	0	20	100%

Dip Card format:

A lay user study was performed with 140 lay persons/drug from three locations: Guangzhou No. 8 People's Hospital, Guangzhou Mental Hospital, and Guangdong Provincial No. 2 People's Hospital. Participants in the study were 72 females and 68 males tested the PCP samples and 7 females and 68 males tested the TCA samples. They had diverse educational and professional backgrounds and ranged in age from 21 to >50. Urine samples were prepared at the following concentrations; negative, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The concentrations of the samples were confirmed by GC/MS. Each sample was aliquoted into individual containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled samples and a device. The results are summarized below.

Dip Card format		Number of samples	OTC user		%Agreement With GC/MS
Drug	Concentration		Negative	Positive	
PCP	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	125%	20	1	19	95%
	150%	20	0	20	100%
	175%	20	0	20	100%
Nortriptyline	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	19	1	95%
	125%	20	1	19	95%
	150%	20	0	20	100%
	175%	20	0	20	100%

All study participants completed questionnaires after the performed the test and recorded their results. The questionnaires covered evaluation of the package insert regarding expiration date of the device, storage, the directions for performing the test, the ease of performing the test, directions for interpreting the results, and ease of interpretation of the

results. These questionnaires demonstrated that the test instructions were easy to understand and that the testing procedure was easy to perform and the results were easy to read.

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

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

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.