

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

A. 510(k) Number:

k121557

B. Purpose for Submission:

New device

C. Measurand:

Cannabinoids and Propoxyphene

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Guangzhou Wondfo Biotech Co., Ltd.

F. Proprietary and Established Names:

Wondfo Cannabinoids Urine Test
Wondfo Propoxyphene Urine Test

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LDJ	II	862.3870 Cannabinoids test system	91, Toxicology
LFG	II	862.3700 Propoxyphene test system	91, Toxicology

H. Intended Use:

1. Intended use(s):

See indication for use below

2. Indication(s) for use:

Wondfo Cannabinoids Urine Test

Wondfo Cannabinoids Urine Test is an immunochromatographic assay for the qualitative determination of 11-nor- Δ^9 -THC-9-COOH (major metabolite of Cannabinoids) in human urine at a cutoff concentration of 50 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 Propoxyphene Urine Test

Wondfo Propoxyphene Urine Test is an immunochromatographic assay for the qualitative determination of d-Propoxyphene 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.

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 for Cannabinoids.

For prescription use for Propoxyphene. Propoxyphene has not been evaluated for Point-of-care 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 dip card 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, Acon Laboratories
 ACON One Step Propoxyphene Test Strip and Device, Acon Laboratories

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

k020771 and k040445 respectively

3. Comparison with predicate:

Similarities and Differences		
Item	Device	Predicates (k020771)
Indications for Use	For the qualitative determination of Cannabinoids in individual human urine.	Same (different number of drugs detected)
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
Calibrator	11-nor- Δ^9 -THC-9-COOH	Same
Specimen Type	Human Urine	Same
Cut Off Value	Cannabinoids: 50 ng/ml	Same
Configurations	Cup, Dip Card	Card, dip card with integrated cup (same)
Intended Use	OTC Use & Prescription Use	Prescription Use

Similarities and Differences		
Item	Device	Predicates (k040445)
Indications for Use	For the qualitative determination of Propoxyphene 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
Calibrator	d-Propoxyphene	Same

Specimen Type	Human Urine	Same
Cut Off Value	Propoxyphene 300 ng/mL	Same
Configurations	Cup, Dip Card	Strip, device
Intended Use	Prescription Use	Prescription Use

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

None were referenced

L. Test Principle:

The Wondfo Cannabinoids Urine Test and Wondfo Propoxyphene Urine Test are immunochromatographic assay for Cannabinoids and Propoxyphene Urine test using a lateral flow, one step system for the qualitative detection of 11-nor- Δ^9 -THC-9-COOH and d-Propoxyphene 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 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:

Cannabinoids

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	Negative	50	50/0	50/0
	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	5/45	4/46
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
	+100%	50	0/50	0/50
Lot 2	Negative	50	50/0	50/0

	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	6/44	4/46
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
	+100%	50	0/50	0/50
Lot 3	Negative	50	50/0	50/0
	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	5/45	5/45
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
+100%	50	0/50	0/50	

Propoxyphene

	Concentration of sample ng/mL	Number of determinations	Dip Card Results #Neg/#Pos	Cup Results #Neg/#Pos
Lot 1	Negative	50	50/0	50/0
	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	6/44	5/45
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
	+100%	50	0/50	0/50
Lot 2	Negative	50	50/0	50/0
	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	5/45	4/46
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
	+100%	50	0/50	0/50
Lot 3	Negative	50	50/0	50/0
	-75%	50	50/0	50/0
	-50%	50	50/0	50/0
	-25%	50	50/0	50/0
	cutoff	50	4/46	7/43
	+25%	50	0/50	0/50
	+50%	50	0/50	0/50
	+75%	50	0/50	0/50
	+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 standards are not supplied with this device; however, 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.

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 Cannabinoids Urine Test and Wondfo Propoxyphene Urine Test unopened stability is 18 months for both formats (cup and dip card) when stored at 4-30° C.

d. Detection limit:

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

e. Analytical specificity:

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
THC (Cannabinoids) 11-nor- Δ 9-THC-9-COOH	50	100%
11-nor- Δ 8-THC-9-COOH	30	167%
11-hydroxy- Δ 9-Tetrahydrocannabinol	2500	2%
Δ 8-Tetrahydrocannabinol	7500	<1%
Δ 9-Tetrahydrocannabinol	10000	<1%
Cannabinol	100000	<1%
Cannabidiol	100000	<1%

Compound	Tested Concentration (ng/mL)	% Cross-reactivity
d-Propoxyphene	300	100%
d-Norpropoxyphene	300	100%

Structurally un-related and interference

The following unrelated compounds were found not to cross-react when tested spiked (100 μ g/mL) into urine spiked with \pm 25% of the cut-off concentration of cannabinoids individually:

4-Acetamidphenol, Acetophenetidin, N-acetylprocainamide, Acetylsalicylic acid, Aminopyrine, Amitriptyline, Amobarbital, Amoxicillin, Ampicillin,

Ascorbic Acid, D,L- Amphetamine, L-Amphetamine, Apomorphine, Aspartame, Atropine, Benzilic acid, Benzoic acid, Benzoylcegonine, Benzphetamine, Bilirubin, Brompheniramine, Caffeine, Chloralhydrate, Chloramphenicol, Chlordiazepoxide, Chlorothiazide, (\pm) Chlolorpheniramine, Chlorpromazine, Chlorquine, Cholesterol, Clomipramine, Clonidine, Cocaine hydrochloride, Codeine, Cortisone, (-) Cotinine, Creatinine, Deoxycorticosterone, Dextromethorphan, Diazepam, Diclofenac, Diflunisal, Digoxin, Diphenhydramine, Doxylamine, Ecgonine hydrochloride, Ecgonine methylester, (-) Y Ephedrine, Erythromycin, β -Estradiol, Estrone-3-sulfate, Ethyl-p-aminobenzoate, Fenopropfen, Furosemide, Gentsic acid, Hemoglobin, Hydralazine, Hydrochlorothiazide, Hydrocodone, Hydrocortisone, O-Hydroxyhippuric, 3-Hydroxytyramine, Ibuprofen, Imipramine, Iproniazid, (+/-) Isoproterenol, Isoxsuprine, Ketamine, Ketoprofen, Labetalol, Levorphanol, Loperamide, Maprotiline, Meprobamate, Methadone, Methoxyphenamine, (+) 3,4 Methylendioxyamphetamine, (+) 3,4 Methylendioxy methamphetamine, Methylphenidate, Methyprylon, Morphine-3- β -D glucuronide, Nalorphine, Naloxone, Nalidixic Acid, Naltrexone, Naproxen, Niacinamide, Nifedipine, Norcodein, Norethindrone, D –Norpropoxphene, Noscapine, D,L- Octopamine, Oxalic Acid, Oxazepam, Oxolinic acid, Oxycodone, Oxymetazoline, p-Hydroxymethamphetamine, Papaverine, Penicillin-G, Pentazocine, Pentobarbital, Perphenazine, Phencyclidine, Phenelzine, Phenobarbital, Phentermine, L-Phenylephrine, β -Phenylethylamine, β -Phenyllethylamine, Phenylpropanolamine, Prednisolone, Prednisone, Procaine, Promazine, Promethazine, D,L- Propranolol, D-Propoxphene, D-Pseudoephedrine, Quinidine, Quinine, Ranitidine Salicylic Acid, Secobarbital, Serotonin (5-Hydroxytyramine), Sulfamethazine, Sulindac, Temazepam, Tetracycline, Tetrahydrocortisone, 3 acetate, Tetrahydrocortisone3 (5 -Dglucuronide), Tetrahydrozoline, Thebaine, Thiamine, Thioridazine, D, L-Thyroxine, Tolbutamide, Triamterene, Trifluoperazine, Trimethoprim, Trimipramine, Tryptamine, D,L-Tryptophan, Tyamine, PrD, L-Tyrosine, Uric Acid, Verapamil, Zomepirac

The following unrelated compounds were found not to cross-react when tested spiked (100 μ g/mL) into urine spiked with \pm 25% of the cut-off concentration of propoxyphene individually:

Acetophenetidin, Acetylsalicylic acid, Aminopyrine, Amoxicillin, Ampicillin, Apomorphine, Aspartame, Atropine, Benzilic acid, Benzoic acid, Benzphetamine, Bilirubin, Caffeine, Chloralhydrate, Chloramphenicol, Chlorothiazide, D,L-Chlolorpheniramine, Chlorpromazine, Chlorquine, Cholesterol, Clonidine, L- Cotinine, Cortisone, Creatinine, D-Pseudoephedrine, Dextromethorphan, β -Dglucuronide, Diclofenac, Diflunisal, Digoxin, Diphenhydramine, Ecgonine methylester, L- Ephedrine, Erythromycin, β -Estradiol, Estrone-3-sulfate, Ethyl-p-aminobenzoate, Fenopropfen, Furosemide, Gentsic acid, Hemoglobin, Hydralazine,

Hydrochlorothiazide, Hydrocortisone, O-Hydroxyhippuric, 3-Hydroxytyramine, Isoxsuprine, L- Isoproterenol, Ketoprofen, Labetalol, Loperamide, Meprobamate, Methoxyphenamine, Morphine-3- β -D-glucuronide, Naloxone, Nalidixic Acid, Naltrexone, Naproxen, Niacinamide, Nifedipine, Norethindrone, , Noscapine, D,L- Octopamine, Oxalic Acid, Oxolinic acid, Oxymetazoline, Papaverine, Penicillin-G, Perphenazine, Phenelzine, L-Phenylephrine, β -Phenylethylamine, Phenylpropanolamine, , Prednisone, D,L- Propranolol, Quinidine, Quinine, Ranitidine Salicylic Acid, Serotonin, Sulfamethazine, Sulindac, Tetracycline, Tetrahydrocortisone, Tetrahydrozoline, Thiamine, Thioridazine, D, L-Thyrosine, Tolbutamide, Triamterene, Trifluoperazine, Trimethoprim, D,L-Tryptophan, Tyamine, Uric Acid, Verapamil, Zomepirac

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 each 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 urine samples 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 each 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 pHs and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Cutoff studies were performed for cannabinoids and propoxyphene 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 cannabinoids and propoxyphene in the samples were determined by GC/MS.

An additional 125 drug free negative samples were obtained for each drug and spiked with either cannabinoids and propoxyphene 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:

Cannabinoids

	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	9/81	11/79
	+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	11/79	8/82
	+25% cutoff	90	0/90	0/90
	+50% cutoff	90	0/90	0/90

Propoxyphene

	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	10/80	9/81
	+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	8/82	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	9/81	10/80
	+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 Cannabinoids Urine Test and Wondfo Propoxyphene 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:

Cannabinoids

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%)
Viewer A	Positive	0	0	2	18	22
	Negative	10	12	16	0	0
Viewer B	Positive	0	0	1	18	22
	Negative	10	12	17	0	0
Viewer C	Positive	0	0	1	18	22
	Negative	10	12	17	0	0
Lay Person	Positive	0	0	2	18	22
	Negative	10	12	16	0	0

Cannabinoids

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%)
Viewer A	Positive	0	0	1	18	22
	Negative	10	12	17	0	0
Viewer B	Positive	0	0	1	18	22
	Negative	10	12	17	0	0
Viewer C	Positive	0	0	1	18	22
	Negative	10	12	17	0	0
Lay Person	Positive	0	0	1	18	22
	Negative	10	12	17	0	0

Discordant table:

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	GDA 19	47	positive
Viewer A	GDA 20	49	positive
Viewer B	GDA 20	49	positive
Viewer C	GDA 19	47	positive
Lay person	GDA 19	47	positive
Lay person	GDA 20	49	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	GDA 20	49	positive
Viewer B	GDA 19	47	positive
Viewer C	GDA 19	47	positive
Lay person	GDA 20	49	positive

Propoxyphene

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%)
Viewer A	Positive	0	0	1	25	15
	Negative	10	18	11	0	0
Viewer B	Positive	0	0	2	25	15
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	1	25	15
	Negative	10	18	11	0	0

Propoxyphene

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%)
Viewer A	Positive	0	0	1	25	15
	Negative	10	18	11	0	0
Viewer B	Positive	0	0	1	25	15
	Negative	10	18	11	0	0
Viewer C	Positive	0	0	1	25	15
	Negative	10	18	11	0	0

Discordant result

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	PPX317	297.4	positive
Viewer B	PPX63	295.6	positive
Viewer B	PPX318	293.8	positive
Viewer C	PPX63	295.6	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	PPX318	293.8	positive
Viewer B	PPX317	297.4	positive
Viewer C	PPX317	297.4	positive

Lay-user study for Cannabinoids

Test Cup format:

A lay user study was performed at three intended user sites with 140 lay persons. Participants in the study were 66 females and 74 males tested the cannabinoids 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	
Cannabinoids	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	19	1	85%
	+25%	20	1	19	90%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

Dip Card format:

A lay user study was performed at three intended user sites with 140 lay persons. Participants in the study were 63 females and 77 males tested the cannabinoids 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	
Cannabinoids	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	85%
	+25%	20	0	20	95%
	+50%	20	0	20	100%
	+75%	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.