K121987

510(k) SUMMARY

AUG 1 2012

1. Date: July 23, 2012

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4. Device Name: Wondfo Amphetamine Urine Test
Wondfo Secobarbital Urine Test
Wondfo Oxazepam Urine Test

Classification:

Product Code	CFR #
DKZ	21CFR 862.3100
DIS	21CFR 862.3150
JXM	21CFR 862.3170

5. Predicate Devices: K020771
Acon Laboratories, Inc.
One Step Drug Screen Test

6. Intended Use
Wondfo Amphetamine, Secobarbital, and Oxazepam Urine Tests are intended for the qualitative determination of d-Amphetamine , Secobarbital, and Oxazepam at a specific cut-off concentration in human urine samples. They are intended for healthcare professional use and over the counter use.

7. Device Description
Immunochromatograph assays for Amphetamine, Secobarbital, and Oxazepam Urine Tests use a lateral flow, one step system for the qualitative detection of d-Amphetamine , Secobarbital, and Oxazepam (target analyte) 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.

8. Substantial Equivalence Information

Item	Device	Predicate
Indication(s) for use	For the qualitative determination of Amphetamine, Barbiturates, Benzodiazepines individual in human urine.	Same (but the number of drugs detected different)
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 Values	Amphetamine: 1000ng/ml Secobarbital : 300 ng/ml Oxazepam: 300ng/ml	Same (but the number of drugs detected different)
Configurations	Cup, dip card	Strip, Device
Intended Use	OTC Use & Prescription Use	Prescription Use

9. Standard/Guidance Document Reference

- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
- Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988
- Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
- Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
- Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J. Clin. Chem. 33,33B-40B, 1987

10. Test Principle

It is a rapid test for the qualitative detection of d-Amphetamine, Secobarbital, and Oxazepam in urine samples. It is a lateral flow chromatographic immunoassay. When the absorbent end is immersed into a urine sample, the urine is absorbed into the device by capillary action and mixes with the antibody-dye conjugate, flowing across the pre-coated membrane. At analyte concentration below the target cut off, antibody-dye conjugates bind to the drug-protein conjugate immobilized in the Test Region (T) of the device.

This produces a colored test line that indicates a negative result. When analyte concentration is above the cutoff, analyte molecules bind 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. No colored band shows in the test region, indicating a potentially positive result.

11. Performance Characteristics

1. Analytical Performance

a. Precision

Precision studies were carried out for 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. For each concentration, tests were performed two runs per day for 25 days. The results obtained are summarized in the following table.

Drug	**-100% cutoff**	**-75% cutoff**	**-50% cutoff**	**-25% Cutoff**	**cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**	**+100% cutoff**
AMP	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
Secobarbital	50-/0+	50-/0+	50-/0+	50-/0+	43+/7-	50+/0-	50+/0-	50+/0-	50+/0-
Oxazepam	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity

Not applicable

c. Stability

It is stable at 4-30°C for 23 months.

d. Cut-off

Test	**Calibrator**	**Cut-off (ng/ml)**
Amphetamine (AMP)	D-Amphetamine	1000
Secobarbital	Secobarbital	300
Oxazepam	Oxazepam	300

e. Interference

Compounds that show no interference at a concentration of 100 μg/mL are summarized in the following tables.

AMP

4-Acetamidophenol	(-) Y Ephedrine	Penicillin-G
Acetophenetidin	Erythromycin	Pentazocaine
N-Acetylprocainamide	β-Estradiol	Pentobarbital
Acetylsalicylic acid	Estrone-3-sulfate	Perphenazine
Aminopyrine	Ethyl-p-aminobenzoate	Phencyclidine
Amitryptyline	Fenfluramine	Phenelzine
Amobarbital	Fenoprofen	Phendimetrazine
Amoxicillin	Furosemide	Phenobarbital
Ampicillin	Gentisic acid	Phetoin
Ascorbic acid	Hemoglobin	L-Phenylephrine
Apomorphine	Hydralazine	β-Phenylethlamine
Aspartame	Hydrochlorothiazide	Phenylpropanolamine
Atropine	Hydrocodone	Prednisolone
Benzilic acid	Hydrocortisone	Prednisone
Benzoic acid	O-Hydroxyhippuric acid	Procaine
Benzoylecgonine	3-Hydroxytyramine	Promazine
Bilirubin	Ibuprofen	Promethazine
Brompheniramine	Imipramine	D,L-Propanolol
Caffeine	(-) Isoproterenol	Propiomazine
Cannabidiol	Isoxsuprine	D-Propoxyphene
Cannabinol	Ketamine	Quinidine
Chloralhydrate	Ketoprofen	Quinine
Chloramphenicol	Labetalol	Ranitidine
Chlordiazepoxide	Levorphanol	Salicylic acid
Chlorothiazide	Loperamide	Secobarbital
(±) Chlorpheniramine	Maprotiline	Serotonin
Chlorpromazine	Meperidine	Sulfamethazine
Chlorquine	Meprobamate	Sulindac
Cholesterol	Methadone	Temazepam
Clomipramine	Methylphenidate	Tetracycline
Clonidine	Morphine-3-Dglucuronide	Tetrahydrocortisone
Cocaine hydrochloride	Nalidixic acid	Tetrahydrozoline
Codeine	Naloxone	Δ9-THC-COOH
Cortisone	Naltrexone	Thebaine
(-) Cotinine	Naproxen	Thiamine
Creatinine	Niacinamide	Thioridazine
Deoxycorticosterone	Nifedipine	D,L-Thyroxine
Dextromethorphan	Norcodein	Tolbutamine
Diazepam	Norethindrone	Triamterene

Diclofenac	D-Norpropoxyphene	Trifluoperazine
Diflunisal	Noscapine	Trimethoprim
Digoxin	D,L-Octopamine	Trimipramine
Diphenhydramine	Oxalic acid	Tryptamine
Doxylamine	Oxazepam	D, L-Tyrosine
Ecgonine hydrochloride	Oxolinic acid	Uric acid
Ecgonine methylester	Oxycodone	Verapamil
(IR,2S)-(-)-Ephedrine	Oxymetazoline	Zomepirac
L-Ephedrine	Papaverine	

Secobarbital

Acetaminophen	L-Ephedrine	Oxycodone
Acetophenetidin	Erythromycin	Oxymetazoline
N-Acetylprocainamide	β-Estradiol	Papaverine
Acetylsalicylic acid	Estrone-3-sulfate	Penicillin-G
Aminopyrine	Ethyl-p-aminobenzoate	Pentazocaine
Amitryptyline	Fenfluramine	Perphenazine
Amoxicillin	Fenoprofen	Phencyclidine
Ampicillin	Furosemide	Phenelzine
Ascorbic acid	Gentisic acid	Phendimetrazine
Apomorphine	Hemoglobin	Phetoin
Aspartame	Hydralazine	L-Phenylephrine
Benzilic acid	Hydrochlorothiazide	β-Phenylethlamine
Benzoic acid	Hydrocodone	Phenylpropanolamine
Benzoylecgonine	Hydrocortisone	Prednisolone
Bilirubin	O-Hydroxyhippuric acid	Prednisone
Brompheniramine	3-Hydroxytyramine	Procaine
Caffeine	Ibuprofen	Promazine
Cannabidiol	Imipramine	Promethazine
Cannabinol	(-) Isoproterenol	D,L-Propanolol
Chloralhydrate	Isoxsuprine	Propiomazine
Chloramphenicol	Ketamine	D-Propoxyphene
Chlordiazepoxide	Ketoprofen	Quinidine
Chlorothiazide	Labetalol	Quinine
(±) Chlorpheniramine	Levorphanol	Ranitidine
Chlorpromazine	Loperamide	Salicylic acid
Chlorquine	Maprotiline	Serotonin
Cholesterol	Meperidine	Sulfamethazine
Clomipramine	Meprobamate	Sulindac
Clonidine	Methadone	Temazepam
Cocaine hydrochloride	Methylphenidate	Tetracycline
Codeine	Morphine-3-β-D glucuronide	Tetrahydrocortisone
Cortisone	Nalidixic acid	Tetrahydrozoline
(-) Cotinine	Naloxone	Thiamine
Creatinine	Naltrexone	Thioridazine
Deoxycorticosterone	Naproxen	D,L-Thyroxine

Dextromethorphan	Niacinamide	Tolbutamine
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

Oxazepam

4-Acetamidophenol	Diaoxin	D.L-Octopamine
Acetophenetidin	Diphenhydramine	Oxalic acid
N-Acetvprocainamide	Doxylamine	Oxolinic acid
Acetvsalicvlic acid	Ecaonine dydrochloride	Pentobarbital
Aminopvrine	Ecqonine methylester	Perphenazine
Amityptvline	(-)-□-Ephedrine	Phencyclidine
Amorbarbital	Fenoprofen	Phenelzine
Amoxicillin	Furosemide	Phenobarbital
Ampicillin	Gentisic acid	Phentermine
l-Ascorbic Acid	Hemoglobin	L-Phenylephrine
D.L-Amphetamine	Hydrocortisone	□-Phenylethylamine
Apormorphine	O-Hydroxyhippuric acid	Phenylpropanotamin e
Aspartame	p-Hydroxy- methamphetamine	Prednisone
Atropine	3-Hydroxytyramine	D.L-Propanolol
Benzillic acid	Ibuprofen	D-Propoxyphene
Benzoic acid	Imipramine	D-Pseudoephedrine
Benzoylecaonine	Iproniazid	Quinine
Benzphetamine	(±)Isoproterenol	Ranitidine
Bilirubin	Isoxsuprine	Salicylic acid
(±) Chlorpheniramine	Ketamine	Secobarbital
Caffeine	Ketoprofen	Serotonin (5-Hydroxytyramine)
Cannabidiol	Labetalol	Sertraline
Chloralhvdrate	Loperamide	Sulfamethazine
Chloramphenicol	Maprotiline	Sulindac
Chlordiazepoxide	Meperidine	Tetrahydrocortisone, 3 Acetate
Chlorothiazide	Meprobamate	Tetrahydrocortisone, (β-D glucuronide)
(±)Chlorpheniramine	Methadone	Tetrahydrozoline
Chlorpromazine	Methoxyphenamine	Thiamine
Chlorquine	() 3,4-Methylenedioxy-amphetamine	Thioridazine
Cholesterol	(+)3,4-Methylenedioxy-	D.L-Tyrosine

	methamphetamine	
Clomipramine	Nalidixic acid	Tolbutamide
Clonidine	Nalorphine	Triamterene
Cocaine hydrochloride	Naloxone	Trifluoperazine
Cortisone	Naltrexone	Trimethoprim
(-)cotinine	Naproxen	Triyptamine
Creatinine	Niacinamide	D.L-Tryptophan
Dextromethlorphan	Nifedipine	Tyramine
Diazepam	Norethindrone	Uric acid
Diclolrfenac	D-Norpropoxyphene	Verapamil
Diflunisal	Noscapine	Zomepirac

f. Specificity

To test the specificity, drug metabolites and other components that are likely to be present in urine samples were tested. Compounds that produced positive results are listed below.

AMP(Amphetamine) **(d-Amphetamine, Cutoff=1000 ng/mL)**	**Result** Positive at 1,000 ng/mL
l-Amphetamine	Positive at 50,000 ng/mL
dl-Amphetamine	Positive at 3,000 ng/mL
(+/-) 3,4-methylenedioxyamphetamine (MDA)	Positive at 5,000 ng/mL
Phentermine	Positive at 3,000 ng/mL
d-methamphetamine	Positive at >100,000
l-methamphetamine	Positive at >100,000
3,4-Methylenedioxyethylamphetamine(MDE)	Positive at 100,000
(+/-)3,4-methylenedioxumethamphetamine (MDMA)	Positive at 100,000

Secobarbital **(Secobarbital, Cutoff=300 ng/mL)**	**Result** Positive at 300 ng/mL
Amobarbital	Positive at 300 ng/mL
Alphenol	Positive at 150 ng/mL
Aprobarbital	Positive at 200 ng/mL
Butabarbital	Positive at 75 ng/mL
Butathal	Positive at 100 ng/mL
Butalbital	Positive at 2,500 ng/mL
Cyclopentobarbital	Positive at 600 ng/mL
Pentobarbital	Positive at 300 ng/mL
Phenobarbital	Positive at 100 ng/mL

Oxzaepam (Oxazepam, Cutoff=300 ng/mL)	**Result** Positive at 300 ng/mL
Alprazolam	Positive at 200 ng/mL
a-Hydroxyalprazolam	Positive at 1,500 ng/mL
Bromazepam	Positive at 1,500 ng/mL
Chlordiazepoxide	Positive at 1,500 ng/mL
Clonazepam HCl	Positive at 800 ng/mL
Clobazam	Positive at 100 ng/mL
Clonazepam	Positive at 800 ng/mL
Clorazepate dipotassium	Positive at 200 ng/mL
Delorazepam	Positive at 1,500 ng/mL
Desalkylflurazepam	Positive at 400 ng/mL
Diazepam	Positive at 200 ng/mL
Estazolam	Positive at 2,500 ng/mL
Flunitrazepam	Positive at 400 ng/mL
D,L-Lorazepam	Positive at 1,500 ng/mL
Midazolam	Positive at 12,500 ng/mL
Nitrazepam	Positive at 100 ng/mL
Norchlordiazepoxide	Positive at 200 ng/mL
Nordiazepam	Positive at 400 ng/mL
Temazepam	Positive at 100 ng/mL
Trazolam	Positive at 2,500 ng/mL

2. Comparison Studies

The method comparison for the Wondfo Amphetamine Urine Test, Wondfo Secobarbital Urine Test and Wondfo Oxazepam 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:

Amphetamine

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	11	29
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	2	11	29
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	1	11	29
	Negative	10	18	11	0	0

Lay Person	Positive	0	0	3	11	29
	Negative	10	18	9	0	0

Amphetamine

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	11	29
	Negative	10	18	11	0	0
Viewer B	Positive	0	0	2	11	29
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	2	11	29
	Negative	10	18	10	0	0
Lay Person	Positive	0	0	2	11	29
	Negative	10	18	10	0	0

Discordant table:

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	AMP63	987	positive
Viewer A	AMP65	993	positive
Viewer B	AMP62	921	positive
Viewer B	AMP65	993	positive
Viewer C	AMP62	921	positive
Lay person	AMP62	921	positive
Lay person	AMP63	987	positive
Lay Person	AMP65	993	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	AMP62	921	positive
Viewer B	AMP62	921	positive
Viewer B	AMP65	993	positive
Viewer C	AMP35	797	positive
Viewer C	AMP63	987	positive
Lay Person	AMP35	797	positive
Lay person	AMP65	993	positive

Secobarbital

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	20	20
	Negative	10	10	18	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Viewer C	Positive	0	0	1	20	20
	Negative	10	10	19	0	0
Lay Person	Positive	0	0	2	20	20
	Negative	10	10	18	0	0

Secobarbital

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	2	20	20
	Negative	10	10	18	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Lay Person	Positive	0	0	3	20	20
	Negative	10	10	17	0	0

Discordant result

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	BAR61	293	positive
Viewer A	BAR216	280	positive
Viewer B	BAR34	243	positive
Viewer B	BAR216	280	positive
Viewer C	BAR35	237	positive
Lay Person	BAR61	293	positive
Lay Person	BAR216	280	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	BAR34	243	positive
Viewer A	BAR216	280	positive
Viewer B	BAR34	243	positive
Viewer B	BAR61	293	positive
Viewer C	BAR35	237	positive
Viewer C	BAR216	280	positive
Lay Person	BAR34	243	positive
Lay Person	BAR35	237	positive
Lay Person	BAR61	293	positive

Oxazepam

	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%)
Positive	0	0	1	20	20
Negative	10	10	19	0	0
Positive	0	0	2	20	20
Negative	10	10	18	0	0
Positive	0	0	2	20	20
Negative	10	10	18	0	0
Positive	0	0	3	20	20
Negative	10	10	17	0	0

Oxazepam

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	2	20	20
	Negative	10	10	18	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	10	18	0	0
Lay Person	Positive	0	0	3	20	20
	Negative	10	10	17	0	0

Discordant result

Viewer	Sample number	GC/MS result	Cup format Viewer result
Viewer A	BZO32	226	positive
Viewer B	BZO32	226	positive
Viewer B	BZO211	233	positive
Viewer C	BZO34	243	positive
Viewer C	BZO65	277	positive
Lay Person	BZO34	243	positive
Lay Person	BZO65	277	positive
Lay Person	BZO211	233	positive

Viewer	Sample number	GC/MS result	Dip Card format viewer results
Viewer A	BZO34	243	positive
Viewer A	BZO65	277	positive
Viewer B	BZO32	226	positive
Viewer B	BZO211	233	positive
Viewer C	BZO34	243	positive
Viewer C	BZO65	277	positive
Lay Person	BZO32	226	positive
Lay Person	BZO34	243	positive
Lay Person	BZO211	233	positive

Lay-user study

Test Cup format:

A lay user study was performed at three intended user sites with 140 lay persons. Participants in the study were 58 females and 82 males tested the amphetamine samples, 59 females and 81 males tested the secobarbital samples 71 females and 69 males tested the oxazepam 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	
Amphetamine	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	1	19	95%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Secobarbital	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	2	18	90%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Oxazepam	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	18	2	90%
	+25%	20	1	19	95%
	+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 61 females and 79 males tested the amphetamine samples, 64 females and 76 males tested the secobarbital samples 66 females and 74 males tested the oxazepam 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	
Amphetamine	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	1	19	95%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Secobarbital	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	17	3	85%
	+25%	20	2	18	90%
	+50%	20	0	20	100%
	+75%	20	0	20	100%
Oxazepam	Negative	20	20	0	100%
	-75%	20	20	0	100%
	-50%	20	20	0	100%
	-25%	20	19	1	95%
	+25%	20	1	19	95%
	+50%	20	0	20	100%
	+75%	20	0	20	100%

3. Clinical Studies

   Not applicable

12. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that Wondfo Amphetamine, Secobarbital, and Oxazepam Urine Tests are substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Guangzhou Wondfo Biotech Co., Ltd.
c/o Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20877

AUG 1 2012

Re: k121987
Trade Name: Wondfo Amphetamine Urine Test
Wondfo Secobarbital Urine Test
Wondfo Oxazepam Urine Test
Regulation Number: 21 CFR §862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Codes: DKZ, DIS, JXM
Dated: June 18, 2012
Received: July 6, 2012

Dear Mr. Shia:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/Medical Devices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K121987

Device Name: Wondfo Amphetamine Urine Test

Indications for Use:

Wondfo Amphetamine Urine Test is an immunochromatographic assay for the qualitative determination of d-Amphetamine in human urine at a cutoff concentration of 1000ng/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.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use X (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K121987

Indications for Use Form

510(k) Number (if known): K121987

Device Name: Wondfo Secobarbital Urine Test

Indications for Use:

Wondfo Secobarbital Urine Test is an immunochromatographic assay for the qualitative determination of Secobarbital (major metabolite of Barbiturates) in human urine at a cutoff concentration of 300ng/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.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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510(k) K121987

Indications for Use Form

510(k) Number (if known): K121987

Device Name: Wondfo Oxazepam Urine Test

Indications for Use:

Wondfo Oxazepam Urine Test is an immunochromatographic assay for the qualitative determination of Oxazepam (major metabolite of Benzodiazepines) in human urine at a cutoff concentration of 300ng/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.

Prescription Use X	And/Or	Over the Counter Use X
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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