K122961

TABLE 4 **SUMMARY** **DEC 2 1 2012**

1. Date: November 1, 2012

2. Submitter:

Guangzhou Wondfo Biotech Co., Ltd.
South China University of Technology
Guangzhou, P.R. China 510641
012-86-20-32296069

3. Name of contact person:

Joe Shia
LSI International Inc.
504 East Diamond Ave.,
Suite F Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6231
Email:shiajl@yahoo.com

4. Device Name: Wondfo Amphetamine Urine Test (AMP 300)
Wondfo Methamphetamine Urine Test (MET 500)

Classification: All are Class II medical devices with the following various product codes with Code of Federal Regulation references:

Product Code	CFR #
DKZ	21 CFR, 862.3100
LAF	21 CFR, 862.3610

5. Predicate Devices:

1. K041822
   Acon Laboratories, Inc.
   ACON® AMP 300 One Step Amphetamine Test Strip, ACON® AMP 300 One Step Amphetamine Test Device

2. K033299
   Acon Laboratories, Inc.
   ACON® mAMP-500 One Step Methamphetamine Test Strip, ACON® mAMP-500 One Step Methamphetamine Test Device

6. Intended Use:

Wondfo Amphetamine Urine Test (AMP 300) and Wondfo Methamphetamine Urine Test (MET 500) are intended for the qualitative determination of d-Amphetamine and D(+)-Methamphetamine (target analyte) at the specific cut-off concentration in human urine. This product is only intended for prescription use and is not intended for point-of-care use. For in vitro diagnostic use only.

7. Device Description:

Assay Principle: Immunochromatograph assay for Amphetamine and Methamphetamine Urine Test using a lateral flow, one step system for the qualitative detection of d-Amphetamine and D(+)-Methamphetamine (target analyte) in human urine. Each assay uses a monoclonal antibody-dye conjugate from mouse against drug with gold chloride and fixed drug-protein conjugate and anti-mouse IgG polyclonal antibody in membrane.

8. Substantial Equivalence Information

A summary comparison of the features of the Wondfo Amphetamine Urine Test (AMP 300) and Wondfo Methamphetamine Urine Test (MET 500) and the predicate devices is provided in the Table 1 & Table 2.

Table 1: Features Comparison of Wondfo Amphetamine Urine Test (AMP 300) and the Predicate Devices

Item	Device	Predicate - K041822
Indication(s) for Use	For the qualitative determination of Amphetamine in human urine.	Same
Calibrator	d-Amphetamine	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
Specimen Type	Human Urine	Same
Cut Off Values	300 ng/mL	Same
Configurations	Cup, Dip Card	Strip, Device
Intended Use	Prescription Use and not for point-of-care use	Prescription Use and for point-of-care use

Table 2: Features Comparison of Wondfo Methamphetamine Urine Test (MET 500) and the Predicate Devices

Item	Device	Predicate - K033299
Indication(s) for Use	For the qualitative determination of D(+)-Methamphetamine in human urine.	Same
Calibrator	D(+)-Methamphetamine	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
Specimen Type	Human Urine	Same
Cut Off Values	500 ng/mL	Same
Configurations	Cup, Dip Card	Strip, Device
Intended Use	Prescription Use and not for point-of-care use	Prescription Use and for point-of-care 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

Wondfo Amphetamine Urine Test (AMP 300) and Wondfo Methamphetamine Urine Test (MET 500) are a one-step lateral flow immunoassay containing a conjugate pad with colloidal gold with anti-drug antibodies, a nitrocellulose membrane, with a test line (T) and a control line (C). The T line is coated with drug-protein conjugate and the C line is coated with goat anti-mouse IgG polyclonal antibodies. The test is a competitive binding immunoassay in which drugs in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of sample is applied, the sample migrates through the test device by capillary action.
If the concentration of drug is below the cutoff level, the anti-drug antibodies in the colloidal gold particles will bind to the drug antigens coated in the test zone producing a band which indicates a negative result. If the drug concentration is at the cutoff level or higher no band will form in the test zone (test line T) indicating a preliminary positive. A band should form in the control region regardless of the presence of drug or metabolite in the sample.

11. Performance Characteristics

11.1. 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.

Cup Format

AMP 300:

Result / AMP 300	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LOT W0770901CU2	50-/0+	50-/0+	50-/0+	50-/0+	47+/3-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0770902CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0770903CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

MET 500:

Result / MET 500	-100% cut off	-75% cut off	-50% cut off	-25% Cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LOT W1170901CU2	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1170902CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1170903CU2	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

Dip Card Format

AMP 300:

Result / AMP 300	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LOT W0770901P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0770902P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W0770903P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-

MET 500:

Result / MET 500	-100% cut off	-75% cut off	-50% cut off	-25% cut off	cut off	+25% cut off	+50% cut off	+75% cut off	+100% cut off
LOT W1170901P	50-/0+	50-/0+	50-/0+	50-/0+	46+/4-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1170902P	50-/0+	50-/0+	50-/0+	50-/0+	44+/6-	50+/0-	50+/0-	50+/0-	50+/0-
LOT W1170903P	50-/0+	50-/0+	50-/0+	50-/0+	45+/5-	50+/0-	50+/0-	50+/0-	50+/0-

b. Linearity
Not applicable

c. Stability
Stable for 18 months when stored at 4 to 30 ℃.

d. Cut-off

Test	Calibrator	Cut-off (ng/mL)
Wondfo Amphetamine Urine Test (AMP 300)	d-Amphetamine	300
Wondfo Methamphetamine Urine Test (MET 500)	D(+)-Methamphetamine	500

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

AMP 300

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	

MET 500

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

f. Specificity

To test the specificity, target drug, drug metabolites and other components that are likely to be present in urine samples were tested. Compounds that produced positive results with the test when tested at levels equal to or greater than the concentrations listed below. Percent cross reactivity of a compound is calculated by dividing the cutoff concentration by the minimum concentration required to obtain a positive result and the multiplying by 100%.

AMP 300

AMP(Amphetamine) (d-Amphetamine, Cutoff=300 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
d-Amphetamine	300	100%
l-Amphetamine	17500	1.7%
dl-Amphetamine	850	35.3%
(+/-) 3,4-methylenedioxyamphetamine (MDA)	1000	30.0%
Phentermine	1000	30.0%
β -Phenylethylamine	100000	0.3%
Tyramine	100000	0.3%
p-Hydroxynorephedrine	100000	0.3%
Phenylpropanolamine	>100,000	Not detected
(±)Phenylpropanolamine	>100,000	Not detected
p-Hydroxyamphetamine	100,000	0.3%
d/l-Norephedrine	100,000	0.3%
d-Methamphetamine	>100,000	Not detected
l-Methamphetamine	>100,000	Not detected
(+/-)3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	Not detected
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	Not detected
Benzphetamine	>100,000	Not detected
Ephedrine	>100,000	Not detected
l-Ephedrine	>100,000	Not detected
l-Epinephrine	>100,000	Not detected
d/l-Epinephrine	>100,000	Not detected

MET 500

MET(Methamphetamine) (D(+)-Methamphetamine, Cutoff=500 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
D(+)-Methamphetamine	500	100%
D-Amphetamine	50000	1.0%
Chloroquine	10000	5.0%
(+/-)-Ephedrine	25000	2.0%
(-)-Methamphetamine	10000	5.0%
(+/-)3,4-methylenedioxumethamphetamine(MDMA)	1000	50.0%
β-Phenylethylamine	25000	2.0%
Trimethobenzamide	5000	10.0%
d/l-Amphetamine	75,000	0.7%
p-Hydroxymethamphetamine	15,000	3.3%
Mephentermine	25,000	2.0%

(1R,2S)-(-)-Ephedrine	50,000	1.0%
l-Phenylephrine	100,000	0.5%

11.2. Comparison Studies

The method comparison for the Wondfo Amphetamine Urine Test (AMP 300), Wondfo Methamphetamine Urine Test (MET 500) were performed in-house with three laboratory assistants with relevant experience 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:

AMP 300:

Cup Format

Wondfo Result		Drug-free	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	29	11
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	1	29	11
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	17	12	0	0

Dip Card Format

Wondfo Result		Drug-free	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	29	11
	Negative	10	17	12	0	0
Viewer B	Positive	0	0	1	29	11
	Negative	10	17	12	0	0
Viewer C	Positive	0	0	1	29	11
	Negative	10	17	12	0	0

Discordant Results of AMP 300

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	AMP3063	281	Positive
Viewer A	AMP3216	259	Positive
Viewer B	AMP3218	287	Positive
Viewer C	AMP3063	281	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	AMP3218	287	Positive
Viewer B	AMP3216	259	Positive
Viewer C	AMP3063	281	Positive

MET 500:

Cup Format

Wondfo Result		Drug-free	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	15	13	0	0
Viewer B	Positive	0	0	2	20	20
	Negative	10	15	13	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	15	13	0	0

Dip Card Format

Wondfo Result		Drug-free	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	20	20
	Negative	10	15	14	0	0
Viewer B	Positive	0	0	1	20	20
	Negative	10	15	14	0	0
Viewer C	Positive	0	0	2	20	20
	Negative	10	15	13	0	0

Discordant Results of MET 500

Viewer	Sample Number	GC/MS Result	Cup Format Viewer Result
Viewer A	MET5061	478	Positive
Viewer A	MET5216	474	Positive
Viewer B	MET5063	499	Positive
Viewer B	MET5215	421	Positive
Viewer C	MET5061	478	Positive
Viewer C	MET5063	499	Positive

Viewer	Sample Number	GC/MS Result	Dip Card Format Viewer Results
Viewer A	MET5063	499	Positive
Viewer B	MET5061	478	Positive
Viewer C	MET5061	478	Positive
Viewer C	MET5063	499	Positive

11.3. Clinical Studies

Not applicable

12. Conclusion

Based on the test principle and performance characteristics of the device, it's concluded that Wondfo Amphetamine Urine Test (AMP 300), Wondfo Methamphetamine Urine Test (MET 500) are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 21, 2012

Guangzhou Wondfo Biotech Co., Ltd.
LSI International Inc.
c/o Joe Shia
504 East Diamond Ave.
Suite F
Gaithersburg, MD 20878

Re: k122961
Trade/Device Name: Wondfo Amphetamine Urine Test (AMP 300)
Wondfo Methamphetamine Urine Test (MET 500)

Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine Test System
Regulatory Class: Class II
Product Code: DKZ, LAF
Dated: November 8, 2012
Received: November 13, 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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
In Vitro Diagnosticsand Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K122961

Device Name: Wondfo Amphetamine Urine Test (AMP 300)
Wondfo Methamphetamine Urine Test (MET 500)

Indications for Use:

Wondfo Amphetamine Urine Test (AMP 300):

Wondfo Amphetamine Urine Test (AMP 300) is an immunochromatographic assay for the qualitative determination of d-Amphetamine in human urine at a cutoff concentration of 300 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use. For in vitro diagnostic use only.

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 Methamphetamine Urine Test (MET 500):

Wondfo Methamphetamine Urine Test (MET 500) is an immunochromatographic assay for the qualitative determination of D(+)-Methamphetamine in human urine at a cutoff concentration of 500 ng/mL. The test is available in a Dip Card format and a Cup format. This product is only intended for prescription use and is not intended for point-of-care use. For in vitro diagnostic use only.

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) K122961

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.

Prescription Use __X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____ (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 Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) K122961