September 25, 2020

Guangzhou Wondfo Biotech Co., Ltd.
% Joe Shia
Manager
LSI International
504 E Diamond Ave., Suite I
Gaithersburg, MD 20877

Re: K202567
Trade/Device Name: Wondfo T-Dip® Multi-Drug Urine Test Panel
Wondfo T-Dip® Multi-Drug Urine Test Panel Rx
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: NFT, NGL, PTH, NFV, NFY, PTG, NGG, LCM, QBF, QAW, NFW
Dated: September 2, 2020
Received: September 4, 2020

Dear Joe 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez- Torres, Ph.D.
Acting Deputy Director
Division of Chemistry and Toxicology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k202567

Device Name
Wondfo T-Dip® Multi-Drug Urine Test Panel

Indications for Use *(Describe)*
Wondfo T-Dip® Multi-Drug Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC 50)	50 ng/mL

Wondfo T-Dip® Multi-Drug Urine Test Panel offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

k202567

Device Name
Wondfo T-Dip® Multi-Drug Urine Test Panel Rx

Indications for Use *(Describe)*

Wondfo T-Dip® Multi-Drug Urine Test Panel Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	Cut-off level
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC 50)	50 ng/mL

Wondfo T-Dip® Multi-Drug Urine Test Panel Rx offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for in vitro diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

K202567

1 Date September 22, 2020

2 Submitter Guangzhou Wondfo Biotech Co., Ltd.
No. 8 Lizhishan Road, Science City, Luogang District
Guangzhou, Guangdong, P.R. China 510641

3 Contact Person Joe Shia
LSI International Inc.
504 East Diamond Ave., Suite F
Gaithersburg, MD 20878
Telephone: 240-505-7880
Fax: 301-916-6213
Email: shiajl@yahoo.com

4 Device Name Wondfo T-Dip® Multi-Drug Urine Test Panel
Wondfo T-Dip® Multi-Drug Urine Test Panel Rx

5 Classification Class II

Product Code Target Drug	Regulation Section	Panel
NFT Amphetamine (AMP)	862.3100, Amphetamine Test System	Toxicology
NGL Buprenorphine (BUP)	862.3650, Opiate Test System	Toxicology
PTH Secobarbital (BAR)	862.3150, Barbiturate Test System	Toxicology
NFV Oxazepam (BZO)	862.3170, Benzodiazepine Test System	Toxicology
NFY Cocaine (COC)	862.3250, Cocaine Test System	Toxicology
PTG 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	862.3620, Methadone Test System	Toxicology
NGG Methamphetamine (MET)	862.3610, Methamphetamine Test System	Toxicology
NGG Methylenedioxymethamphetamine (MDMA)	862.3610, Methamphetamine Test System	Toxicology
NGL	862.3650, Opiate Test System	Toxicology

Morphine (MOP/OPI)		
PTG Methadone (MTD)	862.3620, Methadone Test System	Toxicology
NGL Oxycodone (OXY)	862.3650, Opiate Test System	Toxicology
LCM Phencyclidine (PCP)	Unclassified	Toxicology
QBF Propoxyphene (PPX)	862.3700 Propoxyphene test system.	Toxicology
QAW Nortriptyline (TCA)	862.3910 Tricyclic antidepressant drugs test system	Toxicology
NFW Cannabinoids (THC 50)	862.3870, Cannabinoids Test System	Toxicology

6. Predicate Device K182701
   Wondfo T-Cup® Multi-Drug Urine Test Cup

7. Intended Use
   Wondfo T-Dip® Multi-Drug Urine Test Panel tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL

Cannabinoids (THC 50)	50 ng/mL

Wondfo T-Dip® Multi-Drug Urine Test Panel offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for *in vitro* diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses.
It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

Wondfo T-Dip® Multi-Drug Urine Test Panel Rx tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine at the cutoff concentrations of:

Drug (Identifier)	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC 50)	50 ng/mL

Wondfo T-Dip® Multi-Drug Urine Test Panel offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under same drug condition will be included per device. It is for *in vitro* diagnostic use only. It is intended for prescription use.

The tests may yield positive results for the prescription drugs Buprenorphine, Nortriptyline, Oxazepam, Secobarbital, Propoxyphene, and Oxycodone when taken at or above prescribed doses.
It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

8. Device Description

The Wondfo T-Dip® Multi-Drug Urine Test Panel and Wondfo T-Dip® Multi-Drug Urine Test Panel Rx are rapid, single-use in vitro diagnostic devices. Each test kit contains a test device in one pouch. One pouch contains a test T-Dip® panel and two desiccants, and a package insert. The Wondfo T-Dip® Multi-Drug Urine Test Panel is intended for over-the-counter use and the Wondfo T-Dip® Multi-Drug Urine Test Panel Rx is intended for prescription use.

9. Substantial Equivalence Information

Item	**Proposed Device**		**Predicate (K182701)**
Indication(s) for use	For the qualitative determination of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in human urine.		Same
Methodology	Competitive binding, lateral flow immunochromatographic assay based on antigen-antibody reaction		Same
Type of Test	Qualitative		Same
Specimen Type	Human urine		Same
Target Drug and Cut Off Values	**Target Drug**	**Cutoff (ng/mL)**	Same
	Amphetamine (AMP)	1000 or 500	
	Buprenorphine (BUP)	10	
	Secobarbital (BAR)	300	
	Oxazepam (BZO)	300	
	Cocaine (COC)	300 or 150	

	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300	
	Methamphetamine (MET)	1000 or 500	
	Methylenedioxymethamphetamine (MDMA)	500	
	Morphine (MOP 300/OPI 2000)	2000 or 300	
	Methadone (MTD)	300	
	Oxycodone (OXY)	100	
	Phencyclidine (PCP)	25	
	Propoxyphene (PPX)	300	
	Nortriptyline (TCA)	1000	
	Cannabinoids (THC 50)	50	
Configurations	Test Panel		Cup
Intended Use	Prescription Use and over-the-counter use		For over-the-counter use

10. Test Principle

Wondfo T-Dip® Multi-Drug Urine Test Panel and Wondfo T-Dip® Multi-Drug Urine Test Panel Rx are rapid tests for the qualitative detection of Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine,Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Cannabinoids in urine samples. They are lateral flow chromatographic immunoassay. When urine sample is added to the cup device, urine is absorbed into the test strip and migrates upwards by capillary action. If the concentration of target drug presented in the urine sample is below the cutoff level, the target drug will not saturate the binding sites of its specific monoclonal antibody-coated particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored band will be formed on the test line region. If the concentration of target is beyond the cutoff level, the target drug will saturate the binding sites of its specific monoclonal antibody-particles, thus the antibody-coated particles will not be captured by immobilized drug-conjugate hence no colored band will be formed on the test line region.

A band should be formed on the control line region regardless of the presence of target drug or metabolite in the sample to indicate that the tests have been performed properly.

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, cutoff, +25% cut off, +50% cut off, +75% cut off and +100% cut off. Samples with concentration of -100% cutoff were drug-free urines samples. Other samples were prepared by spiking target drug in drug-free urine samples. Each drug concentration was confirmed

by LC/MS or GC/MS. For each concentration, tests were performed two runs per day for 25 days using three lots of test panels. The results obtained are summarized in the following tables:

T-Dip® Multi-Drug Urine Test Panel BUP 10

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	19.68	17.69	14.89	12.81	10.69	8.29	5.27	2.58	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel PCP 25

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	50.74	43.64	36.98	30.85	24.43	18.49	12.29	6.63	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	6-/44+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	6-/44+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel THC 50

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	99.50	88.57	75.41	62.39	50.04	38.04	25.70	12.18	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel OXY 100

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	198.93	178.79	149.47	122.29	103.53	75.69	48.78	24.68	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+

Lot II	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel BAR 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	599.00	525.62	455.65	374.74	297.26	217.7	142.50	74.48	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel BZO 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	602.91	516.94	448.36	378.24	296.80	216.82	149.66	73.34	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel EDDP 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	597.99	537.04	454.10	376.30	296.48	231.98	152.78	71.21	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel MTD 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	601.73	533.12	444.38	377.94	300.53	221.54	158.88	89.27	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+

Lot III	0-/50+	0-/50+	0-/50+	0-/50+	9-/41+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel MOP 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	603.15	514.08	444.29	366.05	297.98	237.05	158.56	87.33	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel PPX 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	602.35	510.96	445.25	373.09	301.81	238.40	151.24	77.94	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel COC 150

Concentration by GC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	298.12	265.57	228.13	185.01	149.94	111.61	73.28	35.91	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel MDMA 500

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1005.82	874.87	746.39	620.36	496.21	377.55	245.14	120.41	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel TCA 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1994.55	1772.46	1489.61	1244.94	1029.95	764.86	493.08	283.95	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel AMP 500

Concentration by GC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	998.23	880.545	750.15	630.77	500.18	372.34	256.24	125.78	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel MET 500

Concentration by GC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1006.21	862.45	744.97	620.39	497.11	374.32	246.02	123.98	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel OPI 2000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	4008.48	3474.19	2990.67	2429.13	1971.46	1514.16	1051.16	494.48	0

Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel COC 300

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	599.44	528.54	450.89	370.66	299.9	224.66	149.77	78.09	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	10-/40+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	11-/39+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel AMP 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1978.82	1746.3	1508.6	1260.5	1026.56	758.64	505.69	258.23	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+

T-Dip® Multi-Drug Urine Test Panel MET 1000

Concentration by LC/MS (ng/mL) / Lot Number	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	Cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cut-off
	1978.55	1740.9	1506.5	1234.8	1037.23	751.60	491.85	245.71	0
Lot I	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot II	0-/50+	0-/50+	0-/50+	0-/50+	8-/42+	50-/0+	50-/0+	50-/0+	50-/0+
Lot III	0-/50+	0-/50+	0-/50+	0-/50+	7-/43+	50-/0+	50-/0+	50-/0+	50-/0+

The following cutoff values are verified:

Target Drug	**Cut-off level**
Amphetamine (AMP)	1000 ng/mL or 500 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL

Oxazepam (BZO)	300 ng/mL
Cocaine (COC)	300 ng/mL or 150 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	1000 ng/mL or 500 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP 300/OPI 2000)	2000 ng/mL or 300 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Propoxyphene (PPX)	300 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Cannabinoids (THC 50)	50 ng/mL

b. Linearity

Not applicable

c. Stability

The devices are stable at 4-30℃ for 24 months based on real-time stability studies.

d. Interference

Potential interfering substances were added to drug-free urine sample and samples with target drugs of -25% cutoff and +25% cutoff level.

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

Acetaminophen	Acetophenetidin	Acetylsalicylic Acid
Acyclovir	Amiodarone Hydrochloride	Apomorphine
Afrin	Albumin (100mg/dL)	Amlodipine Mesylate
Aminophylline	Amoxicillin	Aripiprazole
Aminopyrine	Ampicillin	Aspartame
Benzilic Acid	Atropine	Atomoxetine
Benzoic Acid	Carbamazepine	Atorvastatin Calcium
Bilirubin	Cefradine	Chloramphenicol
Bupropion	Cephalexin	Chlorothiazide
Captopril	Chloral Hydrate	Chloroquine
Ciprofloxacin Hydrochloride	Clonidine	Cholesterol
Citalopram	Clopidogrel Hydrogen Sulphate	(-) Cotinine
Clarithromycin	Clozapine	chlorpheniramine

Deoxy- corticosterone	D,L-Tyrosine	D,L-Octopamine
Dextromethorphan	Digoxin	D,L-Propranolol
Diclofenac	Diphenhydramine	D-Norpropoxy- phene
Diflunisal	Dirithromycin	Domperidone
D-Pseudo- ephedrine	Ecgonine Methyl Ester	Doxylamine
Duloxetine	Effexor	Epinephrine Hydrochloride
Dicyclomine	Enalapril Maleate	Erythromycin
β-Estradiol	Fentanyl Citrate	Esomeprazole Magnesium
Ethanol (1%)	Fluoxetine Hydrochloride	Furosemide
Fenofibrate	Fluvoxamine	Gabapentin
Fenoprofen	Glucose	Gentisic Acid
Glibenclamide	Haloperidol	3-Hydroxy- tyramine
Gliclazide	Hemoglobin	Isosorbide Dinitrate
Glipizide	Ketamine	Isoxsuprine
Ibuprofen	Kratom powder	Lamotrigine
Ketoconazole	Labetalol	Levofloxacin Hydrochloride
Ketoprofen	Liverite	Levonorgestrel
Lidocaine Hydrochloride	Loperamide	Levothyroxine Sodium
Lisinopril	Loratadine	Minocycline
Lithium Carbonate	Naproxen	Nalidixic Acid
Metoprolol Tartrate	Mifepristone	Niacinamide
Magnesium	Mirtazapine	Nifedipine
Meperidine	Montelukast Sodium	Nikethamide
Meprobamate	Phenelzine	Sulfamethazine
Mosapride Citrate	Pioglitazone Hydrochloride	Sulindac
Maprotiline	Piracetam	Tetrahydrocortisone 3 -acetate
Nimodipine	Pravastatin Sodium	Tetrahydrocortisone 3-(β-D-glucuronide)
Norethindrone	Prednisone	Tetrahydrozoline
N-Acetylprocain-amide	Propylthiouracil	Tetracycline
O-Hydroxyhippu-ric Acid	Promethazine	Thiamine
Olanzapine	Quetiapine Fumarate	Thioridazine
Omeprazole	Quinine	Topiramate
Oxalic Acid	Ranitidine	Tramadol Hydrochloride
Oxolinic Acid	Rifampicin	Trazodone Hydrochloride
Oxymetazoline	Risperidone	Triamterene
Ondansetran	Salicylic Acid	Trifluoperazine
Paliperidone	Serotonin	Trimethoprim
Pantoprazole	Sertraline Hydrochloride	Uric Acid
Papaverine	Sildenafil Citrate	Valproate
Paroxetine Hydrochloride	Simvastatin	Verapamil

Penfluridol	Sodium Valproate	Vitamin B2
PenicillinV Potassium	Spironolactone	Vitamin C
Penicillin-G		

e. Specificity

To test the specificity, drug metabolites and other components that are likely to cross-react in urine samples were spiked into drug-free urine. These urine samples were tested using three lots of each device.

Percent cross-reactivity, provided in the below table, was calculated as the concentration of analyte tested that yielded a positive result, divided by the cutoff concentration, multiplied by 100; compounds that did not yield a positive result at the highest concentration tested have relative cross reactivity results represented by a dash in the table below:

BUP 10 (Buprenorphine, Cutoff=10 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Buprenorphine -3-D-Glucuronide	15	66.7%
Norbuprenorphine	20	50%
Norbuprenorphine-3-D-Glucuronide	200	5%
Morphine	>100,000	--
Oxymorphone	>100,000	--
Hydromorphone	>100,000	--

PCP (Phencyclidine) (Phencyclidine, Cutoff=25 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
4-Hydroxyphencyclidine	12500	0.2%

THC 50 (11-nor-Δ9-THC-9-COOH, Cutoff=50 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
11-nor-Δ8-THC 50-9-COOH	30	167%
(-)-11-nor-9-carboxy-Δ 9-THC 50	50	100%
11-nor-Δ9-THC 50-carboxy glucuronide	100	50%
11-hydroxy-Δ9-Tetrahydrocannabinol	5000	1%
Δ8- Tetrahydrocannabinol	1300	4%
Δ9- Tetrahydrocannabinol	5000	1%
Cannabinol	20000	0.25%
Cannabidiol	100000	0.05%

OXY 100 (Oxycodone, Cutoff=100 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Dihydrocodeine	20000	0.5%
Hydrocodone	10000	1%
Oxymorphone	1000	10%
Codeine	100000	0.1%
Hydromorphone	32000	0.3125%
Morphine	>100,000	--
Acetylmorphine	>100,000	--
Buprenorphine	>100,000	--
Ethylmorphine	>100,000	--
Thebaine	>100,000	--

COC 150 (Benzoylecgonine, Cutoff=150 ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Cocaine	375	40%
Cocaethylene	6250	2.4%
Ecgonine	16000	<1%
Ecgonine methyl ester	>100,000	--
Norcocaine	>100,000	--

BAR 300 (Secobarbital, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Amobarbital	10000	3%
Alphenol	150	200%
Aprobarbital	200	150%
Butabarbital	75	400%
Butathal	100	300%
Butalbital	2500	12%
Cyclopentobarbital	600	50%
Pentobarbital	2500	12%
Phenobarbital	10000	3%

BZO 300 (Oxazepam, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Alprazolam	200	150%
a-Hydroxyalprazolam	1500	20%
Bromazepam	500	60%

Chlordiazepoxide	1500	20%
Clobazam	100	300%
Clonazepam	800	37.5%
Clorazepate dipotassium	200	150%
Delorazepam	1500	20%
Desalkylflurazepam	400	75%
Diazepam	200	150%
Estazolam	1000	30%
Flunitrazepam	2500	12%
Midazolam	12500	2.4%
Nitrazepam	4000	7.5%
Norchlordiazepoxide	200	150%
Nordiazepam	500	60%
Temazepam	250	120%
Triazolam	1200	25%
Demoxepam	2000	15%
Flurazepam	500	60%
D,L-Lorazepam	1500	20%

EDDP 300 (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Cutoff = 300 ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Methadone	300000	0.1%
EMDP	300000	0.1%
Doxylamine	>100,000	--
Disopyramide	>100,000	--
LAAM (Levo-alpha-acetylmethadol) HCl	>100,000	--
Alpha Methadol	>100,000	--

MTD 300 (Methadone, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Doxylamine	50000	0.6%
EDDP	>100,000	--
EMDP	>100,000	--
LAAM	>100,000	--
Alpha Methadol	>100,000	--

MOP 300 (Morphine, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Normorphine	300	100%

Codeine	300	100%
s-Monoacetylmorphine	300	100%
Ethyl Morphine	100	300%
Heroin	300	100%
Hydrocodone	5000	6%
Hydromorphone	1000	30%
Morphinie-3-β-d-glucuronide	1000	30%
Oxycodone	>100000	--
Oxymorphone	100000	0.3%
Thebaine	3000	10%
Levorphanol	10000	3%
6-Monoacetylmorphine (6-MAM)	150	200%
Norcodeine	6250	4.8%
Procaine	150000	0.2%

PPX 300 (Propoxyphene, Cutoff=300ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
d-Norpropoxyphene	300	100%

MDMA 500 (3,4-Methylenedioxymethamphetamine HCl, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
3,4-Methylenedioxyamphetamine HCl (MDA)	3000	17%
3,4-Methylenedioxyethylamphetamine (MDEA)	300	167%
d-methamphetamine	>100,000	--
d-amphetamine	>100,000	--
l-methamphetamine	50000	1%
l-amphetamine	>100,000	--

AMP 500 (Amphetamine, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
l-Amphetamine	25000	2%
dl- Amphetamine	1500	33%
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	2500	20%
Phentermine	1500	33%
Hydroxyamphetamine	8000	6.25%
d-Methamphetamine	>100,000	--
l-Methamphetamine	>100,000	--

(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	>100,000	--
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	>100,000	--
Ephedrine	>100,000	--
β-Phenylethylamine	100000	0.5%
Tyramine	100000	0.5%
p-Hydroxynorephedrine	100000	0.5%
Phenylpropanolamine	>100,000	--
(±)Phenylpropanolamine	>100,000	--
p-Hydroxyamphetamine	100000	0.5%
d/l-Norephedrine	100000	0.5%
Benzphetamine	>100,000	--
l-Ephedrine	>100,000	--
l-Epinephrine	>100,000	--
d/l-Epinephrine	>100,000	--

MET 500 (D(+)-Methamphetamine, Cutoff=500ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
D-Amphetamine	25000	2%
L- Amphetamine	37500	1.3%
Chloroquine	10000	5%
(+/-)-Ephedrine	25000	2%
D/L-Methamphetamine	500	100%
L-Methamphetamine	10000	5%
(+/-)3,4Methylenedioxy-n-ethylamphetamine (MDEA)	500	100%
(+/-)3,4- Methylenedioxyamphetamine(MDA)	500	100%
(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	2000	25%
β-Phenylethylamine	25000	2%
Trimethobenzamide	5000	10%
d/l-Amphetamine	75000	0.7%
p-Hydroxymethamphetamine	15000	3.3%
Mephentermine	25000	2%
(1R,2S)-(-)-Ephedrine	50000	1%
l-Phenylephrine	100000	0.5%
(-)-Methamphetamine	12500	4%

TCA 1000 (Nortriptyline, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Nordoxepine	1000	100%
Trimipramine	3000	33.3%
Amitriptyline	1500	66.7%
Promazine	1500	66.7%
Desipramine	200	500%
Imipramine	400	250%
Clomipramine	12500	8%
Doxepine	2000	50%
Maprotiline	2000	50%
Promethazine	25000	4%
Cyclobenzaprine	800	125%
Norclomipramine	12500	8%

COC 300 (Benzoylecgonine, Cutoff=300ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
Cocaine	750	40%
Cocaethylene	12500	2.4%
Ecgonine	32000	<1%
Ecgonine methyl Ester	>100000	--
Norcocaine	>100,000	--

AMP 1000 (d-Amphetamine, Cutoff=1000ng/mL)	Minimum concentration required to obtain a positive result (ng/mL)	% Cross-Reactivity
l-Amphetamine	50000	2%
d1-Amphetamine	3000	33.3%
Phentermine	3000	33.3%
(+/-) 3,4-Methylenedioxyamphetamine (MDA)	5000	20%
Hydroxyamphetamine	>100000	--
d-Methamphetamine	>100000	--
l-Methamphetamine	>100000	--
Ephedrine	>100000	--
(+/-)3,4- Methylenedioxymethamphetamine (MDMA)	100000	1%
β-Phenylethylamine	100000	1%
Tyramine	100000	1%

p-Hydroxynorephedrine	100000	1%
Phenylpropanolamine	>100000	--
(±)Phenylpropanolamine	>100000	--
p-Hydroxyamphetamine	100000	1%
d/l-Norephedrine	100000	1%
Benzphetamine	>100000	--
l-Ephedrine	>100000	--
l-Epinephrine	>100000	--
d/l-Epinephrine	>100000	--
Hydroxyamphetamine	8000	12.5%

MET 1000 (D(+)-Methamphetamine, Cutoff=1000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
(+/-)3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	1000	100%
D/L-Methamphetamine	1000	100%
p-Hydroxymethamphetamine	30000	3.3%
D-Amphetamine	>100000	--
L-Amphetamine	75000	1.3%
Chloroquine	50000	2%
(+/-)-Ephedrine	50000	2%
(-)-Methamphetamine	25000	4%
(+/-)3,4-Methylenedioxyamphetamine (MDA)	1000	100%
(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	4000	25%
β-Phenylethylamine	50000	2%
Trimethobenzamide	10000	10%
d,l-Amphetamine	100000	1%
Mephetermine	50000	2%
(1R,2S)-(-)-Ephedrine	>100000	--
l-phenylephrine	>100000	--
L-Methamphetamine	25000	4%

OPI 2000 (Morphine, Cutoff=2000ng/mL)	**Minimum concentration required to obtain a positive result (ng/mL)**	**% Cross-Reactivity**
Codeine	2000	100%
Ethyl Morphine	1500	133%
Hydrocodone	12500	16%
Hydromorphone	3500	57%

Levorphanol	75000	2.7%
6-Monoacetylmorphine（6-MAM）	1500	133%
Morphine 3-β-D-glucuronide	2000	100%
Norcodeine	12500	16%
Normorphine	50000	4%
Oxycodone	25000	8%
Oxymorphone	25000	8%
Procaine	150000	1.3%
Thebaine	5000	40%
Heroin	2000	100%
s-Monoacetylmorphine	2000	100%

f. Effect of Urine Specific Gravity and Urine pH

To investigate the effect of urine specific gravity, urine samples with specific gravity from 1.000 to 1.035 were spiked with target drugs at +25% cutoff and -25% cutoff levels. Three viewers tested each sample using test devices from three different lots. The results were all positive for samples at +25% cutoff and all negative for samples at -25% cutoff, indicating that urine specific gravity between 1.000 and 1.035 has no effect on the accuracy and precision of the test device.

To investigate the effect of urine pH, urine samples with pH value from 4 to 9 were spiked with target drugs at +25% cutoff and -25% cutoff levels. Three viewers tested each sample using test devices from three different lots. The results were all positive for samples at +25% cutoff and all negative for samples at -25% cutoff, indicating that urine pH value between 4.0 and 9.0 has no effect on the accuracy and precision of the test device.

2. Comparison Studies

The method comparison studies for Wondfo T-Dip® Multi-Drug Urine Test Panel were performed in-house with three operators.

Operators ran 80 (40 negative and 40 positive) unaltered urine samples. The samples were blind labeled and compared to LC/MS or GC/MS results. The results are presented in the table below:

For T-Dip® Multi-Drug Urine Test Panel:

AMP 500

Wondfo T-Dip®		Drug-Free	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and the 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	30	10
	Negative	10	17	11	0	0
Viewer B	Positive	0	0	1	30	10

	Negative	10	17	12	0	0
Viewer C	Positive	0	0	1	30	10
	Negative	10	17	12	0	0

Discordant Results for AMP 500:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20327	479.507	+
Viewer B	20327	479.507	+
Viewer C	20716	480.687	+
Viewer A	20716	480.687	+

BUP 10

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	28	10
	Negative	10	18	10	2	0
Viewer B	Positive	0	0	2	28	10
	Negative	10	18	10	2	0
Viewer C	Positive	0	0	2	28	10
	Negative	10	18	10	2	0

Discordant Results for BUP 10:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20181	10.039	-
Viewer B	20181	10.039	-
Viewer C	20181	10.039	-
Viewer A	20317	11.063	-
Viewer B	20317	11.063	-
Viewer C	20317	11.063	-
Viewer A	20644	8.226	+
Viewer B	20644	8.226	+
Viewer C	20644	8.226	+
Viewer A	20611	9.000	+
Viewer B	20611	9.000	+
Viewer C	20611	9.000	+

BAR 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	29	11
	Negative	10	19	10	0	0
Viewer B	Positive	0	0	1	28	11
	Negative	10	19	10	1	0
Viewer C	Positive	0	0	1	28	11
	Negative	10	19	10	1	0

Discordant Results for BAR 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20564	247.29	+
Viewer B	20564	247.29	+
Viewer C	20564	247.29	+
Viewer B	20332	307.799	-
Viewer C	20012	307.127	-

BZO 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	29	10
	Negative	10	15	13	1	0
Viewer B	Positive	0	0	0	28	10
	Negative	10	15	15	2	0
Viewer C	Positive	0	0	3	29	10
	Negative	10	15	12	1	0

Discordant Results for BZO 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20556	274.237	+
Viewer C	20556	274.237	+
Viewer C	20848	286.984	+
Viewer A	21006	289.534	+

Viewer C	21006	289.534	+
Viewer A	20605	307.387	-
Viewer B	20605	307.387	-
Viewer C	20605	307.387	-
Viewer B	20995	313.241	-

COC 150

Wondfo T-Dip®		Drug-Free	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and the 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	31	9
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	1	30	9
	Negative	10	18	11	1	0
Viewer C	Positive	0	0	2	30	9
	Negative	10	18	10	1	0

Discordant Results for COC 150:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	21001	145.437	+
Viewer B	21001	145.437	+
Viewer C	20447	133.375	+
Viewer A	20261	146.311	+
Viewer C	20261	146.311	+
Viewer B	21126	162.825	-
Viewer C	21051	150.712	-

EDDP 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	32	8
	Negative	10	18	11	0	0
Viewer B	Positive	0	0	1	32	8

	Negative	10	18	11	0	0
Viewer C	Positive	0	0	1	32	8
	Negative	10	18	11	0	0

Discordant Results for EDDP 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	21064	246.737	+
Viewer B	21064	246.737	+
Viewer C	21064	246.737	+

MET 500

Wondfo T-Dip®		Drug-Free	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and the 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	3	20	20
	Negative	10	15	12	0	0

Discordant Results for MET 500:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20402	478.249	+
Viewer B	20402	478.249	+
Viewer C	20402	478.249	+
Viewer A	20731	499.295	+
Viewer B	20731	499.295	+
Viewer C	20731	499.295	+
Viewer C	20459	384.376	+

MDMA 500

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)

Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	18	10	0	0

Discordant Results for MDMA 500:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	21109	409.82	+
Viewer B	21109	409.82	+
Viewer C	21109	409.82	+
Viewer A	20810	417.972	+
Viewer B	20810	417.972	+
Viewer C	20810	417.972	+

MOP 300

Wondfo T-Dip®		Drug-Free	Low Negative by GC/MS (less than -50%)	Near Cutoff Negative by GC/MS (Between -50% and the 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	0	29	10
	Negative	10	18	12	1	0
Viewer B	Positive	0	0	0	29	10
	Negative	10	18	12	1	0
Viewer C	Positive	0	0	0	29	10
	Negative	10	18	12	1	0

Discordant Results for MOP 300:

Viewer	Sample Number	GC/MS Result (ng/mL)	T-Dip Result
Viewer A	20893	304.731	-
Viewer B	20893	304.731	-
Viewer C	20893	304.731	-

MTD 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS	Near Cutoff Positive by LC/MS	High Positive by LC/MS (greater than +50%)

				(Between -50% and the Cutoff)	(Between the cutoff and +50%)	
Viewer A	Positive	0	0	2	28	12
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	1	27	12
	Negative	10	18	11	1	0
Viewer C	Positive	0	0	2	27	12
	Negative	10	18	10	1	0

Discordant Results for MTD 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20646	282.733	+
Viewer B	20646	282.733	+
Viewer C	20646	282.733	+
Viewer A	20404	285.038	+
Viewer C	20404	285.038	+
Viewer B	20572	309.555	-
Viewer C	20572	309.555	-

OXY 100

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	30	10
	Negative	10	18	11	0	0
Viewer B	Positive	0	0	1	29	10
	Negative	10	18	11	1	0
Viewer C	Positive	0	0	0	29	10
	Negative	10	18	12	1	0

Discordant Results for OXY 100:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20008	75.7	+
Viewer B	20008	75.7	+
Viewer B	20840	113.792	-
Viewer C	20840	113.792	-

PCP 25

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	28	10
	Negative	10	20	9	2	0
Viewer B	Positive	0	0	1	29	10
	Negative	10	20	9	1	0
Viewer C	Positive	0	0	1	29	10
	Negative	10	20	9	1	0

Discordant Results for PCP 25:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	21197	20.203	+
Viewer B	21197	20.203	+
Viewer C	21197	20.203	+
Viewer A	20041	25.049	-
Viewer B	20041	25.049	-
Viewer C	20065	25.105	-
Viewer A	20065	25.105	-

PPX 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	31	8
	Negative	10	17	11	1	0
Viewer B	Positive	0	0	2	31	8
	Negative	10	17	11	1	0
Viewer C	Positive	0	0	2	31	8
	Negative	10	17	11	1	0

Discordant Results for PPX 300:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20831	245.38	+

Viewer B	20831	245.38	+
Viewer C	20831	245.38	+
Viewer A	20108	252.045	+
Viewer B	20108	252.045	+
Viewer C	20108	252.045	+
Viewer A	20805	314.373	-
Viewer B	20805	314.373	-
Viewer C	20805	314.373	-

TCA 1000

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	29	10
	Negative	10	18	10	1	0
Viewer B	Positive	0	0	2	29	10
	Negative	10	18	10	1	0
Viewer C	Positive	0	0	2	29	10
	Negative	10	18	10	1	0

Discordant Results for TCA 1000:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20720	806.195	+
Viewer B	20720	806.195	+
Viewer C	20720	806.195	+
Viewer A	20937	812.065	+
Viewer B	20937	812.065	+
Viewer C	20937	812.065	+
Viewer A	20534	1007.857	-
Viewer B	20534	1007.857	-
Viewer C	20534	1007.857	-

THC 50

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS	High Positive by LC/MS (greater than +50%)

					(Between the cutoff and +50%)	
Viewer A	Positive	0	0	2	30	10
	Negative	10	19	9	0	0
Viewer B	Positive	0	0	2	30	10
	Negative	10	19	9	0	0
Viewer C	Positive	0	0	2	30	10
	Negative	10	19	9	0	0

Discordant Results for THC 50:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	20822	45.118	+
Viewer B	20822	45.118	+
Viewer C	20822	45.118	+
Viewer A	20385	43.304	+
Viewer B	20385	43.304	+
Viewer C	20385	43.304	+

AMP 1000

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	1	30	10
	Negative	10	16	13	0	0
Viewer B	Positive	0	0	1	28	10
	Negative	10	16	13	2	0
Viewer C	Positive	0	0	1	28	10
	Negative	10	16	13	2	0

Discordant Results for AMP 1000:

Viewer	Sample Number	LC/MS Result (ng/mL)	T-Dip Result
Viewer A	21354	797.646	+
Viewer B	21354	797.646	+
Viewer C	21354	797.646	+
Viewer B	21426	1012.27	-
Viewer C	21426	1012.27	-
Viewer B	21240	1014.805	-

Viewer C	21240	1014.805	-

COC 300

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	3	28	11
	Negative	10	13	14	1	0
Viewer B	Positive	0	0	3	28	11
	Negative	10	13	14	1	0
Viewer C	Positive	0	0	3	28	11
	Negative	10	13	14	1	0

Discordant Results for COC 300:

Viewer	Sample Number	LC/MS Result	T-Dip Result
Viewer A	21495	283.934	+
Viewer B	21495	283.934	+
Viewer C	21495	283.934	+
Viewer A	21503	292.623	+
Viewer B	21503	292.623	+
Viewer C	21503	292.623	+
Viewer A	21368	293.871	+
Viewer B	21368	293.871	+
Viewer C	21368	293.871	+
Viewer A	21467	309.73	-
Viewer B	21467	309.73	-
Viewer C	21467	309.73	-

MET 1000

Wondfo T-Dip®		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	24	15
	Negative	10	18	10	1	0
Viewer B	Positive	0	0	2	24	15
	Negative	10	18	10	1	0

Viewer C	Positive	0	0	2	24	15
	Negative	10	18	10	1	0

Discordant Results for MET 1000:

Viewer	Sample Number	LC/MS Result	T-Dip Result
Viewer A	21253	888.241	+
Viewer B	21253	888.241	+
Viewer C	21253	888.241	+
Viewer A	21334	890.705	+
Viewer B	21334	890.705	+
Viewer C	21334	890.705	+
Viewer A	21375	1036.001	-
Viewer B	21375	1036.001	-
Viewer C	21375	1036.001	-

OPI 2000

Wondfo Q-Cup		Drug-Free	Low Negative by LC/MS (less than -50%)	Near Cutoff Negative by LC/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC/MS (Between the cutoff and +50%)	High Positive by LC/MS (greater than +50%)
Viewer A	Positive	0	0	2	30	10
	Negative	10	18	10	0	0
Viewer B	Positive	0	0	3	30	10
	Negative	10	18	9	0	0
Viewer C	Positive	0	0	1	30	10
	Negative	10	18	11	0	0

Discordant Results for OPI 2000:

Viewer	Sample Number	LC/MS Result	T-Dip Result
Viewer A	21270	1830.086	+
Viewer B	21270	1830.086	+
Viewer C	21270	1830.086	+
Viewer B	21453	1882.994	+
Viewer A	21429	1947.150	+
Viewer B	21429	1947.150	+

Lay-user study:

A lay user study was performed using urine samples prepared at the following concentrations; -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drug(s) into drug free-pooled urine specimens. The

concentrations of the samples were confirmed by LC/MS or GC/MS. Each sample was aliquoted into individual containers and blind-labeled. A total of 280 participants with diverse educational and professional backgrounds aged 20 years and older were recruited from three sites. Ninety-four males and 46 females tested T-Dip® Multi-Drug Urine Test Panel Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150); 88 male and 52 females tested T-Dip® Multi-Drug Urine Test Panel Configuration 2 (including AMP 1000, MET 1000, MOP 2000 (OPI), COC 300). Each participant was provided one package insert, one blind labeled test solution, and one test device. The results are summarized below:

Lay-User Study Results for T-Dip® Multi-Drug Urine Test Panel Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150):

Assay	Results	Concentration						
		-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP 500	Negative	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
BAR 300	Negative	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
BZO 300	Negative	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
BUP 10	Negative	20	20	20	17	2	0	0
	Positive	0	0	0	3	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	85%	90%	100%	100%
COC 150	Negative	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
EDDP 300	Negative	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20

	Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%
MDMA 500	**Negative**	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%
MET 500	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
MOP 300	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
MTD 300	**Negative**	20	20	20	18	3	0	0
	Positive	0	0	0	2	17	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	85%	100%	100%
OXY 100	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
PCP 25	**Negative**	20	20	20	17	2	0	0
	Positive	0	0	0	3	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	85%	90%	100%	100%
PPX 300	**Negative**	20	20	20	18	3	0	0
	Positive	0	0	0	2	17	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	85%	100%	100%
TCA 1000	**Negative**	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%

THC 50	**Negative**	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%

Lay-User Study Results for T-Dip® Multi-Drug Urine Test Panel Configuration 2 (AMP 1000, MET 1000, MOP 2000 (OPI), COC 300):

Assay	**Results**	**Concentration**						
		-100% cutoff	**-75% cutoff**	**-50% cutoff**	**-25% cutoff**	**+25% cutoff**	**+50% cutoff**	**+75% cutoff**
AMP 1000	**Negative**	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
BAR 300	**Negative**	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
BZO 300	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
BUP 10	**Negative**	20	20	20	18	3	0	0
	Positive	0	0	0	2	17	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	85%	100%	100%
COC 300	**Negative**	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
EDDP 300	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%

MDMA 500	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
MET 1000	**Negative**	20	20	20	19	1	0	0
	Positive	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	95%	100%	100%
OPI 2000	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
MTD 300	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
OXY 100	**Negative**	20	20	20	18	1	0	0
	Positive	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	95%	100%	100%
PCP 25	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%
PPX 300	**Negative**	20	20	20	19	2	0	0
	Positive	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	95%	90%	100%	100%
TCA 1000	**Negative**	20	20	20	20	0	0	0
	Positive	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	100%	100%	100%	100%
THC 50	**Negative**	20	20	20	18	2	0	0
	Positive	0	0	0	2	18	20	20

	Total	20	20	20	20	20	20	20
	Percentage of correct results (%)	100%	100%	100%	90%	90%	100%	100%

Participants were given surveys on the ease of understanding the instruction for use. All participants indicated that the device instruction is easy to understand and follow. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

Clinical Studies:

Not applicable.

12. Conclusion

Based on the test principle and performance characteristics of the device including precision, cut-off, interference, specificity, method comparison and lay-user studies of the devices, it's concluded that WondfoT-Dip® Multi-Drug Urine Test Panel and Wondfo T-Dip® Multi-Drug Urine Test Panel Rx are substantially equivalent to the predicate devices.