510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K222667

B Applicant

VivaChek Biotech (Hangzhou) Co., Ltd

C Proprietary and Established Names

Wisdiag Multi-Drug Urine Test Cup, Wisdiag Multi-Drug Urine Test Cup Rx

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFT	Class II	21 CFR 862.3100 - Amphetamine Test System	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate test system	TX - Clinical Toxicology
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
NFV	Class II	21 CFR 862.3170 - Benzodiazepine test system	TX - Clinical Toxicology
NFY	Class II	21 CFR 862.3250 - Cocaine and cocaine metabolite test system	TX - Clinical Toxicology
PTG	Class II	21 CFR 862.3620 - Methadone test system	TX - Clinical Toxicology
NGG	Class II	21 CFR 862.3610 - Methamphetamine test system	TX - Clinical Toxicology

Product Code(s)	Classification	Regulation Section	Panel
QBF	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
QAW	Class II	21 CFR 862.3910 - Tricyclic antidepressant drugs test system	TX - Clinical Toxicology
NFW	Class II	21 CFR 862.3870 - Cannabinoid test system	TX - Clinical Toxicology
LCM	Unclassified		

II Submission/Device Overview:

A Purpose for Submission:

New device

B Measurand:

Amphetamine, Buprenorphine, Secobarbital, Oxazepam, Cocaine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline and Marijuana

C Type of Test:

Qualitative, lateral flow immunochromatographic assay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

Wisdiag Multi-Drug Urine Test Cup 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 Marijuana 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
Marijuana (THC) - 50 ng/mL

Wisdiag Multi-Drug Urine Test Cup offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under the 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 of 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.

Wisdiag Multi-Drug Urine Test Cup 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 ng/mL

Wisdiag Multi-Drug Urine Test Cup Rx offers any combinations from 2 to 15 drugs of abuse tests but only one cutoff concentration under the 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 of 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.

C Special Conditions for Use Statement(s):

Rx and OTC

D Special Instrument Requirements:

Not applicable; this is a visually read single use device.

IV Device/System Characteristics:

A Device Description:

The Wisdiag Multi-Drug Urine Test Cup and Wisdiag Multi-Drug Urine Test Cup Rx are rapid, single-use in vitro diagnostic devices. Each test kit contains; a drug test cup (inside foil pouch), user instruction sheet, an identification label and a specimen mailing box and bag.

B Principle of Operation:

The immunochromatographic assays of Wisdiag Multi-Drug Urine Test Cup tests use a lateral flow, one step system for the qualitative detection of target analytes in human urine.

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.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Wondfo T-Cup Multi-Drug Urine Test Cup

B Predicate 510(k) Number(s):

K182701

C Comparison with Predicate(s):

Device & Predicate Device(s):	K222667	K182701
Device Trade Name	Wisdiag Multi-Drug Urine Test Cup & Wisdiag Multi-Drug Urine Test Cup Rx	Wondfo T-Cup Multi-Drug Test Cup
General Device Characteristic Similarities		
Intended Use	Qualitative detection of drugs of abuse in urine	same
Test Principle	Competitive binding, lateral flow immunochromatographic assay	same
Matrix	Urine	same
Test time	5 minutes	same
Test drug cutoffs (ng/mL)	Amphetamine (AMP) – 1000 or 500	same
	Buprenorphine (BUP) – 10	
	Secobarbital (BAR) – 300	
	Oxazepam (BZO) - 300	
	Cocaine (COC) – 300 or 150	
	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP) - 300	

Device & Predicate Device(s):	K222667	K182701
	Methamphetamine (MET) – 1000 or 500	
	Methylenedioxymethamphetamine (MDMA) - 500	
	Methadone (MTD) - 300	
	Morphine (MOP 300/OPI 2000) –2000 or 300	
	Oxycodone (OXY) - 100	
	Phencyclidine (PCP) - 25	
	Propoxyphene (PPX) - 300	
	Nortriptyline (TCA) - 1,000	
	Cannabinoids (THC) - 50	
General Device Characteristic Differences		
Conditions For Use	Rx & OTC versions available	OTC

VI Standards/Guidance Documents Referenced:

None referenced.

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

Precision studies were carried out for samples with concentrations of -100% cutoff, - 75% cut off, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff. 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/MS. For each concentration, tests were conducted in singlicate in two (2) runs per day for twenty-five (25) days using three (3) lots of test cups. The results of all combined lots are summarized in the following tables:

Drug	Result	+100% Cutoff	+75% Cutoff	+50% Cutoff	+25% Cutoff	Cutoff	-25% Cutoff	-50% Cutoff	-75% Cutoff	-100% Cutoff
BUP 10	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150

Drug	Result	+100% Cutoff	+75% Cutoff	+50% Cutoff	+25% Cutoff	Cutoff	-25% Cutoff	-50% Cutoff	-75% Cutoff	-100% Cutoff
PCP 25	Neg	0	0	0	0	72	150	150	150	150
	Pos	150	150	150	150	78	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
THC 50	Neg	0	0	0	0	76	150	150	150	150
	Pos	150	150	150	150	74	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
OXY 100	Neg	0	0	0	0	76	150	150	150	150
	Pos	150	150	150	150	74	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
BAR 300	Neg	0	0	0	0	71	150	150	150	150
	Pos	150	150	150	150	79	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
BZO 300	Neg	0	0	0	0	76	150	150	150	150
	Pos	150	150	150	150	74	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
EDDP 300	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
MTD 300	Neg	0	0	0	0	73	150	150	150	150
	Pos	150	150	150	150	77	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
MOP 300	Neg	0	0	0	0	73	150	150	150	150
	Pos	150	150	150	150	77	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
PPX 300	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
COC 150	Neg	0	0	0	0	77	150	150	150	150
	Pos	150	150	150	150	73	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
MDMA 500	Neg	0	0	0	0	71	150	150	150	150
	Pos	150	150	150	150	79	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
TCA 1000	Neg	0	0	0	0	73	150	150	150	150
	Pos	150	150	150	150	77	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
AMP 500	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
MET 500	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
OPI 2000	Neg	0	0	0	0	74	150	150	150	150
	Pos	150	150	150	150	76	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150

Drug	Result	+100% Cutoff	+75% Cutoff	+50% Cutoff	+25% Cutoff	Cutoff	-25% Cutoff	-50% Cutoff	-75% Cutoff	-100% Cutoff
COC 300	Neg	0	0	0	0	77	150	150	150	150
	Pos	150	150	150	150	73	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
AMP 1000	Neg	0	0	0	0	76	150	150	150	150
	Pos	150	150	150	150	74	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150
MET 1000	Neg	0	0	0	0	73	150	150	150	150
	Pos	150	150	150	150	77	0	0	0	0
	Total	150	150	150	150	150	150	150	150	150

2. Linearity:

   Not applicable.

3. Analytical Specificity/Interference:

   Cross-Reactivity:
   Percent cross-reactivity, provided in the below table, was calculated as the minimum concentration of analyte tested that yielded a Percent cross-reactivity that was calculated as (cut-off concentration / lowest concentration of cross reactant that gives a positive result) x 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. Cross-reactivity for this device was determined through adding the potential interfering substances to drug-free urine samples.

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
BUP 10	Buprenorphine	10	100%
	Burprenorphine-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 25	Phencyclidine	25	100%
	4-Hydroxyphencyclidine	12,500	0.2
THC 50	11-nor-Δ^9-THC-9-COOH	50	100%
	(-)- 11-nor-9-carboxy-Δ^9-THC	50	100%
	11-nor-Δ^8-THC-9-COOH	50	100%
	11-nor-Δ^9 -THC-carboxy glucuronide	100	50%

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	Cannabidiol	100,000	--
	Cannabinol	100,000	--
	Δ^8-Tetrahydrocannabinol	15,000	0.5%
	Δ^9-Tetrahydrocannabinol	15,000	0.5%
	11-hydroxy-Δ^9-Tetrahydrocannabinol	5,000	1%
OXY 100	Oxycodone	100	100%
	Dihydrocodeine	20,000	0.5%
	Hydrocodone	80	125%
	Oxymorphone	1,000	10%
	Codeine	100,000	--
	Hydromorphone	36,000	0.278%
	Morphine	100,000	--
	Acetylmorphine	100,000	--
	Buprenorphine	100,000	--
	Ethylmorphine	100,000	--
	Thebaine	100,000	--
COC 150	Cocaine	375	40%
	Cocaethylene	6,250	2.4%
	Ecgonine	16,000	<1%
	Ecgonine methyl ester	100,000	--
	Norcocaine	100,000	--
BAR 300	Secobarbital	300	100%
	Amobarbital	300	100%
	Alphenol	600	50%
	Aprobarbital	200	150%
	Butabarbital	100	300%
	Butethal	200	150%
	Butalbital	2,000	15%
	Cyclopentobarbital	400	75%
	Pentobarbital	200	150%
	Phenobarbital	200	150%
BZO 300	Oxazepam	300	100%
	Alprazolam	190	157.9%
	a-Hydroxyalprazolam	300	100%
	Bromazepam	500	60%
	Chlordiazepoxide	1,500	20%
	Clobazam	110	272.7%
	Clonazepam	100,000	--
	Clorazepate dipotassium	300	100%
	Delorazepam	100,000	--
	Desalkylflurazepam	200	150%

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	Diazepam	190	157.9%
	Estazolam	5,000	6%
	Flunitrazepam	400	75%
	Midazolam	2,200	13.6%
	Nitrazepam	200	150%
	Norchlordiazepoxide	800	37.5%
	Nordiazepam	150	200%
	Temazepam	100	300%
	Triazolam	6,000	5%
	Demoxepam	2,000	15%
	Flurazepam	100,000	--
	D,L-Lorzepam	75,000	4%
EDDP 300	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300	100%
	Methadone	100,000	--
	EMDP	100,000	--
	Doxylamine	100,000	--
	Disopyramide	100,000	--
	LAAM (Levoo-alpha-acetylmethadol) HCl	100,000	--
	Alpha Methadol	100,000	--
MTD 300	Methadone	300	100%
	Doxylamine	100,000	--
	EDDP	100,000	--
	EMDP	100,000	--
	LAAM	100,000	--
	Alpha Methadol	100,000	--
MOP 300	Morphine	300	100%
	Normorphine	300	100%
	Codeine	300	100%
	s-Monoacetylmorphine	300	100%
	Ethyl morphine	200	150%
	Heroin	300	100%
	Hydrocodone	700	42.8%
	Hydromorphone	200	150%
	Morphinie-3-β-d-glucuronide	1,000	30%
	Oxycodone	100,000	--
	Oxymorphone	100,000	--
	Thebaine	20,000	1.5%
	Levorphanol	10,000	3%
	6-Monoacetylmorphine (6-MAM)	300	100%
	Norcodeine	6,250	4.8%

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	Procaine	100,000	--
PPX 300	d-Propoxyphene	300	100%
	d-Norpropoxyphene	300	100%
MDMA 500	3,4-Methylenedioxymethamphetamine (MDMA)	500	100%
	3,4-Methylenedioxyamphetamine (MDA)	4,000	12.5%
	3,4-Methylenedioxyethylamphetamine (MDE)	400	125%
	d-methamphetamine	100,000	--
	d-amphetamine	100,000	--
	l-methampetamine	100,000	--
	l-amphetemine	100,000	--
AMP 500	d-Amphetamine	500	100%
	l-Amphetamine	100,000	--
	dl-Amphetamine	1,500	33.3%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	500	100%
	Phentermine	6,000	8.3%
	Hydroxyamphetamine	100,000	--
	d-Methamphetamine	100,000	--
	l-Methamphetamine	100,000	--
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	100,000	--
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	--
	β-Phenylethylamine	100,000	--
	Tyramine	100,000	--
	p-Hydroxynorephedrine	100,000	--
	Phenylpropanolamine	100,000	--
	(+)Phenylpropanolamine	100,000	--
	p-Hydroxyamphetamine	100,000	--
	d/1-Norephedrine	100,000	--
	Benzphetamine	100,000	--
	1-Ephedrine	100,000	--
	1-Epinephrine	100,000	--
	d/1-Epinephrine	100,000	--

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	Ephedrine	100,000	--
MET 500	D(+)-Methamphetamine	500	100%
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	12,500	4%
	D/L-Methamphetamine	500	100%
	p-Hydroxymethamphetamine	15,000	3.3%
	D-Amphetamine	100,000	--
	L-Amphetamine	100,000	--
	Chloroquine	50,000	1%
	(+/-)-Ephedrine	100,000	--
	(-)-Methamphetamine	65,000	0.8%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	100,000	--
	(+/-) 3,4-Methylenedioxymethamphetamine	4,000	12.5%
	β-Phenylethylamine	25,000	2%
	Trimethobenzamide	10,000	5%
	D,l-Amphetamine	100,000	--
	Mephetemine	25,000	2%
	(1R,2S)-(-)-Ephedrine	100,000	--
	1-phenylephrine	100,000	--
	L-Methamphetamine	65,000	0.8%
TCA 1000	Nortriptyline	1,000	100%
	Nordoxepine	1,000	100%
	Trimpramine	3,000	33.3%
	Amitriptyline	450	222.2%
	Promazine	1,500	66.7%
	Desipramine	200	500%
	Imipramine	80	1250%
	Clomipramine	1,200	83.3%
	Doxepin	2,000	50%
	Maprotiline	2,000	50%
	Promethazine	100,000	--
	Cyclobenzaprine	800	125%
	Norclomipramine	12,500	8%
COC 300	Benzoylecgonine	300	100%
	Cocaine	780	38.5%
	Cocathylene	12,500	2.4%
	Ecgonine	32,000	0.9%
	Ecgonine methyl ester	100,000	0.3%

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	Norcocaine	100,000	0.3%
AMP 1000	d-Amphetamine	1,000	100%
	l-Amphetamine	100,000	--
	dl-Amphetamine	3,000	33.3%
	(+/-) 3,4-Methylenedioxyamphetamine (MDA)	1,000	100%
	Phentermine	6,000	16.7%
	Hydroxyamphetamine	100,000	--
	d-Methamphetamine	100,000	--
	l-Methamphetamine	100,000	--
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	100,000	--
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	100,000	--
	β-Phenylethylamine	100,000	--
	Tyramine	100,000	--
	p-Hydroxynorephedrine	100,000	--
	Phenylpropanolamine	100,000	--
	(+)Phenylpropanolamine	100,000	--
	p-Hydroxyamphetamine	100,000	--
	d/1-Norephedrine	100,000	--
	Benzphetamine	100,000	--
	1-Ephedrine	100,000	--
	1-Epinephrine	100,000	--
	d/1-Epinephrine	100,000	--
	Ephedrine	100,000	--
MET 1000	D(+)-Methamphetamine	1,000	100%
	(+/-) 3,4-Methylenedioxyethylamphetamine (MDE)	25,000	4%
	D/L-Methamphetamine	1,000	100%
	p-Hydroxymethamphetamine	30,000	0.3%
	D-Amphetamine	100,000	--
	L-Amphetamine	100,000	--
	Chloroquine	50,000	2%
	(+/-)-Ephedrine	100,000	--
	(-)-Methamphetamine	100,000	--
	(+/-) 3,4-Methylenedioxyamphetamine	100,000	--

Drug/Cutoff ng/mL	Compound	Minimum Concentration obtaining positive result (ng/mL)	Relative Cross-reactivity (%)
	(MDA)		
	(+/-) 3,4-Methylenedioxymethamphetamine	8,000	12.5%
	β-Phenylethylamine	50,000	2%
	Trimethobenzamide	20,000	5%
	D,l-Amphetamine	100,000	--
	Mephetemine	50,000	2%
	(1R,2S)-(-)-Ephedrine	100,000	--
	1-phenylephrine	100,000	--
	L-Methamphetamine	100,000	---
OPI 2000	Morphine	2,000	100%
	Normorphine	50,000	4%
	Codeine	2,000	100%
	s-Monoacetylmorphine	2,000	100%
	Ethyl morphine	1,500	133.3%
	Heroin	2,000	100%
	Hydrocodone	12,500	16%
	Hydromorphone	3,500	57.1%
	Morphinie-3-β-d-glucuronide	2,000	100%
	Oxycodone	25,000	8%
	Oxymorphone	25,000	8%
	Thebaine	50,000	4%
	Levorphanol	75,000	2.7%
	6-Monoacetylmorphine (6-MAM)	2,000	100%
	Norcodeine	12,500	16%
	Procaine	100,000	--

Interference Study:

Potential interference from compounds chemically dissimilar to the target drugs and from endogenous agents was performed by spiking the substances into pooled urine containing target drugs at near-cutoff concentrations (at +25% and -25% of cutoff). Substances were tested for potential interference at concentrations of 100 µg/mL with the exception of albumin that was tested at 100 mg/dL, and ethanol that was tested at 1%. The following substances demonstrated no positive or negative interference on the assays encompassed in this submission.

Acetaminophen	Acetophenetidin	Acetylsalicylic Acid
Acyclovir	Amiodarone Hydrochloride	Apomorphine
Afrin	Albumin	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	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		

pH and Specific Gravity:
Interference by pH and specific gravity were also evaluated using pooled urine specimens containing target drugs at near-cutoff concentrations (at +25% and -25% of cutoff). The results demonstrated that pH levels of 4 to 9 and specific gravity levels of 1.000 to 1.035 do not affect the results of the assays.

4. Assay Reportable Range:

   For characterization of how the device performs analytically around the claimed cutoff concentration, please refer to section VII.A.1 (Precision study), above.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

   The device is traceable to commercially available reference materials.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   The method comparison study of the Wisdiag Multi-Drug Urine Test Cup Rx was performed by three (3) operators with eighty (80) unaltered urine samples (40 negative and 40 positive). Each sample was tested in a blinded fashion by each operator and compared to LC-MS/MS results. The results are shown in the table below.

Drug	Result	Low Neg by LC/MS, between 0 and 50% of the cutoff	Near Cutoff Neg by LC/MS, between -50% and cutoff	Near Cutoff Pos by LC/MS, between cutoff and +50%	High Pos by LC/MS, greater than +50%
AMP 500	Positive	0	2	60	60
	Negative	66	51	0	0

Drug	Result	Low Neg by LC/MS, between 0 and 50% of the cutoff	Near Cutoff Neg by LC/MS, between -50% and cutoff	Near Cutoff Pos by LC/MS, between cutoff and +50%	High Pos by LC/MS, greater than +50%
BUP 10	Positive	0	3	56	60
	Negative	75	42	4	0
BAR 300	Positive	0	0	54	60
	Negative	78	42	6	0
BZO 300	Positive	0	0	48	69
	Negative	75	45	3	0
COC 150	Positive	0	2	53	66
	Negative	75	40	1	0
EDDP 300	Positive	0	2	55	63
	Negative	75	43	2	0
MET 500	Positive	0	0	57	60
	Negative	75	45	3	0
MDMA 500	Positive	0	3	60	60
	Negative	81	36	0	0
MOP 300	Positive	0	2	54	66
	Negative	72	46	0	0
MTD 300	Positive	0	3	58	60
	Negative	78	39	2	0
OXY 100	Positive	0	2	54	63
	Negative	72	46	3	0
PCP 25	Positive	0	3	64	54
	Negative	84	33	2	0
PPX 300	Positive	0	3	53	63
	Negative	78	39	4	0
TCA 1000	Positive	0	3	52	66
	Negative	75	42	2	0
THC 50	Positive	0	2	48	66
	Negative	78	40	6	0
AMP 1000	Positive	0	1	54	63
	Negative	75	44	3	0
COC 300	Positive	0	3	49	69
	Negative	72	45	2	0
MET 1000	Positive	0	0	60	57
	Negative	69	51	3	0
OPI 2000	Positive	0	1	52	66
	Negative	78	41	2	0

Summary of Discordant Results:

Drug Test	Sample ID	Analyte detected	LC-MS/MS Result	Device Result
AMP 500	AMP028	Amphetamine	477.4	Positive
	AMP136*	Amphetamine	499.0	Positive
BUP 10	BUP058*	Buprenorphine	9.8	Positive
	BUP070	Buprenorphine	9.9	Positive
	BUP029*	Buprenorphine	10.2	Negative
	BUP055*	Buprenorphine	10.8	Negative
BAR 300	BAR011**	Barbiturates	303.8	Negative
	BAR017*	Barbiturates	300.9	Negative
	BAR033	Barbiturates	312.2	Negative
BZO 300	BZO018*	Benzodiazepines	303.6	Negative
	BZO058	Benzodiazepines	307.2	Negative
COC 150	COC046	Cocaine	144.8	Positive
	COC146	Cocaine	148.9	Positive
	COC128	Cocaine	162.8	Negative
EDDP	EDDP075*	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	290.6	Positive
	EDDP010	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	318.6	Negative
	EDDP061	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	318.5	Negative
MET 500	MET062	Methamphetamine	519.5	Negative
	MET102*	Methamphetamine	521.1	Negative
MDMA 500	MDMA026*	Methylenedioxymethamphetamine	488.3	Positive
	MDMA060	Methylenedioxymethamphetamine	492.0	Positive
MOP 300	MOP057	Morphine	293.2	Positive
	MOP150	Morphine	282.8	Positive
MTD 300	MTD022	Methadone	298.2	Positive
	MTD049*	Methadone	289.2	Positive
	MTD003	Methadone	309.1	Negative
	MTD045	Methadone	301.7	Negative
OXY 100	OXY012	Oxycodone	96.3	Positive
	OXY071	Oxycodone	95.2	Positive
	OXY002*	Oxycodone	101.4	Negative
	OXY006	Oxycodone	111.0	Negative
PCP 25	PCP003	Phencyclidine	22.4	Positive
	PCP060*	Phencyclidine	22.7	Positive
	PCP023*	Phencyclidine	25.5	Negative
PPX 300	PPX024*	Propoxyphene	292.5	Positive
	PPX029	Propoxyphene	291.4	Positive
	PPX043*	Propoxyphene	300.7	Negative
	PPX053	Propoxyphene	300.8	Negative
	PPX073	Propoxyphene	303.4	Negative

Drug Test	Sample ID	Analyte detected	LC-MS/MS Result	Device Result
TCA 1000	TCA005*	Nortriptyline	991.3	Positive
	TCA043	Nortriptyline	969.0	Positive
	TCA010	Nortriptyline	1015.1	Negative
	TCA052	Nortriptyline	1015.9	Negative
THC 50	THC014	Cannabinoids	47.8	Positive
	THC054	Cannabinoids	46.8	Positive
	THC036	Cannabinoids	50.5	Negative
	THC062*	Cannabinoids	50.9	Negative
	THC069*	Cannabinoids	53.5	Negative
	THC076	Cannabinoids	53.9	Negative
AMP 1000	AMP116	Amphetamine	998.8	Positive
	AMP095	Amphetamine	1035.1	Negative
	AMP102*	Amphetamine	1048.4	Negative
COC 300	COC028	Cocaine	296.4	Positive
	COC143*	Cocaine	283.8	Positive
	COC033	Cocaine	317.7	Negative
	COC138	Cocaine	318.7	Negative
MET 1000	MET123	Methamphetamine	1049.5	Negative
	MET138*	Methamphetamine	1068.2	Negative
OPI 2000	MOP076	Morphine	1943.3	Positive
	MOP089	Morphine	2070.0	Negative
	MOP139	Morphine	2105.7	Negative

*Represents samples which resulted in discordant results with two (2) different operators.
**Represents samples which resulted in discordant results with three (3) different operators.

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

A lay user study was performed involving a total of 280 participants from 3 sites. 66 males and 74 females used the Wisdiag Multi-Drug Urine Test Cup Configuration 1 (including AMP 500, MET 500, MOP 300, COC 150); 72 males and 68 females used the Wisdiag Multi-Drug Urine Test Cup Configuration 2 (Group 2, including AMP 1000, MET 1000,

MOP 2000 (OPI), COC 300). Each participant was provided one package insert, one test solution, and one test device. Test solutions were randomly assigned to participants, one solution per participant and were tested in a blinded fashion. Following testing, users completed a study questionnaire to assess usability and user comprehension, and the results from this questionnaire were found to be acceptable. Participants aged 20 and over, with diverse educational backgrounds, were recruited. Results from the lay user testing are provided in the below table:

		Drug Concentration by LC-MS/MS						
Drug	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	+25% Cutoff	+50% Cutoff	+75 Cutoff
AMP 500	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
BUP 10	Neg	20	20	20	19	2	0	0
	Pos	0	0	0	1	18	20	20
	Total	20	20	20	20	20	20	20
BAR 300	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
BZO 300	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
COC 150	Neg	20	20	20	18	1	0	0
	Pos	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
EDDP 300	Neg	20	20	20	20	0	0	0
	Pos	0	0	0	0	20	20	20
	Total	20	20	20	20	20	20	20
MDMA 500	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
MET 500	Neg	20	20	20	19	1	0	0
	Pos	0	0	0	1	19	20	20
	Total	20	20	20	20	20	20	20
MOP 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
MTD 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
OXY 100	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
PCP 25	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20

		Drug Concentration by LC-MS/MS						
Drug	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	+25% Cutoff	+50% Cutoff	+75 Cutoff
PPX 300	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
TCA 1000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
THC 50	Neg	20	20	20	18	1	0	0
	Pos	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20
Group #2 Results								
AMP 1000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
BUP 10	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
BAR 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
BZO 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
COC 300	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
EDDP 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
MDMA 500	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
MET 1000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
MTD 300	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Total	20	20	20	20	20	20	20
OPI 2000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
OXY 100	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20

		Drug Concentration by LC-MS/MS						
Drug	Results	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	+25% Cutoff	+50% Cutoff	+75 Cutoff
PCP 25	Neg	20	20	20	20	1	0	0
	Pos	0	0	0	0	19	20	20
	Toal	20	20	20	20	20	20	20
PPX 300	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
TCA 1000	Neg	20	20	20	19	0	0	0
	Pos	0	0	0	1	20	20	20
	Total	20	20	20	20	20	20	20
THC 50	Neg	20	20	20	18	1	0	0
	Pos	0	0	0	2	19	20	20
	Total	20	20	20	20	20	20	20

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

Not Applicable.

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.