510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY

I Background Information:

A 510(k) Number

K244043

B Applicant

Hangzhou Alltest Biotech Co.,Ltd

C Proprietary and Established Names

AllTest Multi-Drug Rapid Test Cup; AllTest Multi-Drug Test Cup

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
NFT	Class II	21 CFR 862.3100 - Amphetamine test system	TX - Clinical Toxicology
PTH	Class II	21 CFR 862.3150 - Barbiturate test system	TX - Clinical Toxicology
NGL	Class II	21 CFR 862.3650 - Opiate 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

QBF	Class II	21 CFR 862.3700 - Propoxyphene test system	TX - Clinical Toxicology
NGM	Unclassified		
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
NGI	Class II	21 CFR 862.3640 - Morphine test system	TX - Clinical Toxicology

II Submission/Device Overview:

A Purpose for Submission:

New Device (adding four additional analytes to the previously cleared device under K233019)

B Measurand:

Amphetamine, Secobarbital, Benzodiazepines, Buprenorphine, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine, Nortriptyline, Oxycodone, 2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine, Tramadol, Propoxyphene, Fentanyl and 6-monoacetylmorphine.

C Type of Test:

Qualitative lateral flow immunoassay

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

AllTest Multi-Drug Rapid Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana, Tramadol, Propoxyphene, Fentanyl and 6-monoacetylmorphine in human urine at the cutoff concentrations of:

Drug (Identifier) Cut-off level

Amphetamine (AMP)	500 or 1000 ng/mL
Buprenorphine (BUP)	10 ng/mL
Secobarbital (BAR)	300 ng/mL
Benzodiazepines (BZO)	300 ng/mL
Cocaine (COC)	150 or 300 ng/mL
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300 ng/mL
Methamphetamine (MET)	500 or 1000 ng/mL
Methylenedioxymethamphetamine (MDMA)	500 ng/mL
Morphine (MOP/OPI)	300 or 2000 ng/mL
Methadone (MTD)	300 ng/mL
Oxycodone (OXY)	100 ng/mL
Phencyclidine (PCP)	25 ng/mL
Nortriptyline (TCA)	1000 ng/mL
Marijuana (THC)	50 ng/mL
Tramadol (TRA)	100 ng/mL
Propoxyphene (PPX)	300 ng/mL
Fentanyl(FYL)	1 ng/mL
6-monoacetylmorphine (6-MAM)	10 ng/mL

AllTest Multi-Drug Rapid Test Cup can be a single drug test cup or used for any combination of the above listed analytes. It is for in vitro diagnostic use only. It is intended for OTC use.

The tests may yield positive results for the prescription drugs 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.

AllTest Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana, Tramadol, Propoxyphene Fentanyl and 6-monoacetylmorphine in human urine at the cutoff concentration of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500 or 1000
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methamphetamine (MET)	d-Methamphetamine	500 or 1000
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500

Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50
Tramadol (TRA)	Tramadol	100
Propoxyphene (PPX)	Propoxyphene	300
Fentanyl (FYL)	Fentanyl	1
6-monoacetylmorphine (6-MAM)	6-monoacetylmorphine	10

AllTest Multi-Drug Test Cup can be a single drug test cup or used for any combination of the above listed analytes. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

D Special Instrument Requirements:

Not Applicable. (These devices are single use and disposable.)

IV Device/System Characteristics:

A Device Description:

AllTest Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana, Tramadol, Propoxyphene, Fentanyl and 6-monoacetylmorphine in human urine. 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.

B Principle of Operation:

The Multi-Drug Rapid Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels

of specific drugs in urine. During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick.

The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.

A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

V Substantial Equivalence Information:

A Predicate Device Name(s):

AllTest Multi-Drug Rapid Test Cup; AllTest Multi-Drug Rapid Test Panel; AllTest Multi-Drug Rapid Test Cup Rx; AllTest Multi-Drug Rapid Test Panel Rx

B Predicate 510(k) Number(s):

K233019

C Comparison with Predicate(s):

Device & Predicate Device(s):	Candidate K244043	Predicate K233019
Device Trade Name	AllTest Multi-Drug Rapid Test Cup AllTest Multi-Drug Test Cup	AllTest Multi-Drug Rapid Test Cup AllTest Multi-Drug Rapid Test Cup Rx AllTest Multi-Drug Rapid Test Panel AllTest Multi-Drug Rapid Test Panel Rx
General Device Characteristic Similarities		
Intended Use/Indications For Use	For the qualitative determination of drugs and drug metabolites in human urine.	Same
Specimen Type	Human Urine	Same
Methodology	Competitive binding, lateral flow immunochromatographi	Same

	c assays based on the principle of antigen antibody immunochemistry.	
General Device Characteristic Differences		
Calibrator and Cutoff Values	Amphetamine (AMP): 500 or 1000 ng/ml Benzodiazepines (BZO): 300 ng/mL Cocaine (COC): 150 or 300 ng/mL 11-Nor-Δ9-Tetrahydrocannabinol-9-COOH (THC): 50 ng/mL Methamphetamine (MET): 500 or 1000 ng/mL Morphine (MOP/OPI): 300 or 2000 ng/mL Oxycodone (OXY): 100 ng/mL Secobarbital (BAR): 300 ng/mL Methadone (MTD): 300 ng/mL Buprenorphine (BUP): 10 ng/mL D,L-Methylenedioxymethamphetamine (MDMA): 500 ng/mL Phencyclidine (PCP): 25 ng/mL Nortriptyline (TCA): 1000 ng/mL 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP): 300 ng/mL Tramadol (TRA): 100 ng/mL Propoxyphene (PPX): 300 ng/mL Fentanyl (FYL):1 ng/mL	Same except TRA 100 ng/mL PPX 300 ng/mL FYL 1 ng/mL 6-MAM 10 ng/mL

	6-Monoacetylmorphine(6-MAM): 10 ng/mL	

VI Standards/Guidance Documents Referenced:

None.

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% cutoff, -50% cutoff, -25% cutoff, cutoff, +25% cutoff, +50% cutoff, +75% cutoff and +100% cutoff using 3 lots of the AllTest Multi-Drug Rapid Test Cup. These samples were prepared by spiking drug in negative urine samples. Each drug concentration was confirmed by LC-MS/MS. All sample aliquots were blindly labeled by the person who prepared the samples and didn't take part in the sample testing. For each concentration, tests were performed 1 replicate per run per lot (one operator per lot), 2 runs per day for 25 days in a randomized order. The results obtained for Tramadol 100, Propoxyphene 300, Fentanyl 1 and 6-monoacetylmorphine 10 are summarized in the following tables. The rest of the data for Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, EDDP, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana were reported in k233019.

Tramadol (TRA) 100 ng/mL

Lot #	Concentration by LC/MS (ng/mL)								
	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut-off
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	22-/28+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+

Propoxyphene (PPX) 300 ng/mL

Lot #	Concentration by LC/MS (ng/mL)								
	-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	cutoff	+25% cutoff	+50% cutoff	+75% cutoff	+100% cut-off
Lot 1	50-/0+	50-/0+	50-/0+	49-/1+	22-/28+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	23-/27+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 3	50-/0+	50-/0+	50-/0+	50-/0+	20-/30+	1-/49+	0-/50+	0-/50+	0-/50+

Fentanyl (FYL) 1 ng/mL

Lot #	Concentration by LC/MS (ng/mL)								
	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	Cutoff +25%	Cutoff +50%	Cutoff +75%	Cutoff +100%
Lot 1	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 2	50-/0+	50-/0+	50-/0+	48-/2+	23-/27+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+

6-monoacetylmorphine (6-MAM) 10 ng/mL

Lot #	Concentration by LC/MS (ng/mL)								
	-100% Cutoff	-75% Cutoff	-50% Cutoff	-25% Cutoff	Cutoff	Cutoff +25%	Cutoff +50%	Cutoff +75%	Cutoff +100%
Lot 1	50-/0+	50-/0+	50-/0+	48-/2+	24-/26+	0-/50+	0-/50+	0-/50+	0-/50+
Lot 2	50-/0+	50-/0+	50-/0+	50-/0+	25-/25+	1-/49+	0-/50+	0-/50+	0-/50+
Lot 3	50-/0+	50-/0+	50-/0+	49-/1+	23-/27+	0-/50+	0-/50+	0-/50+	0-/50+

2. Linearity:

Not applicable.

3. Analytical Specificity/Interference:

Cross-reactivity

To test the cross reactivity, target drugs, drug metabolites within the same class of drugs, or substances with similar molecular structures that potentially cross-react were spiked to drug-free specimens and these samples were tested by three different operators using three lots of Multi-Drug Rapid Test Cup. The cross-reacting substances with the lowest concentration that produced a positive result was identified and are listed in the table below. If no cross-reactivity was observed the highest concentration tested is shown.

The study is reported only for Tramadol (TRA)100, Propoxyphene (PPX) 300, Fentanyl (FYL) 1 and 6-monoacetylmorphine (6-MAM)10. The data for Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, EDDP, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana were reported in k233019.

TRA (Tramadol) Cutoff=100 ng/mL	Lowest concentration (ng/mL)	% Cross-Reactivity
Tramadol	100	100%
N-Desmethyl-cis-tramadol	200	50%
O-Desmethyl-cis-tramadol	1000	10%
Venlafaxine	100000	0.1%
(±)-O-Desmethylvenlafaxine	100000	0.1%

PPX (Propoxyphene) Cutoff=300 ng/mL	Lowest concentration (ng/mL)	% Cross-Reactivity
(+)-Propoxyphene	300	100%
(+)-Norpropoxyphene	500	60%

FYL (Fentanyl) Cut-off=1 ng/mL	Lowest concentration (ng/mL)	% Cross-Reactivity
Fentanyl	1	100%
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20000	0.005%
Isobutyryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%
Sufentanil	10	10%
Alfentanil	5000	0.02%
Despropionyl fentanyl (4-ANPP)	2500	0.04%
Remifentanil	>100000	<0.001%
Norfentanyl	>100000	<0.001%
Acetyl norfentanyl	>100000	<0.001%
Norcarfentanil	>100000	<0.001%
6-Acetyl morphine	>100000	<0.001%
Amphetamine	>100000	<0.001%
Buprenorphine	>100000	<0.001%
Buprenorphineglucuronide	>100000	<0.001%
Codeine	>100000	<0.001%
Dextromethorphan	>100000	<0.001%
Dihydrocodeine	>100000	<0.001%
EDDP	>100000	<0.001%
EMDP	>100000	<0.001%
Fluoxetine	>100000	<0.001%
Heroin	>100000	<0.001%
Hydrocodone	>100000	<0.001%
Hydromorphone	>100000	<0.001%
Ketamine	>100000	<0.001%
Levorphanol	>100000	<0.001%

Meperidine	>100000	<0.001%
Methadone	>100000	<0.001%
Morphine	>100000	<0.001%
Morphine-3-glucuronide	>100000	<0.001%
Naloxone	>100000	<0.001%
Naltrexone	>100000	<0.001%
Norbuprenorphine	>100000	<0.001%
Norcodeine	>100000	<0.001%
Norketamine	>100000	<0.001%
Normeperidine	>100000	<0.001%
Normorphine	>100000	<0.001%
Noroxycodone	>100000	<0.001%
Oxycodone	>100000	<0.001%
Oxymorphone	>100000	<0.001%
Pentazocine (Talwin)	>100000	<0.001%
Pipamperone	>100000	<0.001%
Risperidone	>100000	<0.001%
Tapentadol	>100000	<0.001%
Thioridazine	>100000	<0.001%
Tilidine	>100000	<0.001%
Tramadol	>100000	<0.001%
Tramadol-O-Desmethyl	>100000	<0.001%
Tramadol-N-Desmethyl	>100000	<0.001%
Isotonitaze	>100000	<0.001%
Cyclopropylfentanyl	3	33.3%
AH-7921 HCL	>100000	<0.001%

6-MAM (6-monoacetylmorphine) Cutoff=10ng/mL	Lowest concentration (ng/mL)	% Cross-Reactivity
6-Monoacetylmorphine	10	100%
Hydrocodone	>100000	<0.01%
Hydromorphone	>100000	<0.01%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Procaine	>100000	<0.01%
Thebaine	>100000	<0.01%
Diacetylmorphine (heroin)	300	3.3%
Acetylcodeine	>100000	<0.01%
Buprenorphine	>100000	<0.01%
Dihydrocodeine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Mitragynine (kratom)	>100000	<0.01%
Norbuprenorphine	>100000	<0.01%
s-Monoacetylmorphine	10	100%
Codeine	>100000	<0.01%

Ethylmorphine	>100000	<0.01%
Levorphanol tartrate	>100000	<0.01%
Morphine-3-β-D-glucuronide	>100000	<0.01%
Norcodeine	>100000	<0.01%
Normorphine	>100000	<0.01%
Oxycodone	>100000	<0.01%
Dextromethorphan	>100000	<0.01%
Imipramine hydrochloride	>100000	<0.01%
Levacetylmethadol (LAAM)	>100000	<0.01%
Meperidine	>100000	<0.01%
(±)-Methadone	>100000	<0.01%
Naloxone hydrochloride	>100000	<0.01%
Naltrexone hydrochloride	>100000	<0.01%
Naproxen	>100000	<0.01%
Noroxycodone HCL	>100000	<0.01%
Noroxymorphone HCL	>100000	<0.01%
(+)-Norpropoxyphene maleate	>100000	<0.01%
Oxymorphone-3β-D-glucuronide	>100000	<0.01%
Tapentadol HCl	>100000	<0.01%
Tramadol hydrochloride	>100000	<0.01%
Chlordiazepoxide	>100000	<0.01%
Clobazam	>100000	<0.01%
D-Amphetamine	>100000	<0.01%
(±)-Amphetamine	>100000	<0.01%

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. To evaluate interference, potential interfering substances found in human urine of physiological or pathological conditions were added to drug-free urine and target drugs urine with concentrations at 50% below and 50% above cut-off levels in the test. These urine samples were tested using three lots of Multi-Drug Rapid Test Cup and two configurations (combination of different cut off values) by six operators (three operator for each configuration). Compounds that showed no interference at a concentration of 100 μg/mL or at specified concentrations are summarized in the following table.

Acetaminophen	D-Pseudoephedrine	Norfentanyl
Acetone (1000mg/dL)	Duloxetine	Noscapine
Acetophenetidin	4-Dimethyl-aminoantipyrine	(+)-Naproxen
Acetylsalicylic Acid	5, 5-Diphenylhydantoin	19-Norethindrone
Acyclovir	Ecgonine methyl ester	Octopamine
Albumin (100mg/dL)	EMDP	O-Hydroxyhippuric acid
Albuterol sulfate (Proair HFA)	Ephedrine	Olanzapine
Alpha Methadol	Erythromycin	Omeprazole

Aminophylline	Esomeprazole Magnesium (except MTD test)	Oxalic acid (100 mg/dL)
Aminopyrine	Estradiol	Oxolinic acid
Amoxicillin	Estrone	Oxymetazoline
Ampicillin	Ethanol (1%)	Paliperidone
Aripiprazole	Fenofibrate	Papaverine
Aspartame	Fenoprofen	Penicillin-G
Aspirin	Fentanyl (except FYL test)	PenicillinV Potassium
Atomoxetine	Fluoxetine Hydrochloride	Perphenazine
Atorvastatin Calcium	Fluphenazine	Phenacetin
Atropine	Fotemustine	Phenelzine
Azithromycin	Furosemide	Phenethylamine
Baclofen	Gabapentin	Phenylethylamine
Benzilic acid	Galactose (10mg/dL)	Phenylpropanolamine
Benzocaine	Gamma Globulin (500mg/dL)	Prednisone
Benzoic Acid	Gatifloxacin	Pregablin
Benzphetamine	Gemfibrozil	Procaine
Bilirubin	Gentisic acid	Promazine
Boric Acid (1%)	Glucose (3000mg/dL)	Promethazine
Bupropion	Guaiacol glyceryl ether	Propoxyphene (except PPX test)
Caffeine	Hemoglobin	Propranolol
Cannabidiol	Hydralazine	Pseudoephedrine
Captopril	Hydrochlorothiazide	Pyridoxine
Carbamazepine	Hydrocortisone	Pyrilamine
Carfentanil (except FYL test)	3-Hydroxytyramine	Pyrogallol
Carisoprodol	Ibuprofen	Quetiapine
Cefradine	Isoxsuprine	Quinine
Cephalexin	(+/-)-Isoproterenol	Quinolinic Acid
Chloralhydrate	Ketamine	R- (-)-Apomorphine
Chloramphenicol	Ketoprofen	Ranitidine
Chlordiazepoxide (except BZO test)	LAAM HCl	Riboflavin (10mg/dL)
Chloroquine (except MET test)	Labetalol	Rifampicin
Chlorothiazide	L-Ascorbic Acid	Risperidone
Chlorpromazine	L-Ephedrine	Salicylic Acid
Cholesterol	L-Epinephrine	Serotonin (5-Hydroxytyramine)
Ciprofloxacin Hydrochloride	Levofloxacin Hydrochloride	Sertraline
Citalopram	Levonorgestrel	Sildenafil Citrate
Clarithromycin	Levothyroxine Sodium	Simvastatin
Clonidine	Lidocaine Hydrochloride	Sulfamethazine
Clozapine	Lisinopril	Sulindac
Conjugated Estrogens	Loperamide	Telmisartan
Cortisone	Loratadine	Tetracycline

Creatine Hydrate	L-phenylephrine	Tetrahydrocortisone 3-(β- Dglucuronide)
Creatinine	Magnesium	Tetrahydrocortisone, 3-acetate
Cyclobenzaprine	Maprotiline	Tetrahydrozoline
Cyclodextrin	Meperidine	Theophylline
(-)-Cotinine	Meprobamate	Thiamine
(+)-Chlorpheniramine	Methapyrilene	Thioridazine
D,L-Epinephrine	Methaqualone	Tramadol (except TRA test)
D,L-Octopamine	Methoxyphenamine (except AMP/MET test)	Triamterene
d,l-Propranolol	Methylphenidate	Trifluoperazine
D,L-Tryptophan	Metoprolol Tartrate	Trimethobenzamide
D,L-Tyrosine	Metronidazole (300ug/ml)	Trimethoprim
Delorazepam (except BZO test)	Mifepristone	Tryptamine
Deoxycorticosterone	N-Acetylprocainamide	Tyramine
Desloratadine	NaCl (4000mg/dL)	Urea (2000mg/dL)
Dextromethorphan	Nalidixic Acid	Uric Acid
Diclofenac	Naloxone hydrochloride (except OXY test)	Valproic acid (250ug/ml)
Diflunisal	Naltrexone	Venlafaxine HCl (except TRA test)
Digoxin	Niacinamide	Verapamil
Diphenhydramine HCl	Nicotine	Vitamin B2
Disopyramide (except MTD test)	Nicotinic Acid	Vitamin C
Dopamine HCl	Nifedipine	Zaleplon
Doxepin	Nitroglycerin	Zomepirac sodium salt
Doxylamine	Nordoxepin	

Effect of Urine Specific Gravity and Urine pH

The effect of pH and specific gravity on the accuracy of test measurement of the Multi-Drug Rapid Test Cup were evaluated using pooled urine specimens with concentrations of 0 (drug-free), at 50% below and 50% above each corresponding 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:

   Not applicable.

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

All drug calibrators of the device are traceable to available commercial reference materials.

6. Detection Limit:

See precision data in Section VII.A.1., above, for assay performance around the claimed cutoff concentrations.

7. Assay Cut-Off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section VII.A.1., above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

Eighty (40 negative and 40 positive) unaltered clinical urine samples for each drug were analyzed by LC/MS and by three lots of Multi-Drug Rapid Test Cup device. Samples concentrations are confirmed by LC/MS, ranging from drug-free, < -50% Cutoff, -50% Cutoff ~ Cutoff, Cutoff ~ +50% Cutoff, >+50% Cutoff. The study was conducted by 3 operators (one operator per lot) at an in-house laboratory. Method comparison data were reported only for Tramadol (TRA)100, Propoxyphene (PPX) 300, Fentanyl (FYL) 1 and 6-monoacetylmorphine (6-MAM)10. The data for Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, EDDP, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline and Marijuana were reported in k233019.

Drug	Test Cup Result		Drug-Free	Low Negative by LC-MS/MS (less than -50%)	Near Cutoff Negative by LC-MS/MS (Between -50% and the Cutoff)	Near Cutoff Positive by LC-MS/MS (Between the cutoff and +50%)	High Positive by LC-MS/MS (greater than +50%)
TRA	Operator A	+	0	0	1	11	29
		-	12	14	13	0	0
	Operator B	+	0	0	0	10	29
		-	12	14	14	1	0
	Operator C	+	0	0	1	10	29
		-	12	14	13	1	0
PPX	Operator A	+	0	0	1	10	30
		-	12	13	14	0	0
	Operator B	+	0	0	1	10	30
		-	12	13	14	0	0
	Operator C	+	0	0	0	9	30
		-	12	13	15	1	0

6-MAM	Operator A	+	0	0	1	14	26
		-	12	11	16	0	0
	Operator B	+	0	0	1	13	26
		-	12	11	16	1	0
	Operator C	+	0	0	2	13	26
		-	12	11	15	1	0
FYL	Operator A	+	0	0	2	22	16
		-	12	13	13	2	0
	Operator B	+	0	0	3	22	16
		-	12	13	12	2	0
	Operator C	+	0	0	2	22	16
		-	12	13	13	2	0

Discordant Results are summarized below.

Drug	Operator	Sample Number	LC/MS/MS Result (ng/mL)	Test Result
TRA 100	A, C	S2148	91.6	+
	B, C	S2157	103.0	-
PPX 300	A	S2052	286.3	+
	B	S2017	280.6	+
	C	S2018	319.8	-
6-MAM 10	A, C	S2249	9.5	+
	B, C	S2236	9.6	+
	B, C	S2228	10.2	-
FYL 1	A, C	S1425	1.02	-
	A	S1420	0.87	+
	A, B	S1447	1.01	-
	A, B	S1442	0.91	+
	B, C	S1402	0.92	+
	B	S1422	1.08	-
	B	S1465	0.92	+
	C	S1453	0.82	+
	C	S1439	1.02	-

Lay User Study

A lay user study was conducted to evaluate its two configurations of the 18 drugs for the Multi-Drug Rapid Test Cup. Configuration 1 included COC 300, OPI/MOP 2000, AMP 1000 and MET 1000, AND configuration 2 included COC 150, MOP 300, AMP 500 and MET 500. The study was performed at three intended user sites by 280 lay users (140 for each configuration), and each lay user tested only one sample. The lay users had diverse educational and professional backgrounds and ranged in age from 20 to > 50 years. Urine samples were prepared at the following concentrations: -100%, +/-75%, +/-50%, +/-25% of the cutoff by spiking drugs into drug free-pooled urine specimens. The concentrations of the samples were confirmed by LC-MS/MS. Each sample was aliquoted into individual

containers and blind-labeled. Each participant was provided with the package insert, 1 blind labeled sample and a device. Results are shown below.

Results for configuration 1

Drug	Cutoff (ng/mL)	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
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
BAR	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
BZO	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
BUP	10	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
COC	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
EDDP	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
MDMA	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
MET	1000	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
MOP	2000	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20

		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
MTD	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
OXY	100	Negative	20	20	20	19	2	0	0
		Positive	0	0	0	1	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
PCP	25	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
TCA	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
		Agreement (%)	100%	100%	100%	95.0%	95.0%	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
TRA	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
FYL	1	Negative	20	20	20	17	0	0	0
		Positive	0	0	0	3	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	85.0%	100.0%	100%	100%
6-MAM	10	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	90.0%	100%	100%

Results for configuration 2

Drug	Cutoff (ng/mL)	Results	Concentration						
			-100% cutoff	-75% cutoff	-50% cutoff	-25% cutoff	+25% cutoff	+50% cutoff	+75% cutoff
AMP	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
BZO	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
BUP	10	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
COC	150	Negative	20	20	20	18	1	0	0
		Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
EDDP	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
MDMA	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
		Agreement (%)	100%	100%	100%	95.0%	90.0%	100%	100%
MET	500	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
MOP	300	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
		Negative	20	20	20	18	1	0	0

MTD	300	Positive	0	0	0	2	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
OXY	100	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
PCP	25	Negative	20	20	20	19	1	0	0
		Positive	0	0	0	1	19	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	95.0%	95.0%	100%	100%
TCA	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
		Agreement (%)	100%	100%	100%	95.0%	95.0%	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
TRA	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
		Agreement (%)	100%	100%	100%	90.0%	90.0%	100%	100%
PPX	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
		Agreement (%)	100%	100%	100%	90.0%	95.0%	100%	100%
FYL	1	Negative	20	20	20	18	0	0	0
		Positive	0	0	0	2	20	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	100.0%	100%	100%
6-MAM	10	Negative	20	20	20	18	2	0	0
		Positive	0	0	0	2	18	20	20
		Total	20	20	20	20	20	20	20
		Agreement (%)	100%	100%	100%	90.0%	90.0%	100%	100%

Lay users were also given surveys on the ease of understanding the package insert instructions. All lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on each package insert and the scores revealed a reading Grade Level of 7.

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):

Not applicable.

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.