



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY**

I Background Information:

A 510(k) Number

K261409

B Applicant

Bioteke Corporation (Wuxi) Co., Ltd.

C Proprietary and Established Names

BioTeke Multi-Drug Urine Test Cup

D Regulatory Information

Product Code(s)	Class	Regulation Section	Regulation Name	Panel
NFT	II	862.3100	Amphetamine Test system	Toxicology (91)
PTH	II	862.3150	Barbiturate Test System	
NGL	II	862.3650	Opiate Test System	
NFV	II	862.3170	Benzodiazepines Test System	
NFY	II	862.3250	Cocaine and metabolites Test System	
PTG	II	862.3620	Methadone Test system	
NGG	II	862.3610	Methamphetamine Test System	
NGM		Unclassified	Enzyme immunoassay Phencyclidine	
QAW	II	862.3910	Tricyclic Antidepressant Drugs Test System	
NFW	II	862.3870	Cannabinoids Test System	

II Submission/Device Overview:

A Purpose for Submission:

New Device

B Measurand:

Amphetamine, Phenobarbital, Buprenorphine, Oxazepam, Benzoyllecgonine, Fentanyl, Methylenedioxymethamphetamine, Methamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, 11-nor- Δ^9 -THC-9-COOH, Nortriptyline.

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:

BioTeke® Multi-Drug Urine Test Cup is a competitive binding, lateral flow immunochromatographic assay. It is a rapid drug test for the qualitative and simultaneous detection of drugs and drug metabolites in human urine. It is for in vitro diagnostic use only. Prescription Use Only. Drug test cut-off concentrations are listed below:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	Amphetamine	500
Phenobarbital (BAR)	Phenobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Oxazepam (BZO)	Oxazepam	300
Cocaine (COC)	Benzoyllecgonine	150
Fentanyl (FTY)	Fentanyl	1
Methylenedioxymethamphetamine (MDMA)	Methylenedioxymethamphetamine	500
Methamphetamine (MET)	Methamphetamine	500
Morphine (MOP/OPI)	Morphine	300
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50
Nortriptyline (TCA)	Nortriptyline	1000

BioTeke® Multi-Drug Urine Test Cup can be a single drug test cup or used for any combination of the above listed analytes. The test provides only preliminary test results. A more specific method must be used in order to obtain a confirmed result. GC/MS or LC/MS is the preferred method.

C Special Conditions for Use Statement(s):

Rx Only

D Special Instrument Requirements:

N/A

IV Device/System Characteristics:

A Device Description:

BioTeke® Multi-Drug Urine Test Cup is immunochromatographic assays that use a lateral flow system for the qualitative detection of single or multiple drugs in human urine.

The device is a cup format. Each test device is sealed with sachets of desiccant in an aluminum pouch. The device is packaged in a ready-to-use format.

B Principle of Operation:

The BioTeke® Multi-Drug Urine Test Cup utilizes a competitive binding immunochromatographic assay. The membrane's test region (T) is pre-coated with specific drug-protein conjugates, and the binding pad contains colored microsphere-labeled antibody conjugates. A visible control line in the control region (C) confirms adequate sample volume and proper flow, indicates a valid test. During testing, urine is added directly to the test cup; if no free drug is present, the antibody conjugate binds to the T-line conjugate and generates a red test line (negative result), whereas if the drug saturates the antibody conjugate, no line forms in the test region (positive result), with the C-line serving as the kit's internal control.

V Substantial Equivalence Information:

A Predicate Device Name(s):

AllTest Multi-Drug Urine Test Cup

B Predicate 510(k) Number(s):

K241428

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K261409</u>	<u>K241428</u>
Device Trade Name	BioTeke Multi-Drug Urine Test Cup	AllTest Multi-Drug Urine Test Cup
General Device Characteristic Similarities		

Intended Use/Indications For Use	Qualitative detection of drugs of abuse in urine.	Same
Specimen Type	Human Urine	Same
Methodology	Competitive binding, lateral flow immunochromatographic assay	Same
Target Drug and Cut Off Values	Target drugs	Cutoff
	Amphetamine (AMP)	500
	Barbiturates (BAR)	300
	Buprenorphine (BUP)	10
	Benzodiazepines (BZO)	300
	Cocaine (COC)	150
	Fentanyl (FTY)	1
	Methylenedioxymethamphetamine (MDMA)	500
	Methamphetamine (MET)	500
	Morphine (MOP/OPI)	300
	Methadone (MTD)	300
	Oxycodone (OXY)	100
	Phencyclidine (PCP)	25
	Marijuana (THC)	50
	Nortriptyline (TCA)	1000
Configurations	Test Cup	Same
General Device Characteristic Differences		
Use Setting	Prescription Use Only	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% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cutoff and -100% cutoff. Samples were prepared by spiking target drugs in drug-free urine samples. Each drug concentration was confirmed by LC-MS/MS. For each concentration, tests were performed

two runs per day for 25 days using three lots of test cups. The results obtained are summarized in the following tables:

Drug	Lot No.	+100% cutoff	+75% cutoff	+50% cutoff	+25% cutoff	cutoff	-25% cutoff	-50% cutoff	-75% cutoff	-100% cutoff
AMP 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	49-/1+	50-/0+	50-/0+	50-/0+
BAR 300	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	29-/21+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
BUP 10	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	30-/20+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
BZO 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
COC 150	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
FTY 1	Lot 1	0-/50+	0-/50+	0-/50+	2-/48+	29-/21+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
MDM A 500	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
MET 500	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
MOP 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
MTD 300	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	50-/0+	50-/0+	50-/0+	50-/0+

	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
OXY 100	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	1-/49+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
PCP 25	Lot 1	0-/50+	0-/50+	0-/50+	1-/49+	27-/23+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	28-/22+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	2-/48+	26-/24+	50-/0+	50-/0+	50-/0+	50-/0+
THC 50	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	21-/29+	49-/1+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	22-/28+	48-/2+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	49-/1+	50-/0+	50-/0+	50-/0+
TCA 100	Lot 1	0-/50+	0-/50+	0-/50+	0-/50+	23-/27+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 2	0-/50+	0-/50+	0-/50+	0-/50+	25-/25+	50-/0+	50-/0+	50-/0+	50-/0+
	Lot 3	0-/50+	0-/50+	0-/50+	0-/50+	24-/26+	50-/0+	50-/0+	50-/0+	50-/0+

2. Linearity:

Not applicable. This device is intended for qualitative use only.

3. Analytical Specificity/Interference:

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

Percent cross-reactivity, provided in the table below, was calculated as the cutoff concentration divided by the concentration of analyte tested that yielded a positive result, multiplied by 100%.

Drug/ Cutoff	Compound	Minimum concentration required to obtain a positive result (ng/mL)	% Cross- Reactivity
AMP 500	Amphetamine	500	100%
	(+/-)- Methylenedioxyamphetamine(MDA)	50	1000%
	(+/-)3,4- Methylenedioxyethylamphetamine (MDEA)	100000	0.50%

	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	1000	50%
	R (-)-Amphetamine	500	100%
	Methamphetamine	>100000	<0.5%
	Ephedrine Hydrochloride	>100000	<0.5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	Hydroxyamphetamine	>100000	<0.5%
	D,L-Amphetamine	1000	50%
	D-Amphetamine	2000	25%
	L-Amphetamine	>100000	<0.5%
	Phentermine	>100000	<0.5%
	β-Phenylethylamine	>100000	<0.5%
	Tyramine	>100000	<0.5%
	p-Hydroxynorephedrine	>100000	<0.5%
	D,L-Norephedrine	>100000	<0.5%
	p-Hydroxyamphetamine	>100000	<0.5%
	D-Methamphetamine	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	Phenylpropanolamine	>100000	<0.5%
	Benzphetamine	>100000	<0.5%
	L-Ephedrine	>100000	<0.5%
	L-Epinephrine	>100000	<0.5%
	D,L-Epinephrine	>100000	<0.5%
BAR 300	Phenobarbital	300	100%
	Barbital	300	100%
	Secobarbital Sodium	2000	15%
	Pentobarbital	2000	15%
	Alphenal	300	100%
	Amobarbital	300	100%
	Aprobarbital	500	60%
	Butabarbital	>100000	<0.3%
	Butethal	300	100%
	Cyclopentobarbital	500	60%
	Butalbital	>100000	<0.3%
BUP 10	Buprenorphine	10	100%
	Buprenorphine-3-D-Glucuronide	20	50%
	Norbuprenorphine	20	50%
	Morphine	>100000	<0.01%
	Oxymorphone	>100000	<0.01%
	Hydromorphone	>100000	<0.01%
	Codeine Phosphate	>100000	<0.01%
	Norbuprenorphine-3-D-Glucuronide	1000	1%
	Nalorphine	>100000	<0.01%
BZO 300	Oxazepam	300	100%
	Alprazolam	200	150%
	Chlordiazepoxide	300	100%

	Clobazam	200	150%
	Clonazepam	200	150%
	Diazepam	300	100%
	Estazolam	100	300%
	Flunitrazepam	300	100%
	Midazolam	10000	3%
	Nitrazepam	200	150%
	Nordiazepam	200	150%
	Temazepam	100	300%
	Triazolam	300	100%
	Flurazepam	300	100%
	Lorazepam	10000	3%
	Lormetazepam	100	300%
	a-Hydroxyalprazolam	>100000	<0.3%
	Bromazepam	>100000	<0.3%
	Clorazepate Dipotassium	300	100%
	Desalkylflurazepam	>100000	<0.3%
	D,L-Lorazepam	>100000	<0.3%
	Norchlordiazepoxide	300	100%
	R,S-Lorazepam glucuronide	>100000	<0.3%
	Demoxepam	>100000	<0.3%
	Delorazepam	>100000	<0.3%
COC 150	Benzoyllecgonine	150	100%
	Cocaine Hydrochloride	10000	1.50%
	Ecgonine methyl ester	>100000	<0.15%
	Cocaethylene	>100000	<0.15%
	Ecgonine	>100000	<0.15%
FTY 1	Fentanyl	1	100%
	Acetyl fentanyl	1	100%
	Sufentanil	10	10%
	Alfentanil	5000	0.02%
	Remifentanil	>100000	<0.001%
	Norfentanyl	>100000	<0.001%
	Acrylfentanyl	>100000	<0.001%
	ω-1-Hydroxyfentanyl	>100000	<0.001%
	Isobutyryl fentanyl	>100000	<0.001%
	Ocfentanil	5	20%
	Butyryl fentanyl	>100000	<0.001%
	Furanyl fentanyl	>100000	<0.001%
	Valeryl fentanyl	>100000	<0.001%
	(±) β-hydroxythiofentanyl	5	20%
	4-Fluoro-isobutyrylfentanyl	>100000	<0.001%
	Para-fluorobutyryl fentanyl	5	20%
	Para-fluoro fentanyl	5	20%
	(±)-3-cis-methyl fentanyl	>100000	<0.001%
	Carfentanil	>100000	<0.001%
	Despropionyl fentanyl (4-ANPP)	>100000	<0.001%

	Acetyl norfentanyl	>100000	<0.001%
	Norcarfentanyl	>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%
MDM A 500	(±)3,4-Methylenedioxymethamphetamine(MDMA)	500	100%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	1000	50%

	(+/-)-Methylenedioxyamphetamine(MDA)	1000	50%
	Amphetamine	1000	50%
	R (-)-Amphetamine	1000	50%
	Methamphetamine	10000	5%
	Ephedrine Hydrochloride	10000	5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	d-methamphetamine	>100000	<0.5%
	d-amphetamine	>100000	<0.5%
	l-amphetamine	>100000	<0.5%
	d,l-Amphetamine	>100000	<0.5%
	d,l-Methamphetamine	>100000	<0.5%
	Phentermine	>100000	<0.5%
	Phenylephrine	>100000	<0.5%
MET 500	Methamphetamine	500	100%
	(±)3,4-Methylenedioxymethamphetamine(MDMA)	1000	50%
	(+/-)3,4-Methylenedioxyethylamphetamine (MDEA)	10000	5%
	(+/-)-Methylenedioxyamphetamine(MDA)	10000	5%
	Methoxyphenamine Hydrochloride	>100000	<0.5%
	Chloroquine	10000	5%
	Amphetamine	1000	50%
	R (-)-Amphetamine	1000	50%
	Ephedrine Hydrochloride	10000	5%
	Pseudoephedrine Hydrochloride	>100000	<0.5%
	D-Methamphetamine	>100000	<0.5%
	L-Methamphetamine	>100000	<0.5%
	Fenfluramine	>100000	<0.5%
	p-Hydroxymethamphetamine	>100000	<0.5%
	D,L-Methamphetamine	1000	50%
	β-Phenylethylamine	>100000	<0.5%
	Mephetermine	>100000	<0.5%
	L-Amphetamine	>100000	<0.5%
	D-Amphetamine	>100000	<0.5%
	D,L-Amphetamine	>100000	<0.5%
	Trimethobenzamide	>100000	<0.5%
	l-phenylephrine	>100000	<0.5%
	(1R,2S)-(-)-Ephedrine	>100000	<0.5%
	Procaine hydrochloride	>100000	<0.5%
	Phentermine	>100000	<0.5%
MOP 300	Morphine	300	100%
	6-acetylmorphine	300	100%

	Codeine Phosphate	250	120%
	EthylMorphine	200	150%
	Heroin	500	60%
	Hydrocodone	1000	30%
	Levorphanol tartrate	1500	20%
	Morphine-3- β -d-glucuronide	1000	30%
	Thebaine	10000	3%
	Morphine-6- β -D-glucuronide	1000	30%
	Dihydrocodeine	>100000	<0.3%
	Hydromorphone	>100000	<0.3%
	Nalorphine hydrochloride	1000	30%
	s-Monoacetylmorphine	500	60%
	6-Monoacetylmorphine (6-MAM)	500	60%
	Codeine-6- β -D-glucuronide	>100000	<0.3%
	6-Acetylcodeine	>100000	<0.3%
	Normorphine	>100000	<0.3%
	Oxycodone	>100000	<0.3%
	Oxymorphone	>100000	<0.3%
	Norcodeine	>100000	<0.3%
	Procaine hydrochloride	>100000	<0.3%
	Norpropoxyphene	>100000	<0.3%
MTD 300	Methadone	300	100%
	EDDP	>100000	<0.3%
	EMDP	>100000	<0.3%
	Doxylamine	>100000	<0.3%
	EsomeprazoleMagnesium	10000	3%
	LAAM	>100000	<0.3%
	Alpha Methadol	>100000	<0.3%
	Disopyramide	>100000	<0.3%
	Pheniramine	>100000	<0.3%
OXY 100	Oxycodone	100	100%
	Hydrocodone	50000	0.20%
	Hydromorphone	25000	0.40%
	Naloxone Hydrochloride	>100000	<0.1%
	Naltrexone Hydrochloride	>100000	<0.1%
	Oxymorphone	100	100%
	Noroxycodone	1000	10%
	Noroxymorphone	25000	0.40%
	Dihydrocodeine	12500	0.80%
	Codeine Phosphate	100000	0.10%
	Morphine	>100000	<0.1%
	Buprenorphine	>100000	<0.1%
	Ethyl Oxycodone	>100000	<0.1%
	Levorphanol tartrate	>100000	<0.1%
	Oxymorphone-3 β -D-glucuronide	>100000	<0.1%
	Acetylmorphine	>100000	<0.1%
	Ethylmorphine	>100000	<0.1%

	Thebaine	>100000	<0.1%
	6-acetylmorphine	>100000	<0.1%
PCP 25	Phencyclidine	25	100%
	Pheniramine	50000	0.05%
	4-Hydroxyphencyclidine	>100000	<0.025%
TCA 1000	Nortriptyline	1000	100%
	Amitriptyline Hydrochloride	1500	66.70%
	Chlorphenamine Maleate	>100000	<1%
	Clomipramine Hydrochloride	1000	100%
	Cyclobenzaprine Hydrochloride	>100000	<1%
	Desipramine	300	333.3%
	Doxepin Hydrochloride	10000	10%
	Duloxetine Hydrochloridum	>100000	<1%
	Imipramine Hydrochloride	500	200%
	Desmethylinipramine Hydrochloride	250	400%
	Chlorpromazine Hydrochloride	>100000	<1%
	Maprotiline Hydrochloride	>100000	<1%
	Promethazine Hydrochloride	50000	2%
	Norclomipramine	>100000	<1%
	Nordoxepine	>100000	<1%
	Promazine	>100000	<1%
	Trimipramine	>100000	<1%
	Maprotiline	>100000	<1%
THC 50	11-nor-9-Carboxy- Δ^9 -THC	50	100%
	($\pm$)-11-nor-9-Carboxy- Δ^9 -THC	50	100%
	Δ^8 -Tetrahydrocannabinol	>100000	<0.05%
	Δ^9 -Tetrahydrocannabinol	1000	5%
	Cannabinol	10000	0.50%
	Cannabidiol	>100000	<0.05%
	11-nor- Δ^8 -THC-9-COOH	>100000	<0.05%
	11-nor- Δ^9 -THC - carboxylglucuronide	100	50%
	11-hydroxy- Δ^9 - Tetrahydrocannabinol	>100000	<0.05%

To evaluate potential interference, non-structurally related compounds were added to drug-free urine and to urine samples containing the target drugs at 50% below and 50% above each corresponding cutoff.

Compounds that show no interference at a concentration of 100 $\mu\text{g/mL}$ are summarized in the following table.

Ranitidine Hydrochloride	Sertraline Hydrochloride	Nitroglycerin
Gatifloxacin	Diflunisal	Nordoxepin
Naloxone Hydrochloride	Fenofibrate	Norethindrone
Cefalexin	Aripiprazole	Norfentanyl

Benzylpenicillin	Propranolol Hydrochloride	O-Hydroxyhippuric acid
Ibuprofen	Citalopram Hydrobromide	Albumin (100mg/dL)
Aspirin	Lisinopril	Albuterol sulfate (Proair HFA)
Caffeine	Quetiapine Fumarate	Alpha Methadol
Atropine Sulfate	Apomorphine Hydrochloride	Aminophylline
Bilirubin	Estrone	Aminopyrine
Dopamine Hydrochloride	Creatine	Ascorbic acid
Salicylic Acid	Desloratadine	Benzilic acid
Ampicillin	Baclofen	Benzphetamine
Creatinine	Olanzapine	Boric Acid
Loratadine	Pregabalin	Cannabidiol
γ-Cyclodextrin	4-(methylamino)-antipyrine	Carfentanil
Urea	Cortisone	Cephalexin
Vitamin C	Chlorothiazide	Chloralhydrate
Oxalic Acid	D-Glucoseanhydrous	Chloroquine
Benzoic Acid	Cholesterol	Chlorpheniramine
Methoxyphenamine Hydrochloride	5 - Hydroxytryptamine Hydrochloride	Doxepin (except TCA test)
Digoxin	Chloramphenicol	Sodium Carbonate
Paracetamol	Tetracycline	Ecgonine methyl ester
Metformin Hydrochloride	Erythromycin	EMDP
Chlorphenamine Maleate	Clarithromycin	Ephedrine (except MDMA and MET test)
Diphenhydramine Hydrochloride	Amoxicillin	Esomeprazole Magnesium (except MTD test)
Clonidine Hydrochloride	Cefradine	Ethanol
Levonorgestrel	Ciprofloxacin	Fenoprofen
Metoprolol Tartrate	Levofloxacin	Galactose
Phenacetin	Phenoxymethylpenicillin	Gamma Globulin (500mg/dL)
Nicotinamide	Rifampicin	Gentisic acid
Vitamin B6	Azithromycin	Glucose (3000mg/dL)
Theophylline	Tyrosine	Hemoglobin
Perphenazine	Tryptophan	Hydroxytyramine
Carbamazepine	Pethidine Hydrochloride	Isoproterenol
Hydrocortisone	Papaverine Hydrochloride	L-Ephedrine
Epinephrine	Noscapine	L-Epinephrine
Fluphenazine Hydrochloride	Tramadol Hydrochloride	LAAM HCl

Isoprenaline Hydrochloride	Ketamine Hydrochloride	L-Thyroxine
Norepinephrine Bitartrate	Paliperidone	Octopamine
Estradiol	Quinine Sulfate	Oxolinic acid
Metronidazole	Mifepristone	Penicillin-G
Naproxen	Phenelzine	Penicillin-V Potassium
Prednisone	Sildenafil Citrate	Phentermine
Dextromethorphan Hydrobromide	Aspartame	Promethazine (except TCA test)
Sulpiride	Nalidixic Acid	Propoxyphene
Phenylpropanolamine Hydrochloride	Isoxsuprine Hydrochloride	Pseudoephedrine
Verapamil Hydrochloride	Atomoxetine Hydrochloride	Riboflavin
Desoxycortone Acetate	Duloxetine Hydrochloride	Sulfamethazine
Oxymetazoline Hydrochloride	Doxylamine	Tetrahydrocortisone 3-β-D-glucuronide
Maprotiline Hydrochloride	Interferonalpha	Tetrahydrocortisone 3-acetate
Phenylephrine Hydrochloride	Zanamivir	Conjugated Estrogens
Hydralazine Hydrochloride	Ribavirin	Cotinine
Gemfibrozil	Oseltamivir	Cyclobenzaprine
Loperamide Hydrochloride	Peramivir	D-Pseudoephedrine
Hydrochlorothiazide	Lopinavir	D,L-Epinephrine
Captopril	Tetrahydrozoline	D,L-Isoproterenol
Clozapine	Arbidol	D,L-Octopamine
Salbutamol Sulfate	L-Phenylephrine	D,L-Propranolol
Sulindac	Ceftriaxone	D,L-Tryptophan
Ketoprofen	Meropenem	D,L-Tyrosine
Nifedipine	Tobramycin	Delorazepam
Lidocaine Hydrochloride	Phenethylamine	Deoxycorticosterone
Thioridazine Hydrochloride	Beclomethasone	Diclofenac sodium
Omeprazole	Dexamethasone	Magnesium
Vitamin B2	Flunisolide	Meperidine
Vitamin B1	Triamcinolone acetonide	Meproamate
Procaine Hydrochloride	Budesonide	Methapyrilene
Triamterene	Mometasone	Methaqualone
Nicotinic Acid	Fluticasone	N-Acetylprocainamide
Chlorpromazine Hydrochloride	Histamine Hydrochloride	NaCl

Labetalol Hydrochloride	DL-Menthol	Naltrexone hydrochloride
Aminophenazone	Benzocaine	Niacinamide
Fluoxetine Hydrochloride	Mupirocin	Nicotine
Venlafaxine Hydrochloride	3-Hydroxytyramine	Thiamine
Furosemide	Acetaminophen	Trifluoperazine
Risperidone	Acetone (1000mg/dL)	Trimethobenzamide
Atorvastatin Calcium	Acetophenetidin	Trimethoprim
Simvastatin	Acetylsalicylic acid	Tyramine
Telmisartan	Acyclovir	Uric acid
Gabapentin	Disopyramide	Valproic acid (250ug/ml)
Zaleplon	DL-Tryptophan	Zomepirac
Bupropion Hydrochloride	DL-Tyrosine	β-Estradiol

Effect of Urine Density and Urine pH

Interference by urine pH and specific gravity was evaluated using pooled urine specimens with concentrations of 0 (drug-free), 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 did not affect the results of the assays.

4. Detection Limit and Assay Reportable Range:

Not applicable. This device is intended for qualitative use only.

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

The stability results support a shelf life of 24 months at 35.6-86°F (2-30°C) based on real-time stability study data.

6. Assay Cut-Off:

Analytical performance of the device around the claimed cutoff is described in the precision section VII.A1. above.

B Comparison Studies:

1. Method Comparison with Predicate Device:

The method comparison study for the device was conducted by three operators. Operators ran 80 (40 negative and 40 positive) unaltered urine clinical samples for each drug. The samples were blind labeled and compared to LC-MS/MS results. The results are presented in the table below:

Drug test	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%)
AMP	Operator A	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
BAR	Operator A	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator B	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
	Operator C	Positive	0	0	1	22	18
		Negative	12	16	11	0	0
BUP	Operator A	Positive	0	0	1	22	18
		Negative	12	16	11	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
BZO	Operator A	Positive	0	0	0	19	21
		Negative	12	16	12	0	0
	Operator B	Positive	0	0	0	19	21
		Negative	12	16	12	0	0
	Operator C	Positive	0	0	1	19	21
		Negative	12	16	11	0	0
COC	Operator A	Positive	0	0	0	20	20
		Negative	12	14	14	0	0
	Operator B	Positive	0	0	0	20	20
		Negative	12	14	14	0	0
	Operator C	Positive	0	0	1	20	20
		Negative	12	14	13	0	0
FTY	Operator A	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator B	Positive	0	0	1	22	18
		Negative	12	16	11	0	0
	Operator C	Positive	0	0	1	22	18
		Negative	12	16	11	0	0
MD MA	Operator A	Positive	0	0	0	23	16
		Negative	12	17	11	1	0
	Operator B	Positive	0	0	0	22	16
		Negative	12	17	11	2	0
		Positive	0	0	0	24	16

	Operator C	Negative	12	17	11	0	0
MET	Operator A	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
MOP	Operator A	Positive	0	0	0	22	18
		Negative	12	15	13	0	0
	Operator B	Positive	0	0	1	20	18
		Negative	12	15	12	2	0
	Operator C	Positive	0	0	1	22	18
		Negative	12	15	12	0	0
MTD	Operator A	Positive	0	0	1	22	18
		Negative	12	16	11	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	1	21	18
		Negative	12	16	11	1	0
OXY	Operator A	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	2	22	18
		Negative	12	16	10	0	0
PCP	Operator A	Positive	0	0	0	21	17
		Negative	12	17	11	2	0
	Operator B	Positive	0	0	0	22	17
		Negative	12	17	11	1	0
	Operator C	Positive	0	0	0	23	17
		Negative	12	17	11	0	0
THC	Operator A	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
	Operator B	Positive	0	0	0	21	18
		Negative	12	16	12	1	0
	Operator C	Positive	0	0	0	22	18
		Negative	12	16	12	0	0
TCA	Operator A	Positive	0	0	0	24	16
		Negative	12	18	10	0	0
	Operator B	Positive	0	0	0	23	16
		Negative	12	18	10	1	0
	Operator C	Positive	0	0	0	24	16
		Negative	12	18	10	0	0

Discordant results are summarized below:

Drug	Operator	Sample No.	LC-MS/MS Result	Accurate Result
AMP 500	B	A57	524.71	-
	C	A57	524.71	-
BAR 300	A	B31	315.09	-
	C	B61	288.47	+
BUP 10	A	C13	9.6	+
	B	C58	10.59	-
BZO 300	C	D73	286.45	+
COC 150	C	E21	143.13	+
FTY 1	B	F11	0.97	+
	C	F11	0.97	+
	A	F02	1.07	-
MDMA 500	A	G04	512.53	-
	B	G04	512.53	-
	B	G53	516.96	-
MET 500	B	H56	530.03	-
MOP 300	B	I04	282.25	+
	C	I04	282.25	+
	B	I66	307.47	-
	B	I75	307.73	-
MTD 300	A	J03	292.51	+
	C	J51	293.03	+
	B	J40	311.38	-
	C	J67	312.27	-
OXY 100	C	K58	96.03	+
	C	K22	97.38	+
	B	K01	103.35	-
PCP 25	A	L45	26	-
	A	L70	26.11	-
	B	L45	26	-
THC 50	B	M07	51.89	-
TCA 1000	B	N12	1055.42	-

2. Matrix Comparison:

Not applicable.

C Clinical Studies:

1. Clinical Sensitivity:

Not applicable.

2. Clinical Specificity:

Not applicable.

3. Clinical Cut-Off:

Not applicable.

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

Not applicable.

D 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 support a substantial equivalence decision.