

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

**A. 510(k) Number:**

k143599

**B. Purpose for Submission:**

New device

**C. Measurand:**

Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine, Opiates, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants

**D. Type of Test:**

Qualitative immunoassay

**E. Applicant:**

Chemtron Biotech, Inc.

**F. Proprietary and Established Names:**

Chemtrue Drug Screen Cup Tests  
Chemtrue Drug Screen Cup Tests with OPI 2000

**G. Regulatory Information:**

	Product Code	Classification	Regulation Section	Panel
Buprenorphine	DJG	Class II	21CFR 862.3650, Opiate Test System	Toxicology (91)
Amphetamine	DKZ	Class II	21CFR 862.3100, Amphetamine Test System	Toxicology (91)
Cocaine	DIO	Class II	21 CFR 862.3250, Cocaine and metabolites Test System	Toxicology (91)
Marijuana	LDJ	Class II	21 CFR 862.3870, Cannabinoids Test System	Toxicology (91)
Morphine	DNK	Class II	21 CFR 862.3640, Morphine Test System	Toxicology (91)
Opiates	DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
Methamphetamine	LAF	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
Phencyclidine	LCM	Class II	Unclassified, Enzyme immunoassay Phencyclidine	Toxicology (91)
Benzodiazepines	JXM	Class II	21 CFR 862.3170, Benzodiazepines Test System	Toxicology (91)
Barbiturates	DIS	Class II	21 CFR 862.3150, Barbiturates Test System	Toxicology (91)
Ecstasy	DJC	Class II	21 CFR 862.3610, Methamphetamine Test System	Toxicology (91)
Methadone	DJR	Class II	21 CFR 862.3620, Methadone Test System	Toxicology (91)
Oxycodone	DJG	Class II	21 CFR 862.3650, Opiate Test System	Toxicology (91)
Tricyclic Antidepressants	LFG	Class II	21 CFR 862.3910, Tricyclic Antidepressant Drugs Test System	Toxicology (91)

## H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below

2. Indication(s) for use:

### Chemtrue Drug Screen Cup Tests

The Chemtrue® Drug Screen Cup Tests are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Morphine 300, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

Analyte	Abbreviation	Calibrator	Cutoff Concentration (ng/mL)
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylcegonine	300
Methamphetamine	MAMP	d-Methamphetamine	1000
Morphine	MOR	Morphine	300
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor- $\Delta^9$ -THC9 COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtrue® Drug Screen Cup Tests panel can consist of any combination of the above listed drug analytes.

The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cutoff concentration levels for these drugs in urine.

### **Chemtruce Drug Screen Cup Tests with OPI 2000**

The Chemtruce Drug Screen Cup Tests with OPI 2000 are rapid lateral flow immunoassays for the qualitative detection of Buprenorphine, Amphetamine, Cocaine, Marijuana, Opiates 2000, Methamphetamine, Phencyclidine, Benzodiazepines, Barbiturates, Ecstasy, Methadone, Oxycodone and Tricyclic Antidepressants drugs in human urine. The test cut-off concentrations and the compounds the tests are calibrated to are as follows:

<b>Analyte</b>	<b>Abbreviation</b>	<b>Calibrator</b>	<b>Cutoff Concentration (ng/mL)</b>
Buprenorphine	BUP	Buprenorphine	10
Tricyclic Antidepressants	TCA	Nortriptyline	1000
Amphetamine	AMP	d-Amphetamine	1000
Cocaine	COC	Benzoylcegonine	300
Methamphetamine	MAMP	d-Methamphetamine	1000
Opiates 2000	OPI	Morphine	2000
Phencyclidine	PCP	Phencyclidine	25
Marijuana	THC	11-nor- $\Delta^9$ -THC9 COOH	50
Benzodiazepines	BZO	Oxazepam	300
Barbiturates	BAR	Secobarbital/Pentobarbital	300
Ecstasy	MDMA	d,l-Methylenedioxy methamphetamine	500
Methadone	MTD	Methadone	300
Oxycodone	OXY	Oxycodone	100

The Chemtruce Drug Screen Cup Tests with OPI 2000 panel can consist of any combination of the above listed drug analytes.

The tests are intended for prescription and Over-The-Counter (OTC) use.

The tests provide only a preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed assay result. Gas Chromatography / Mass Spectrometry (GC/MS) or Liquid Chromatography / Mass Spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drugs of abuse test result, particularly when preliminary positive results are indicated.

The tests are not intended to differentiate between drugs of abuse and prescription use of Benzodiazepines, Barbiturates, Buprenorphine, Oxycodone and Tricyclic Antidepressants. There are no uniformly recognized cutoff concentration levels for these drugs in urine.

3. Special conditions for use statement(s):

For in vitro diagnostic use only.

4. Special instrument requirements:

Not applicable, as the devices are visually-read single-use devices.

**I. Device Description:**

The devices are for use with human urine only. They consist of:

- A test cup with 1 to 13 drug test strips
- Transport vial, transport bag, and mailing box (for confirmation testing)
- Package insert (instructions for use)

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

Innovacon Spectrum II Test Card with Integrated Cups  
OnTrak TesTcup® II Pro 5-AS and OnSite CupKit™ Pro 5-AS

2. Predicate 510(k) number(s):

k061718  
k060896

3. Comparison with predicate:

<b>Similarities and Differences</b>		
<b>Item</b>	<b>Device</b>	<b>Predicate (k061718 and k060896)</b>
Intended Use	Same	For the qualitative detection of drugs of abuse in human urine
Results	Same	Qualitative
Methodology	Same	Lateral flow, competitive binding immunoassay based on the principle of antigen and antibody immunochemistry.
Storage	2 – 30° C until expiration date	k061718: 2 – 30° C until expiration date; k060896: 15 – 30°C until expiration date

Intended Users	Prescription and over the counter users	Prescription users (k060896); Prescription users, including point-of-care (k061718)
Cutoffs (ng/mL)	<p>Buprenorphine – same            Barbiturates – same            Tricyclic Antidepressants – same            Opiates 2000 – same            MDMA – same            Methadone – same            Oxycodone – same            Propoxyphene – not included in device</p> <p>Amphetamine – 1000            Benzodiazepines – 300            Cocaine – 300            Methamphetamine – 1000            Phencyclidine – same            Marijuana – same</p> <p>Morphine –300</p>	<p>k061718            Buprenorphine – 10            Barbiturates – 300            Tricyclic Antidepressants – 1000            Opiates 2000 – 2000            MDMA – 500            Methadone – 300            Oxycodone – 100            Propoxyphene – 300</p> <p>k061718 and k060896            Amphetamine – 1000 / 300            Benzodiazepines – 300 / 200            Cocaine – 300 / 150            Methamphetamine – 1000 /500 / 300            Phencyclidine – 25            Marijuana – 50</p> <p>k060896            Morphine – 300/2000</p>
Format	Cup only	k061718: Cup and Dipcard; k060896: Cup only

**K. Standard/Guidance Document Referenced (if applicable):**

Design Considerations for Devices Intended for Home Use - Guidance for Industry and Food and Drug Administration Staff

**L. Test Principle:**

The Chemtrue® Drug Screen Cup Tests are rapid lateral flow immunoassays in which drug-protein conjugates in the test device compete with drugs or drug metabolites that may be present in urine. On each test strip, a drug-protein conjugate is added to the test band of the membrane – known as the test region (T), and the anti-drug antibody-colloidal gold conjugate pads are placed at the forward end of the membrane. Monoclonal anti-drug antibodies derived from mice are used on the BUP, AMP, COC, MET, MOR, OPI2000, PCP, THC, BAR, MDMA, MTD, and OXY tests. Monoclonal anti-drug antibodies derived from

sheep and mice are used on the TCA and BZO tests. If target drugs are present in the urine specimen below its cut-off concentration, the solution of the colored antibody-colloidal gold conjugates moves along with the sample solution by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugates then complexes with the drug-protein conjugates to form visible lines. Therefore, the formation of the visible precipitant in the test band indicates a negative result. If the target drug level exceeds its cut-off concentration, the drug/metabolite antigen competes with drug protein conjugates on the test band region for the limited antibody on the colored drug antibody-colloidal gold conjugate pad. The drug will saturate the limited antibody binding sites and the colored antibody-colloidal gold conjugate cannot bind to the drug-protein conjugate at the test region of the test strip. Therefore, absence of the color band on the test region indicates a preliminary positive result. A band should form in the control region (C) of the devices regardless of the presence of drug in the sample to indicate that the test has been performed properly.

**M. Performance Characteristics (if/when applicable):**

Performance characteristics for Buprenorphine (BUP) and Tricyclic Antidepressants (TCA) test strips in cup format were established in k142396, unless otherwise noted. The same BUP and TCA test strips from k142396 are used in the candidate devices.

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision performance of the test strips of the devices was evaluated using 3 lots and 3 operators. Drug-free (negative) urine samples were analyzed and also spiked to concentrations of -50% of cutoff, -25% of cutoff, cutoff, cutoff + 25% and cutoff + 50%. Each drug concentration was confirmed by GC/MS. Each lot was evaluated by a different operator and results were collected over ten non-consecutive days. Results are summarized below.

Drug	Concentration Tested	Operator 1/ Lot 1	Operator 2/ Lot 2	Operator 3/ Lot 3	Total of the three operators
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
AMP	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	4/6	6/4	14/16
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30

Drug	Concentration Tested	Operator 1/ Lot 1	Operator 2/ Lot 2	Operator 3/ Lot 3	Total of the three operators
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
BAR	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	5/5	5/5	14/16
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
BZO	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	7/3	4/6	4/6	15/15
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
COC	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	4/6	4/6	12/18
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
MAMP	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	5/5	4/6	5/5	14/16
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
MOR 300	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	5/5	5/5	14/16
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
PCP	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	4/6	4/6	12/18
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30

Drug	Concentration Tested	Operator 1/ Lot 1	Operator 2/ Lot 2	Operator 3/ Lot 3	Total of the three operators
		Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
MTD	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	6/4	6/4	5/5	17/13
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
OXY	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	5/5	3/7	5/5	13/17
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
OPIATES 2000	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	5/5	5/5	2/8	12/18
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
THC	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	5/5	5/5	5/5	15/15
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30
MDMA	Negative	70/0	70/0	70/0	210/0
	-50% of cutoff	10/0	10/0	10/0	30/0
	-25% of cutoff	10/0	10/0	10/0	30/0
	Cutoff	4/6	5/5	4/6	13/17
	+25% of cutoff	0/10	0/10	0/10	0/30
	+50% of cutoff	0/10	0/10	0/10	0/30

*b. Linearity/assay reportable range:*

Not applicable. These devices are intended for qualitative use only.

*c. Traceability, Stability, Expected values (controls, calibrators, or methods):*

Stability: Device stability has been evaluated through accelerated and real-time studies. The real-time studies are ongoing. Protocols and acceptance criteria were

described and found to be acceptable. The manufacturer claims that the devices are stable for two years (24 months) when stored at 2–30° C.

Quality control: Control materials are not supplied with the devices; however the labeling provides information on how to obtain quality control materials.

*d. Detection limit:*

See Precision/Reproducibility section in M.1.a above.

*e. Analytical specificity:*

For each drug, specificity was evaluated by spiking various concentrations of similarly structured drug compounds into drug-free urine. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay. The percent cross-reactivity of those compounds is listed below with the calibrator analyte(s) in bold:

Target Drug	Compound	Concentration Equivalent to the Cutoff (ng/mL)	Cross-Reactivity (%)
AMP	<b>d-Amphetamine</b>	<b>1000</b>	<b>100</b>
	Methylenedioxyethylamphetamine (MDEA)	>100,000	<1
	d,l-Methamphetamine	>100,000	<1
	Phenylephrine	>100,000	<1
	d-Methamphetamine	>100,000	<1
	l-Methamphetamine	>100,000	<1
	d,l - Methylenedioxy methamphetamine (MDMA)	>100,000	<1
	l-Amphetamine	>100,000	<1
	Ephedrine	>100,000	<1
	Pseudoephedrine	>100,000	<1
	d/l-Amphetamine	2500	40
	d,l-3,4-Methylenedioxyamphetamine (MDA)	3000	33
Phentermine	5000	20	

BAR	<b>Secobarbital</b>	<b>300</b>	<b>100</b>
	<b>Pentobarbital</b>	<b>300</b>	<b>100</b>
	Alphenal	500	60
	Amobarbital	800	38
	Aprobarbital	500	60
	Barbital	10,000	3
	Butobarbital	500	60
	Butalbital	3000	10
	Cyclopentobarbital	750	40
	Phenobarbital	2000	15
BZO	<b>Oxazepam</b>	<b>300</b>	<b>100</b>
	Alprazolam	300	100
	Alpha-Hydroxyalprazolam	100	300
	Bromazepam	500	60
	Chlordiazepoxide	2,500	12
	Clobazam	200	150
	Clonazepam	10,000	3
	Clorazepate	350	86
	Desalkylflurazepam	65	462
	Diazepam	200	150
	Estazolam	500	60
	Flunitrazepam	375	80
	Flurazepam	90	333
	Lorazepam	600	50
	Lormetazepam	7,500	4
	Midazolam	900	33
	Nitrazepam	200	150
	Nordiazepam	150	200
	Temazepam	350	86
	Triazolam	1,000	30
COC	<b>Benzoylcegonine</b>	<b>300</b>	<b>100</b>
	Cocaine	500	60
	Cocaethylene	20,000	1.5

MAMP	<b>d-Methamphetamine</b>	<b>1000</b>	<b>100</b>
	1-Methamphetamine	>100,000	<1
	d,l-Amphetamine	>100,000	<1
	Phentermine	>100,000	<1
	d,l – Methamphetamine	5000	20
	d-Amphetamine	10,000	10
	l-Amphetamine	>100,000	<1
	Ephedrine	>100,000	<1
	Phenylephrine	10,000	10
	Pseudoephedrine	>100,000	<1
	3,4- Methylenedioxy methamphetamine (MDMA)	5000	20
	d,l- Methylenedioxy ethylamphetamine (MDEA)	100,000	1
	d,l-3,4- Methylenedioxyamphetamine (MDA)	>100,000	<1
MOR 300	<b>Morphine</b>	<b>300</b>	<b>100</b>
	Codeine	300	100
	6-Acetylmorphine	500	60
	Diacetylmorphine (Heroin)	2,000	15
	Hydrocodone	50,000	<1
	Hydromorphone	5,000	6
	Oxycodone	50,000	0.6
	Oxymorphone	>100,000	<0.3
	Procaine	>100,000	<0.3
PCP	<b>Phencyclidine</b>	<b>25</b>	<b>100</b>
	Pheniramine	>100,000	<1
MTD	<b>Methadone</b>	<b>300</b>	<b>100</b>
	Doxylamine	100,000	0.3
	Pheniramine	>100,000	<1
	2-ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine (EDDP)	>100,000	<1
OXY	<b>Oxycodone</b>	<b>100</b>	<b>100</b>
	Codeine	100,000	0.1
	Hydrocodone	100,000	0.1
	Oxymorphone	100	100

OPIATES 2000	<b>Morphine</b>	<b>2000</b>	<b>100</b>
	Codeine	2000	100
	Diacetylmorphine (Heroin)	2000	100
	Hydrocodone	50,000	4
	Hydromorphone	50,000	4
	Oxycodone	100,000	2
	6-Acetylmorphine	1500	133
	Oxymorphone	100,000	2
	Acetaminophen	100,000	2
	Normorphine	100,000	2
	Ethylmorphine	1500	133
	Norcodeine	100,000	2
THC	<b>11-nor-<math>\Delta^9</math>-THC-9-COOH</b>	<b>50</b>	<b>100</b>
	11-nor- $\Delta^8$ -THC-9-COOH	30	167
	$\Delta^9$ -Tetrahydrocannabinol	12,000	0.4
	Cannabidiol	>100,000	<0.05
	Cannabinol	>100,000	<0.05
MDMA	<b>d,l - Methylenedioxy methamphetamine (MDMA)</b>	<b>500</b>	<b>100</b>
	1-Methamphetamine	>100,000	<0.5
	Ephedrine	>100,000	<0.5
	Pseudoephedrine	>100,000	<0.5
	d,1- Amphetamine	>100,000	<0.5
	l-Amphetamine	>100,000	<0.5
	Phentermine	>100,000	<0.5
	d,l- Methamphetamine	>100,000	<0.5
	Phenylephrine	>100,000	<0.5
	Methylenedioxy ethylamphetamine (MDEA)	1000	50
	d,l-3,4- Methylenedioxyamphetamine (MDA)	15,000	3
	d-Methamphetamine	100,000	0.5
d-Amphetamine	100,000	0.5	

The sponsor also evaluated the potential for positive and negative interference from non-structurally related compounds, endogenous compounds, pH, and specific gravity. The structurally unrelated compounds and endogenous substances study was performed by spiking structurally unrelated compounds and endogenous substances at a concentration of 100  $\mu\text{g/mL}$  into urine samples containing drug at  $\pm 25\%$  of the respective drug cutoff concentrations. The following structurally unrelated substances showed no positive or negative interference in this study:

Acetaminophen	5, 5-Diphenylhydantoin	Octopamine
Acetone	Dopamine	Oxalic Acid
Acetylsalicylic Acid	Erythromycin	Papaverine
Amoxicillin	Estradiol	Penicillin-G
Ampicillin	Estrone	Perphenazine
R-(-)-Apomorphine	Ethanol	Phenelzine
L-Ascorbic Acid	Fenofibrate	Phenylethylamine
Aspirin	Fentanyl	Prednisone
Aspartame	Fotemustine	Promazine
Atropine	Furosemide	Promethazine
Baclofen	Gemfibrozil	d-Propoxyphene
Benzocaine	Guaiacolglyceryl ether	d,l-Propranolol
Benzoic Acid	Gentisic acid	Pyridoxine
Carisoprodol	Hydralazine	Pyrilamine
Chloramphenicol	Hydrocortisone	Pyrogallol
Chlordiazepoxide	3-Hydroxytyramine	Quinidine
(+)-Chlorpheniramine	(+/-)-Isoproterenol	Quinine
Chlorpromazine	Ketamine	Quinolinic Acid
Clofibrate	Meprobamate	Ranitidine
Clonidine	Methapyrilene	Salicylic Acid
Cortisone	Methylphenidate	Sulfamethazine
(-)-Cotinine	Nalidixic Acid	Sulindac
Creatine Hydrate	Naloxone	Tetracycline
Cyclobenzaprine	Naltrexone	Tetrahydrozoline
Cyclodextrin	(+)-Naproxen	Thiamine
Cyproheptadine	Niacinamide	Thioridazine
Deoxycorticosterone	Nicotinic Acid	Tramadol
Dextromethorphan	Nifedipine	Trifluoperazine
Diclofenac	19-Norethindrone	Tryptamine
Diflunisal	Norpropoxyphene	Tyramine
4-Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine		

The following endogenous substances showed no positive or negative interference in this study:

Albumin	Creatinine	Riboflavin
Bilirubin	Glucose	Sodium Chloride
Cholesterol	Hemoglobin	Uric Acid

Evaluation of Specific Gravity and pH on test results:

To evaluate the effect of pH value on the test results, urine controls at  $\pm 50\%$  of the cutoff value were used. Each control level was adjusted by either 1N NaOH solution or 1N HCl to pH levels of 2.0, 3.0, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0 and 9.0. Each test sample was tested in duplicate.

To evaluate the effect of specific gravity, urine controls at  $\pm 50\%$  of the cutoff values were spiked with deionized water or sugar to obtain specific gravities of 1.001, 1.010, 1.015, 1.020, 1.025, and 1.030. Each test sample was tested in duplicate.

The results demonstrated that pH and specific gravity do not affect the results from the device.

*f. Assay cut-off:*

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

2. Comparison studies:

The sponsor performed a method comparison study comparing performance of the test strips of the cup devices to the GC/MS reference method. For each drug test, at least 40 unaltered positive clinical samples and 40 unaltered negative clinical samples with known GC/MS values were tested. Results are summarized below:

*a. Method comparison with predicate device:*

Amphetamine

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	$\leq$ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	$\geq$ cutoff +50%
POS	0	0	16	25
NEG	67	25	1*	0

Agreement among positives =  $41/42 = 98\%$

Agreement among negatives =  $81/81 = 100\%$

\*Sample contained amphetamine at 1061 ng/mL

Barbiturates

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	$\leq$ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	$\geq$ cutoff +50%
POS	0	0	12	28
NEG	44	11	0	0

Agreement among positives =  $40/40 = 100\%$

Agreement among negatives =  $55/55 = 100\%$

### Benzodiazepines

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	15	25
NEG	40	9	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 49/50 = 98%

\*Sample contained Oxazepam at 253 ng/mL

### Cocaine

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	15	25
NEG	40	9	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 49/50 = 98%

\*Sample contained benzoylecgonine at 292 ng/mL

### Ecstasy

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	12	28
NEG	42	14	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 56/57 = 98%

\*Sample contained MDMA at 498 ng/mL

### Methamphetamine

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	15	25
NEG	40	10	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 50/50 = 100%

Methodone

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	14	26
NEG	40	10	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 50/50 = 100%

Morphine 300

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	16	74
NEG	40	10	0	0

Agreement among positives = 90/90 = 100%

Agreement among negatives = 50/50 = 100%

Oxycodone

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	9	31
NEG	40	10	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 50/50 = 100%

Opiates 2000

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	14	27
NEG	40	9	0	0

Agreement among positives = 41/41 = 100%

Agreement among negatives = 49/50 = 98%

\*Sample contained morphine at 1179 ng/mL and codeine at 522 ng/mL

Phencyclidine (PCP)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1*	16	24
NEG	40	10	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 50/51 = 98%

\*Sample contained PCP at 24.6 ng/mL

THC

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff -50%	cutoff -50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	15	25
NEG	40	11	0	0

Agreement among positives = 40/40 = 100%

Agreement among negatives = 51/51 = 100%

b. *Matrix comparison:*

Not applicable. This device is for use with urine samples only.

3. Clinical studies:

a. *Clinical Sensitivity:*

Not applicable

b. *Clinical specificity:*

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

A consumer study was performed for all analytes, including BUP and TCA, to evaluate the ability of untrained users to interpret the devices properly when given only the labeling (package insert) provided with the devices. One hundred (100) intended lay-users participated in this study from three (3) intended user sites with GC/MS confirmed urine samples at the following concentrations: negative, 50%, 75%, 125% and 150% of the cutoff. Samples were created by spiking drugs into drug-free urine pool. Each sample was aliquotted into an individual blind-labeled container. Each lay-user was provided with a package insert in English only and one blind-labeled sample for testing.

Drug (cutoff in ng/mL)	Cutoff	Conc. by GC/MS (ng/mL)	n	Lay Person Results		%Agreement With GC/MS
				Negative	Positive	
AMP (1000)	-100%	0	60	60	10	100
	-50%	500	10	10	0	100
	-25%	750	10	10	0	100
	+25%	1250	10	0	10	100
	+50%	1500	10	0	10	100
BAR (300)	-100%	0	60	60	10	100
	-50%	150	10	10	0	100
	-25%	225	10	10	0	100

	+25%	375	10	0	10	100
	+50%	450	10	0	10	100

BZO (300)	-100%	0	60	60	10	100
	-50%	150	10	10	0	100
	-25%	225	10	10	0	100
	+25%	375	10	0	10	100
	+50%	450	10	0	10	100
BUP (10)	-100%	0	30	0	30	100
	-50%	5	30	0	30	100
	-25%	7.5	30	0	30	100
	+25%	12.5	30	30	0	100
	+50%	15	30	30	0	100
COC (300)	-100%	0	60	60	10	100
	-50%	150	10	10	0	100
	-25%	225	10	10	0	100
	+25%	375	10	0	10	100
	+50%	450	10	0	10	100
MDMA (500)	-100%	0	60	60	10	100
	-50%	250	10	10	0	100
	-25%	375	10	10	0	100
	+25%	625	10	0	10	100
	+50%	750	10	0	10	100
MET (1000)	-100%	0	60	60	10	100
	-50%	500	10	10	0	100
	-25%	750	10	10	0	100
	+25%	1250	10	0	10	100
	+50%	1500	10	0	10	100
MTD (300)	-100%	0	60	60	10	100
	-50%	150	10	10	0	100
	-25%	225	10	10	0	100
	+25%	375	10	0	10	100
	+50%	450	10	0	10	100
MOR 300 (300)	-100%	0	60	60	10	100
	-50%	150	10	10	0	100
	-25%	225	10	10	0	100
	+25%	375	10	0	10	100
	+50%	450	10	0	10	100

OPI 2000 (2000)	-100%	0	60	60	60	10
	-50%	1000	10	10	10	0
	-25%	1500	10	10	10	0
	+25%	2500	10	10	0	10
	+50%	3000	10	10	0	10
OXY (100)	-100%	0	60	60	10	100
	-50%	50	10	10	0	100
	-25%	75	10	10	0	100
	+25%	125	10	0	10	100
	+50%	150	10	0	10	100
PCP (25)	-100%	0	60	60	10	100
	-50%	12.5	10	10	0	100
	-25%	18.75	10	10	0	100
	+25%	31.25	10	0	10	100
	+50%	37.5	10	0	10	100
TCA (1000)	-100%	0	30	0	30	100
	-50%	500	30	0	30	100
	-25%	750	30	0	30	100
	+25%	1250	30	30	0	100
	+50%	1500	30	30	0	100
THC (50)	-100%	0	60	60	0	100
	-50%	25	10	0	10	100
	-25%	37.5	10	9	1	90
	+25%	62.5	10	10	0	100
	+50%	75	10	10	0	100

Consumers were also given surveys on the ease of understanding the package insert instructions and  $\geq 98\%$  of the lay users indicated that the device instructions can be easily followed. A Flesch-Kincaid reading analysis was performed on the package inserts and the score revealed a reading grade level of less than 7.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

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