

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

A. 510(k) Number:

k122633

B. Purpose for Submission:

New device

C. Measurand:

d-Amphetamine, Secobarbital, Buprenorphine Glucuroide, Oxazepam, Benzoylcegonine, 3,4-methylenedioxymethamphetamine, Methamphetamine, Methadone, Moprhine, Oxycodone, Phencyclidine, Propoxyphene, Nortriptyline, 11-nor- Δ 9-Tetrahydrocannabinol-9-carboxylic acid

D. Type of Test:

Qualitative lateral flow immunoassay

E. Applicant:

Branan Medical Corporation

F. Proprietary and Established Names:

ToxCup® Drug Screen Cup

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
LDJ	II	862.3870 Cannabinoid test system	Toxicology (91)
DIO	II	862.3250 Cocaine and cocaine metabolite test system	Toxicology (91)
DJG	II	862.3650 Opiate test system	Toxicology (91)
DJC	II	862.3610 Methamphetamine test system	Toxicology (91)
DKZ	II	862.3100 Amphetamine test system	Toxicology (91)
LCM	unclassified	Enzyme immunoassay Phencyclidine	Toxicology (91)
JXM	II	862.3170 Benzodiazepine test system	Toxicology (91)
DIS	II	862.3150 Barbiturate test system	Toxicology (91)
DJR	II	862.3620 Methadone test system	Toxicology (91)
LFG	II	862.3910 Tricyclic antidepressant drugs test system	Toxicology (91)
JXN	II	862.3700 Propoxyphene test system	Toxicology (91)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indications(s) for use:

The ToxCup Drug Screen Cup is an in vitro screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

Abbreviation	Analyte	Cutoff
AMP	Amphetamine	500 ng/mL
BAR	Secobarbital	300 ng/mL
BUPG	Buprenorphine Glucuronide	10 ng/mL
BZO	Oxazepam	300 ng/mL
COC	Benzoyllecgonine	150 ng/mL
MDMA	3,4-methylenedioxymethamphetamine	500 ng/mL
MET	Methamphetamine	500 ng/mL
MTD	Methadone	300 ng/mL
OPI	Morphine	300 ng/mL
OXY	Oxycodone	100 ng/mL
PCP	Phencyclidine	25 ng/mL
PPX	Propoxyphene	300 ng/mL
TCA	Nortriptyline	1000 ng/mL
THC	11-nor- 9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/mL

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The ToxCup Drug Screen Cup is available in double drug analyte cassette dip format. It is intended for prescription point-of-care use and over-the-counter consumer use.

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the ToxCup Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

3. Special conditions for use statement(s):

For over-the counter use.

4. Special instrument requirements:

Not Applicable

I. Device Description:

This device is to be used with human urine samples. The tests are available in the cassette dip format. The cassette format consists of the ToxCup Drug Screen Cup test strips, a plastic cassette dip and a plastic cup base. The plastic cassette dip can hold up to 7 individual test strips. Each test strip can detect up to 2 drugs.

Each test strip consists of an absorbent pad used to deliver sample to the test strip, a drug antibody-colloidal gold conjugate pad, two stripes of drug protein conjugate known as Test regions (T) and a control stripe of goat anti-rabbit IgG antibody (C).

J. Substantial Equivalence Information:

1. Predicate device name(s):

Amedica Home Drug Test Cup

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

k082898

3. Comparison with predicate:

Reagent Similarities and Differences		
Feature	Candidate Device: ToxCup Drug Screen Cup (k122633)	Predicate Device: Amedica Home Drug Test Cup (k082898)
Intended/Indications for Use	Screening Device	Same
Methodology	Competitive immunoassay	Same
Results	Qualitative	Same
Matrix	Human Urine	Same
Cut Off Value	THC: 50 ng/mL Amphetamine: 500 ng/mL Secobarbital: 300 ng/mL Buprenorphine Glucuronide: 10 ng/mL Benzoylcegonine: 150 ng/mL MDMA: 500 ng/mL Methamphetamine: 500ng/mL Methadone: 300 ng/mL Morphine: 300 ng/mL Phencyclidine 25 ng/mL Benzodiazepines 300 ng/mL Nortriptyline 1000 ng/mL Oxycodone 100 ng/mL Propoxyphene 300 ng/mL	THC: 50 ng/mL Amphetamine: 1000 ng/mL Secobarbital: 300 ng/mL Morphine: 300 ng/mL Benzodiazepines 300 ng/mL Methadone: 300 ng/mL Oxycodone 100 ng/mL MDMA: 500 ng/mL Nortriptyline 1000 ng/mL Phencyclidine 25 ng/mL
Configurations	Strip, Cassette	Card
Intended Use	Over the Counter and Prescription Use	Over the Counter
Test Strip	Tests up to 14 drugs	Tests up to 12 drugs
Method Comparison Total % agreement	≥ 95%	≥ 93%
Storage	Sealed Pouch at 15-30°C	Sealed pouch at 2-30°C
Reading Time	5-8 minutes	4-5 minutes

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

- In Vitro Diagnostic Devices; Guidance for the Preparation of 510(k) Submission
- Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests, Draft Guidance

L. Test Principle:

The tests are available in the cassette dip format. Each test strip consists of an absorbent pad used to deliver sample to the test strip, a drug antibody-colloidal gold conjugate pad, two

stripes of drug protein conjugate known as Test regions (T) and a control stripe of goat anti-rabbit IgG antibody (C).

When the absorbent end of the test device is immersed into the urine sample, the urine is absorbed into the device by capillary action, mixes with the antibody-dye conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), antibody-dye conjugate binds to the drug-protein conjugate immobilized in the T region of the device. This produces a colored Test line, which regardless of its intensity, indicates a negative result.

When sample drug levels are at or above the target cutoff, the free drug in the binding sample binds to the antibody-dye conjugate preventing the antibody-dye conjugate from binding to the drug-protein conjugate immobilized in the T region of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.

To serve as a procedure control, a colored line will appear at the C Region, if the test has been performed properly because of the antibody-dye conjugate binding to anti-rabbit IgG immobilized in the C Region of the device.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The precision study was performed by taking negative urine samples and spiking these with: ± 25, 50, 75, and 100% of the different cut-off values for each drug. The study was performed at three different point-of-care sites for a minimum of 10 days. Each of the three sites had one operator perform the studies on one lot of cups for a total of three lots studied. All samples were randomized and masked three lots drug screen cups were used. A summary of the results is presented in the tables below.

11-nor-9-Tetrahydrocannabinol-9-carboxylic acid = 50 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	6/9	2/13	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	7/8	1/14	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	15/0	8/7	1/14	0/15	0/15	0/15

Benzoylcegonine = 150 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	6/9	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	4/11	0/15	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	15/0	4/11	0/15	0/15	0/15	0/15

Morphine = 300 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	13/2	6/9	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	12/3	4/11	0/15	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	14/1	4/11	0/15	0/15	0/15	0/15

Methamphetamine = 500 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	105/0	15/0	15/0	15/0	7/8	1/14	0/15	0/15	0/15
Site 2	105/0	15/0	15/0	15/0	8/7	1/13	0/15	0/15	0/15
Site 3	105/0	15/0	15/0	15/0	10/5	1/14	0/15	0/15	0/15

Amphetamine = 500 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	13/2	6/9	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	5/10	1/14	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	15/0	4/11	2/13	0/15	0/15	0/15

Oxazepam = 300 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	15/0	5/10	0/15	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	3/12	0/15	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	15/0	4/11	1/14	0/15	0/15	0/15

Secobarbital = 300 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	6/9	2/13	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	7/8	1/14	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	15/0	8/7	1/14	0/15	0/15	0/15

Methadone = 300 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	6/9	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	4/11	0/15	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	15/0	4/11	0/15	0/15	0/15	0/15

Buprenorphine Glucoronide = 10 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	13/2	6/9	0/15	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	12/3	7/8	0/15	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	14/1	9/6	0/15	0/15	0/15	0/15

Nortriptyline = 1000 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	8/7	2/13	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	12/3	2/13	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	14/1	13/2	2/13	0/15	0/15	0/15

3,4-methylenedioxymethamphetamine = 500 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	4/11	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	13/2	5/10	15/0	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	15/0	7/8	15/0	0/15	0/15	0/15

Oxycodone = 100 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	15/0	7/8	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	8/7	0/15	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	15/0	12/3	1/14	0/15	0/15	0/15

Phencyclidine = 25 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	15/0	9/6	1/14	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	15/0	10/5	2/13	0/15	0/15	0/15
Site 3	120-0	15/0	15/0	15/0	10/5	2/13	0/15	0/15	0/15

Propoxyphene = 300 ng/mL cut-off

Site	Negative	-75% Cut-off	-50% Cut-off	-25% Cut-off	Cut-off	+25% Cut-off	+50% Cut-off	+75% Cut-off	+ 100% Cut-off
	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos	Neg/Pos
Site 1	120/0	15/0	15/0	14/1	4/11	0/15	0/15	0/15	0/15
Site 2	120/0	15/0	15/0	13/2	2/13	0/15	0/15	0/15	0/15
Site 3	120/0	15/0	15/0	13/2	5/10	0/15	0/15	0/15	0/15

b. Linearity/assay reportable range:

Not Applicable, the assay is intended for qualitative use

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

Control standards are not supplied with this device; however, this device has internal process controls. A colored line appearing in the control region confirms sufficient sample volume and adequate membrane wicking. Users are informed that the test is invalid if a line fails to appear in the control region.

Professional users are informed in the labeling that external negative and positive urine controls should be used to initially test each new lot of product to ensure proper performance.

Stability

Accelerated stability studies were conducted on three lots of the ToxCup® Drug Screen Tests. Protocols and acceptance criteria were found to be acceptable. The manufacturer claims an 18 month shelf life. Real time studies are on-going.

Read time stability was performed for the ToxCup® Drug Screen Tests. A drug-free urine sample was spiked with the appropriate drug at ± 25%, 50%, and +200% of the cutoff. 20 replicates per level were tested at 2-10 minute intervals from 1-60 minutes. Data supports the recommended read time of 5-8 minutes.

d. Detection limit:

Not applicable, this is a qualitative assay.

e. Analytical specificity:

Cross reactivity was established by spiking structurally related compounds into drug free urine and diluting each to determine the lowest concentration that produced a false positive result. Two devices were tested for each spiked urine solution. Results are expressed as the response equivalent to cutoff, which is the lowest interference concentration that produces a positive result. The percent cross-reactivity, expressed as 100* (cutoff/response equivalent to cutoff) is also presented below:

Structurally related:

11-nor-9-Tetrahydrocannabinol-9-carboxylic acid (Cutoff = 50 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Cannabinol	50000	0.1%
Cannabidiol	100000	0.05%
11-nor- Δ 9-Tetrahydrocannabinol-9-carboxylic acid	50	100%
11-nor- Δ 8-Tetrahydrocannabinol-9-carboxylic acid	50	100%
11-hydroxy- Δ 9-Tetrahydrocannabinol	2500	2%
Δ 8-Tetrahydrocannabinol	7000	0.71%
Δ 9-Tetrahydrocannabinol	10500	0.48%

Benzoylcegonine (Cutoff = 150 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Benzoylcegonine	150	100%
Ecgonine	65500	0.23%

Morphine (Cutoff = 300 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
6-Acetylmorphine	500	60%
6-Acetylcodeine	600	50%
Codeine	300	100%
Dihydrocodeine	500	60%
Ethyl Morphine	300	100%
Heroin	100	300%
Hydrocodone	1000	30%
Hydromorphone	400	75%
Morphine	300	100%
Morphine-3-β-glucuronide	500	60%
Nalorphine	5000	6%

Methamphetamine (Cutoff = 500 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Ephedrine	10000	5%
p-hydroxymethamphetamine	1750	28.57%
D,1-3,4-MDMA	1000	50%
d-methamphetamine	500	100%
l-methamphetamine	25000	2%
Procaine	50000	1%
d,1-3,4-MDEA	20000	2.5%
Trimethobenzamine	75000	0.67%

Amphetamine (Cutoff = 500 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
l-Amphetamine	20000	2.5%
d-Amphetamine	500	100%
D,1-3,4- methylenedioxyamphptamine (MDA)	1500	33.3%
Phentermine	1000	50%
β-phenylethylamine	80000	0.63%

Oxazepam Cutoff= 300 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Alprazolam	150	200%
a-hydroxyalprazolam	50	600%
Bromazepam	800	37.5
Chlordiazepoxide	3000	37.5%
Clonazepam	4000	7.5%
Clobazam	200	150%
Delorazepam	6000	5%
Diazepam	150	200%
Estazolam	300	100%
Flunitrazepam	1000	30%
Flurazepam	300	100%
Lorazepam	1500	20%
Lormetazepam	1000	30%
Medazepam	2000	15%
Nitrazepam	1000	30%
Nordiazepam	100	300%
Oxazepam	300	100%
Phenazepam	1000	30%
Prazepam	1000	30%
Temazepam	150	50%
Trazolam	1500	20%

Secobarbital Cutoff= 300 ng/ml)	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Amobarbital	1500	20%
Alphenal	400	75%
Aprobarbital	400	150%
Allobarbital	1500	20
Butobarbital	400	75%
Butethal	400	75%
Butalbital	300	100%
Barbital	400	75%
Secobarbital	300	100%
Pentobarbital	400	75%
Phenobarbital	400	75%

Methadone Cutoff= 300 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Doxylamine	50,000	0.6%
w-Ethylidene-1,5 Dimethyl-1,3 Diphenylpyrrolidine	50,000	0.6%
Methadone	300	100%
Pheniramine	75,000	0.4%

Buprenorphine Glucuronide Cutoff= 10 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Buprenorphine	100	10%
Buprenorphine Glucuronide	10	100%
Norbuprenorphine	100	10%
Norbuprenorphine Glucuronide	100	10%

Nortriptyline Cutoff= 1000 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Amitriptyline	1000	100%
Clomipramine	7500	13.33%
Cyclobenzaprine	1500	66.67%
Desipramine	750	133.33%
Doxepin	1000	100%
Imipramine	750	133.33%
Nordoxepin	1000	100%
Nortriptyline	1000	100%
Perphenazine	50000	2%
Promazine	10,000	10
Protriptyline	350	285.7%
Trimipramine	1500	66.67%

3,4 methylenediozymethamphetamine Cutoff= 500 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
d,1-3,4-MDA	2000	25%
d,1-3,4-MDEA	250	200%
d,1-3,4-MDMA	500	100%
d-Methamphetamine	50,000	1%

Oxycodone Cutoff= 100 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Codeine	5000	2%
Dihydrocodeine	2000	5%
6-Acetylcodeine	15,000	0.67%
Hydrocodone	300	33.3%
Oxymorphone	3000	3.3%
Oxycodone	100	100%
Hydromorphone	25,000	0.4%
Ethylmorphine	5000	2%

Phencyclidine Cutoff= 25 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
4-Hydroxy Phencyclidine	500	5%
Metaphit	500	5%
Phencyclidine	25	100%
Phencyclidine Morpholine	50,000	0.05%

Propoxyphene Cutoff= 300 ng/ml	Response Equivalent to Cutoff (ng/mL)	% Cross Reactivity
Propoxyphene	300	100%
Norpropoxyphene	500	60%

Structurally Un-related Compounds:

This study was performed by spiking structurally unrelated compounds and endogenous substances up to concentration of 100 µg/mL into urine samples containing drug at ± 50% of the respective drug cutoff concentrations. Testing was performed for on two devices for each urine control. The following compounds showed no interference when tested at the ± 50 % drug concentration.

Acetaminophen	Gentisic acid	Riboflavin
Acetone	Glutethimide	Salicylic Acid
Albumin	Guaiacol Glyceryl Ether	Serotonin
Acetylsalicylic Acid	D-(+)-glucose	Sodium Chloride
Amoxapine	Hemoglobin	Sulfamethazine
Amoxicillin	Hippuric Acid	Sulindac
Ampicillin	Hydrochlorothiazide	Tetracycline
Ascorbic Acid	Hydrocortisone	Thiamine
Apomorphine	Ibuprofen	Thioridazine
Aspartame	(+/-)-Isoproterenol	Trifluoperazine
Atropine Sulfate	Ketamine HCl	Tryptamine
Benzilic Acid	Lidocaine	d,l-Tryptophan
Benzoicaine	Meperidine	Tyramine
Benzoic Acid	Methylphenamine	d,l-Tyrosine
Bilirubin	Methaqualone	Uric Acid
Brompheniramine	2-Methylamine-Propiophenone HCl	Verapamil
Benzphetamine	(1R,2S)-(+)-N-Methyl-Ephedrine	Zomepirac
Cholesterol	Methylphenidate	Cocaine
Caffeine	Nalidixic acid	Setraline
(+/-) Chlorpheniramine	Naloxone	Ecgonine Methyl Ester
Chlorpromazine	Naproxen	Amitriptyline
Chlorquine Diphosphate	Niacinamide	Ephedrine
Cortisone	S (-)-Nicotine	pheniramine
Cotinine	Norepinephrine	β -phenylethylamine
Creatinine	Norethinodrone	procaine
Creatine HCl	Oxalic Acid	
Deoxycorticosterone acetate	Oxolinic Acid	
Dextromethorphan	Papaverine	
Diphenhydramine	Penicillin-G	
Dopamine	Pentazocaine	
4-Dimethylaminotipyrine	Phenothiazine	
Ecgonine methyl ester	Phenylephrine	
(-) Epinephrine	Prednisone	
b- Estradiol	Promethazine	
Estrone-3-sulfate potassium salt	d-Pseudophedrine	
Ethanol	Pyrrolidine	
Ethyl-p-aminobenzoate	Quinidine	
Erythromycin	Quinine	
Furosemide	Ranitidine	

The pH of a drug-free urine pool was adjusted to pH 3, pH 3.5, pH 4, pH 4.5, pH 5, pH 5.5, pH 6, pH 6.5, pH 7, pH 7.5, pH 8, pH 8.5 or pH 9; the urine was spiked with $\pm 50\%$ of the cut-off concentration for each drug and two replicates were tested for each test. Altering the pH of the urine sample did not affect the accuracy of any of the test results.

The specific gravity of a drug-free urine pool was measured by obtaining urine samples with specific gravities of 1.005, 1.010, 1.020, and 1.030 and spiking with $\pm 50\%$ of the cut-off concentration of the cut-off concentration for each drug and two replicates were tested for each test. Altering the specific gravity of the urine sample did not affect the accuracy of any of the test results.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M1.a, above.

2. Comparison studies:

a. Method comparison with predicate device:

The method comparison study was conducted to evaluate the performance of the device for detection of the different analytes at one point of care site using blind labeled urine samples and one lot of ToxCup Drug Screen Cups. For each drug test, at least 40 unaltered positive clinical samples and 40 unaltered negative clinical samples with known GC/MS or LC/MS values were tested. At least 10% of these samples had drug concentrations within the range of cutoff to +50% cutoff. For the phencyclidine test, four diluted urine samples were used in the study. The results of the studies are presented below:

Analyte		Negative	Low Negative by GC/MS (less than 50%)	Near Cutoff Negative by GC/MS (between 50% and cutoff)	Near Cutoff Positive by GC/MS (between cutoff and 50%)	High positive by GC/MS (greater than 40%)	Percent Agreement
Amphetamine	Positive	0	0	2	5	36	100%
	Negative	36	1	2	0	0	95.1%
Oxazepam	Positive	0	0	3	4	39	100%
	Negative	36	0	1	0	0	92.5%
Secobarbital	Positive	0	0	1	6	33	95.1%
	Negative	36	0	3	2	0	97.5%
Methadone	Positive	0	0	0	3	36	97.5%
	Negative	36	0	4	1	0	100%
Buprenorphine Glucuronide	Positive	0	0	1	4	38	97.7%
	Negative	36	0	3	1	0	97.5%
Nortriptyline	Positive	0	0	0	27	11	92.7%
	Negative	36	0	4	3	0	100%
3,4 methylenedioxy-Methamphetamine	Positive	0	0	1	3	40	97.7%
	Negative	36	0	3	1	0	97.5%
Oxycodone	Positive	0	0	2	6	38	100%
	Negative	36	0	4	0	0	95.2%
Phencyclidine	Positive	0	0	0	3	36	95.1%
	Negative	36	0	4	2	0	100%
Propoxyphene	Positive	0	0	2	4	36	100%
	Negative	36	0	2	0	0	95%
11-nor-9-Tetrahydrocannabinol-9-carboxylic acid	Positive	0	0	1	6	35	100%
	Negative	36	2	4	0	0	97.7%
Morphine	Positive	0	0	3	7	34	100%
	Negative	36	0	1	0	0	92.5%
Methamphetamine	Positive	0	0	0	5	67	96%
	Negative	36	2	4	3	0	100%
Benzoylecgonine	Positive	0	0	3	3	37	97.6%
	Negative	36	0	2	1	0	92.7%

The discordant results are listed in the table below.

Cutoff value (ng/mL)	Assay (POS/NEG)	Drug Metabolite GC/MS value (ng/mL)	
		Drug/Metabolite	GC/MS value (ng/mL)
THC 50	Positive	11- Δ 9-THC-COOH	36
Cocaine 150	Positive	Benzoylecgonine	120
Cocaine 150	Positive	Benzoylecgonine	138
Cocaine 150	Positive	Benzoylecgonine	140
Cocaine 150	Negative	Benzoylecgonine	194
Opiate 300	Positive	Morphine	196
Opiate 300	Positive	Morphine	251
Opiate 300	Positive	Morphine	291
Methamphetamine 500	Negative	d-Methamphetamine	544
Methamphetamine 500	Negative	d-Methamphetamine	652
Methamphetamine 500	Negative	d-Methamphetamine	677
Amphetamine 500	Positive	d-Amphetamine	395
Amphetamine 500	Positive	d-Amphetamine	405
Benzodiazepine 300	Positive	Oxazepam	132
Benzodiazepine 300	Positive	Oxazepam	224
Benzodiazepine 300	Positive	Oxazepam	268.4
Barbiturate 300	Positive	Butalbital	202
Barbiturate 300	Negative	Butalbital	311
Barbiturate 300	Negative	Butalbital	357
Methadone 300	Negative	Methadone	304.8
Buprenorphine 10	Positive	Buprenorphine Glucuronide	8.2
Buprenorphine 10	Negative	Buprenorphine Glucuronide	11
Tricyclic Antidepressants 1000	Negative	Nortriptyline	1018
Tricyclic Antidepressants 1000	Negative	Nortriptyline	1065
Tricyclic Antidepressants 1000	Negative	Nortriptyline	1176
3,4 methylenedioxy- Methamphetamine	Positive	3,4 methylenedioxy- Methamphetamine	320
3,4 methylenedioxy- Methamphetamine	Negative	3,4 methylenedioxy- Methamphetamine	505
Oxycodone 100	Positive	Oxycodone	54.7
Oxycodone 100	Positive	Oxycodone	79.3

Phencyclidine 25	Negative	Phencyclidine	29
Phencyclidine 25	Negative	Phencyclidine	31
Propoxyphene 300	Positive	Propoxyphene	273.1
Propoxyphene 300	Positive	Propoxyphene	278

A lay-user study was performed to assess the suitability of the device for home use. Seven drug-free urine sample pools were spiked to 0, $\pm 25\%$, $\pm 50\%$, $\pm 75\%$ of the cutoff of target drug. These concentrations were confirmed by GC/MS and one lot of ToxCup Drug Screen Cup was tested. The testing was performed at three sites by 153 blinded consumers divided between three sites (a minimum of 45 participants per site). Each participant received the package inset, 1-3 blinded samples, and 1-3 ToxCup Drug Screen Cups. The lay persons test result was compared to the GC/MS result to demonstrate accuracy by lay-users.

The participant's ages ranged from 18-over 55 and there were slightly more males than females. They come from a variety of career and education backgrounds. All participants stated that the ToxCup Drug Screen Cup was easy to use, the test results were easy to read and the instructions for confirmation of the test were easy to understand.

Additionally, a Flesh-Kincaid reading analysis revealed that both package inserts had a reading grade level of 7.

The following are the results of the lay-user study pooled together from all three sites:

11-nor-9-Tetrahydrocannabinol-9-carboxylic acid

% of Cutoff	Number of Samples	11-nor-9-Tetrahydrocannabinol-9-carboxylic acid GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	12.4	0/30	100
-50 % Cutoff	30	26.7	0/30	100
-25 % Cutoff	30	37.4	5/25	83.0
+25% Cutoff	30	62.9	27/3	90.0
+50 % Cutoff	30	76.5	30/0	100
+75 % Cutoff	30	86.4	30/0	100

Benzoylcegonine

% of Cutoff	Number of Samples	Benzoylcegonine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	37.5	0/30	100
-50 % Cutoff	30	79	0/30	100
-25 % Cutoff	30	119	4/26	87.0
+25% Cutoff	30	198	26/4	87.0
+50 % Cutoff	30	227	30/0	100
+75 % Cutoff	30	236	30/0	100

Morphine

% of Cutoff	Number of Samples	Morphine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	75	0/30	100
-50 % Cutoff	30	129	0/30	100
-25 % Cutoff	30	200	5/25	83.0
+25% Cutoff	30	322	27/3	90.0
+50 % Cutoff	30	484	30/0	100
+75 % Cutoff	30	475	30/0	100

Methamphetamine

% of Cutoff	Number of Samples	Methamphetamine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	130	0/30	100
-50 % Cutoff	30	266	0/30	100
-25 % Cutoff	30	413	4/26	87.0
+25% Cutoff	30	586	26/4	87.0
+50 % Cutoff	30	811	30/0	100
+75 % Cutoff	30	944	30/0	100

Amphetamine

% of Cutoff	Number of Samples	Amphetamine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	133	0/30	100
-50 % Cutoff	30	280	0/30	100
-25 % Cutoff	30	389	4/26	87.0
+25% Cutoff	30	663	26/4	87.0
+50 % Cutoff	30	740	30/0	100
+75 % Cutoff	30	939	30/0	100

Oxazepam

% of Cutoff	Number of Samples	Oxazepam GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	82	0/30	100
-50 % Cutoff	30	160	0/30	100
-25 % Cutoff	30	245	5/25	83.0
+25% Cutoff	30	403	26/4	87.0
+50 % Cutoff	30	465	30/0	100
+75 % Cutoff	30	535	30/0	100

Secobarbital

% of Cutoff	Number of Samples	Secobarbital GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	77	0/30	100
-50 % Cutoff	30	133	0/30	100
-25 % Cutoff	30	235	4/26	87.0
+25% Cutoff	30	333	26/4	87.0
+50 % Cutoff	30	448	30/0	100
+75 % Cutoff	30	489	30/0	100

Methadone

% of Cutoff	Number of Samples	Methadone GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	78.7	0/30	100
-50 % Cutoff	30	165	0/30	100
-25 % Cutoff	30	217	4/26	87.0
+25% Cutoff	30	366	25/5	83.0
+50 % Cutoff	30	480	30/0	100
+75 % Cutoff	30	547	30/0	100

Buprenorphine Glucuronide

% of Cutoff	Number of Samples	Buprenorphine Glucuronide GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	2.5	0/30	100
-50 % Cutoff	30	4.5	0/30	100
-25 % Cutoff	30	8	5/25	83.0
+25% Cutoff	30	12.3	29/1	97.0
+50 % Cutoff	30	14	30/0	100
+75 % Cutoff	30	15.3	30/0	100

Nortriptyline

% of Cutoff	Number of Samples	Nortriptyline GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	222	0/30	100
-50 % Cutoff	30	436	0/30	100
-25 % Cutoff	30	723	4/26	87.0
+25% Cutoff	30	1105	26/4	87.0
+50 % Cutoff	30	1508	30/0	100
+75 % Cutoff	30	1761	30/0	100

3,4 methylenedioxy-Methamphetamine

% of Cutoff	Number of Samples	3,4 methylenedioxy-Methamphetamine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	130	0/30	100
-50 % Cutoff	30	256	0/30	100
-25 % Cutoff	30	382	4/26	87.0
+25% Cutoff	30	626	28/2	93.0
+50 % Cutoff	30	838	30/0	100
+75 % Cutoff	30	917	30/0	100

Oxycodone

% of Cutoff	Number of Samples	Oxycodone GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	27.8	0/30	100
-50 % Cutoff	30	51	0/30	100
-25 % Cutoff	30	82	4/26	80.0
+25% Cutoff	30	124	27/3	90.0
+50 % Cutoff	30	145	30/0	100
+75 % Cutoff	30	178	30/0	100

Phencyclidine

% of Cutoff	Number of Samples	Phencyclidine GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
Negative	210	0	0/210	100
-75 % Cutoff	30	6.9	0/30	100
-50 % Cutoff	30	13.7	0/30	100
-25 % Cutoff	30	17.2	4/26	87.0
+25% Cutoff	30	29.2	25/5	83.0
+50 % Cutoff	30	38.7	30/0	100
+75 % Cutoff	30	46.3	30/0	100

Propoxyphene

% of Cutoff	Number of Samples	Propoxyphene GS/MS Concentration (ng/mL)	Lay person results: Pos/Neg	Percentage of Correct Results
-100% of the Cut-off	210	0	0/210	100
-75 % Cutoff	30	74	0/30	100
-50 % Cutoff	30	153	0/30	100
-25 % Cutoff	30	204	4/26	87.0
+25% Cutoff	30	337	28/2	93.0
+50 % Cutoff	30	424	30/0	100
+75 % Cutoff	30	506	30/0	100

The overall percent agreement between the Lay person and the GC/MS method was:

Analyte	Overall Percent Agreement
11-nor- 9-Tetrahydrocannabinol-9-carboxylic acid	96.1%
Benzoylecgonine	96.3%
Morphine	96.1%
Methamphetamine	96.3%
Amphetamine	95.2%
Oxazepam	95.7%
Secobarbital	96.3%
Methadone	95.7%
Buprenorphine Glucuronide	97.1%
Nortriptyline	96.3%
3,4-methylenedioxymethamphetamine	97.1%
Oxycodone	95.7%
Phencyclidine	94.7%
Propoxyphene	96.1%

b. *Matrix comparison:*

Not applicable.

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):

Not Applicable

4. Clinical cut-off:

Not Applicable

5. Expected values/Reference range

Specific ranges for each analyte/methodology are listed in the package insert.

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.