

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

A. 510(k) Number:

k050540

B. Purpose for Submission:

Clearance of new device.

C. Measurand:

Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Methamphetamine (methamphetamine), Methamphetamine (MDMA), Methadone, Opiates (300 and 2000), Oxycodone, and Phencyclidine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

UCP Biosciences, Inc.

F. Proprietary and Established Names:

UCP Rapid™ Drug Screening Test Strips

UCP Rapid™ Drug Screening Test Devices

G. Regulatory Information:

1. Regulation section:

862.3100, Amphetamine Test System
862.3150, Barbiturate Test System
862.3170, Benzodiazepine Test System
862.3870, Cannabinoids Test System
862.3250, Cocaine and Cocaine Metabolite Test System
862.3620, Methadone Test System
862.3610, Metamphetamine Test System (includes MDMA)
862.3650, Opiates and Test System (includes Oxycodone)
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

All Class II

3. Product code:

DKZ, DIS, JXM, LDJ, DIO, DJC, DJR, DJG, LCM, respectively

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):
see indications below.
2. Indication(s) for use:
The UCP Rapid™ Drug Screening Tests are rapid, qualitative, competitive binding immunoassays for the detection of Amphetamine, Barbiturate, Benzodiazepine, Cannabinoid, Cocaine, Methamphetamine (methamphetamine), Methamphetamine (MDMA), Methadone, Opiates, Oxycodone, and Phencyclidine and their metabolites in human urine at the following cutoff concentrations:

| | |
|--|------------|
| Amphetamine (d-Amphetamine) | 1000 ng/mL |
| Barbiturate (Secobarbital) | 300 ng/mL |
| Benzodiazepine (Oxazepam) | 300 ng/mL |
| Cannabinoid (11-nor- Δ^9 -THC-9 COOH) | 50 ng/mL |
| Cocaine (Benzoylecgonine) | 300 ng/mL |
| Methamphetamine (d-Methamphetamine) | 1000 ng/mL |
| MDMA (d,l-MDMA) | 500 ng/mL |
| Methadone (Methadone) | 300 ng/mL |
| Opiates 300 (Morphine) | 300 ng/mL |
| Opiates 2000 (Morphine) | 2000 ng/mL |
| Oxycodone (Oxycodone) | 100 ng/mL |
| Phencyclidine (Phencyclidine) | 25 ng/mL |

The test provides only preliminary test results, which should be confirmed by other methods such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated. The tests are not intended to be used in monitoring the drug levels.
3. Special conditions for use statement(s):
For Professional and In Vitro Diagnostics use only.
4. Special instrument requirements:
Not applicable, as the device is a visually-read single-use device.

I. Device Description:

The UCP Rapid™ Drug Screening Test Strip and Device is a competitive binding immunoassay used for the qualitative determination of drug and drug metabolite. The devices contain membrane strips coated with drug-protein conjugates (purified bovine albumin) on the T zone, goat polyclonal antibody against gold-protein conjugate at the C zone and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibodies specific against Amphetamine, Barbiturate, Benzodiazepine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Opiates, Oxycodone, THC and Phencyclidine. Both devices are single-use and visually read. One is a dipstick device and the other is a cassette device.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON AMP One Step Amphetamine Test Strip and Test Device
ACON mAMP One Step Methamphetamine Test Strip and Test Device
ACON BAR One Step Barbiturates Test Strip and Test Device
ACON BZO One Step Benzodiazepine Test Strip and Test Device
ACON COC One Step Cocaine Test Strip and Test Device
ACON OPI One Step Opiates Test Strip and Test Device
ACON MOP One Step Opiates Test Strip and Test Device
ACON MDMA One Step Ecstasy Test Strip and Test Device
ACON MTD One Step Methadone Test Strip and Test Device
ACON OXY One Step Oxycodone Test Strip and Test Device
ACON PCP One Step Phencyclidine Test Strip and Test Device
ACON THC One Step Marijuana Test Strip and Test Device

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

k011672, k011673, k012824, k012300, k010841, k011353, k013380, k022589, k012595, k033047, k011730 and k003557 respectively.

3. Comparison with predicate:

| Similarities | | |
|-----------------------|--|--|
| Item | Device | Predicate |
| Intended use | Qualitative determination of drugs in human urine. | Qualitative determination of drugs in human urine. |
| Matrix | Human Urine | Human Urine |
| Test Principle | Immunochromatographic, lateral flow | Immunochromatographic, lateral flow |
| Cutoff Concentrations | same | same |

Differences are the manufacturers and reagent formulations.

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

Department of Health and Human Service, Mandatory Guidelines for Federal Workplace Drug Testing Program, Fed Register. 53(69): 11970-11979, 1988.
Urine Testing for Drugs of Abuse. National Institute on Drug Abuse (NIDA) research Monograph 73, 1986.

L. Test Principle:

The UCP Rapid™ Drug Screening Tests is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When sufficient amount of

sample is applied to the sample pad of the test device, the sample migrates through the test device by capillary action. If the drug or drug metabolite concentration in the sample is below the cutoff level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line (in the test region) of the nitrocellulose membrane to form a red line, a negative result. If the concentration of drug in the sample is at a cutoff level or higher, it will bind with antibodies conjugates with colloidal gold particles so that no line will develop in the test region, a positive result. The colloidal gold antibody conjugate should bind to the C line (control region) and form a purple-colored band regardless of the presence of drug or drug metabolite in the urine specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Precision/Reproducibility studies were performed using commercially available drug standards in which the drug concentrations were confirmed by GC/MS. The standard was diluted in normal, drug-free human urine to give drug concentrations at the following levels: 0, 50% below cutoff, 25% below cut-off, cutoff, 25% above cut-off and 50% above cut-off. A total of 60 determinations were made at each concentration for each analyte. Testing was performed four times per day for five days by three operators (two are trained laboratory workers and one is a professional with limited laboratory experience) using one lot of testing devices in the sponsor's facility. All samples tested at 0, -50% yielded negative results and all samples +50% yielded positive results. Within lot Precision Study data for -25%, cutoff and + 25% is summarized below:

25% Below Cutoff

| | AMP | BAR | BZD | COC | MET | MDMA | MTD | OPI 300 | OPI 2000 | OXY | PCP | THC |
|------------------------|-------|------|------|------|------|------|------|------------|-------------|-------|-------|------|
| Total # determinations | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Concentration (ng/mL) | 750 | 225 | 225 | 225 | 750 | 375 | 225 | 225 | 1500 | 75 | 18.75 | 37.5 |
| #NEG/#POS | 50/10 | 51/9 | 60/0 | 55/5 | 57/3 | 59/1 | 55/5 | 56/4 | 60/0 | 50/10 | 60/0 | 60/0 |
| Precision | 83% | 85% | 100% | 92% | 95% | 98% | 92% | 93% | 100% | 83% | 100% | 100% |

Cutoff

| | AMP | BAR | BZD | COC | MET | MDMA | MTD | OPI 300 | OPI 2000 | OXY | PCP | THC |
|------------------------|------|------|------|------|------|------|------|------------|-------------|------|------|------|
| Total # determinations | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Concentration (ng/mL) | 1000 | 300 | 300 | 300 | 1000 | 500 | 300 | 300 | 2000 | 100 | 25 | 50 |
| #NEG/#POS | 3/57 | 2/58 | 4/56 | 0/60 | 2/58 | 4/56 | 4/56 | 3/57 | 4/56 | 0/60 | 3/57 | 2/58 |
| Precision | 95% | 97% | 93% | 100% | 97% | 93% | 93% | 95% | 93% | 100% | 95% | 97% |

25% Above Cutoff

| | AMP | BAR | BZD | COC | MET | MDMA | MTD | OPI 300 | OPI 2000 | OXY | PCP | THC |
|------------------------|------|------|------|------|------|------|------|---------|----------|------|-------|------|
| Total # determinations | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 | 60 |
| Concentration (ng/mL) | 1250 | 375 | 375 | 375 | 1250 | 625 | 375 | 375 | 2500 | 125 | 31.25 | 62.5 |
| #NEG/#POS | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 | 0/60 |
| Precision | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Inter Lot Reproducibility:

To test inter lot reproducibility, normal human urine known to be drug-free was spiked with commercially available drug standard to the following levels: 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. Testing was performed using three different lot numbers, 20 samples of each lot were run at each of the concentrations for each drug over 30 days. All samples tested at 0, -50% yielded negative results and all samples +50% yielded positive results. Inter lot Precision Study data from -25%, cutoff and +25% is summarized below:

| 25% Below | Total # determination | | | # Negative/# Positive | | | inter Lot Precision (%) | | | Average Lot |
|-----------|-----------------------|-------|-------|-----------------------|-------|-------|-------------------------|-------|-------|-------------|
| | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Precision |
| AMP | 20 | 20 | 20 | 18/2 | 17/3 | 18/2 | 90% | 85% | 90% | 88% |
| BAR | 20 | 20 | 20 | 17/3 | 18/2 | 17/3 | 85% | 90% | 85% | 86.7% |
| BZD | 20 | 20 | 20 | 16/4 | 17/3 | 18/2 | 80% | 85% | 90% | 85% |
| COC | 20 | 20 | 20 | 18/2 | 17/2 | 18/2 | 90% | 85% | 90% | 88.3% |
| MET | 20 | 20 | 20 | 18/2 | 17/3 | 16/4 | 90% | 85% | 80% | 85% |
| MDMA | 20 | 20 | 20 | 16/4 | 18/2 | 16/4 | 80% | 90% | 80% | 83.3% |
| OPI 300 | 20 | 20 | 20 | 17/3 | 18/2 | 17/3 | 85% | 90% | 85% | 86.7% |
| MTD | 20 | 20 | 20 | 17/3 | 16/4 | 18/2 | 85% | 80% | 90% | 85% |
| OPI 2000 | 20 | 20 | 20 | 17/3 | 16/4 | 18/2 | 85% | 80% | 90% | 85% |
| OXY | 20 | 20 | 20 | 18/2 | 18/2 | 17/3 | 90% | 90% | 85% | 88.3% |
| PCP | 20 | 20 | 20 | 18/2 | 16/2 | 18/2 | 90% | 80% | 90% | 86.7% |
| THC | 20 | 20 | 20 | 16/4 | 17/3 | 18/2 | 80% | 85% | 90% | 85% |

| Cutoff | Total # determination | | | # Negative/# Positive | | | inter Lot Precision (%) | | | Average Lot |
|----------|-----------------------|-------|-------|-----------------------|-------|-------|-------------------------|-------|-------|-------------|
| | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Precision |
| AMP | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| BAR | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| BZD | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| COC | 20 | 20 | 20 | 1/19 | 20/0 | 20/0 | 95% | 100% | 100% | 98.3% |
| MET | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| MDMA | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OPI 300 | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| MTD | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OPI 2000 | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OXY | 20 | 20 | 20 | 1/19 | 20/0 | 20/0 | 95% | 100% | 100% | 98.3% |
| PCP | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| THC | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |

| 25% Above | Total # determination | | | # Negative/# Positive | | | inter Lot Precision (%) | | | Average Lot |
|-----------|-----------------------|-------|-------|-----------------------|-------|-------|-------------------------|-------|-------|-------------|
| | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Lot 1 | Lot 2 | Lot 3 | Precision |
| AMP | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| BAR | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| BZD | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| COC | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| MET | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| MDMA | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OPI 300 | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| MTD | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OPI 2000 | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| OXY | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| PCP | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |
| THC | 20 | 20 | 20 | 20/0 | 20/0 | 20/0 | 100% | 100% | 100% | 100% |

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

Procedural controls are included in the test strip and device. A red colored line appearing in the control zone is considered as an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and that the correct technique has been used. Users are informed not to interpret the test if no red line appears in the control zone.

Control standards are not supplied with these tests; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test

performance. User should follow local, state and federal guidelines for testing QC material.

Stability:

Real time stabilities studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 2 – 30 °C product is good until expiration date which is 18 months.

d. Detection limit:

Sensitivity of UCP Rapid™ Drug Tests was characterized by validating the test performance around the claimed cutoff concentration of the test. The following targeted drugs were spiked into human urine known to be drug-free:

| Test Name | Targeted Drug |
|--------------------------------------|-----------------------------------|
| Amphetamine (AMP) | d-Amphetamine |
| Barbiturates (BAR) | Secobarbital |
| Benzodiazepine (BZD) | Oxazepam |
| Cocaine (COC) | Benzoyllecgonine |
| Marijuana (THC) | 11-nor- Δ^9 COOH |
| Methadone (MTD) | Methadone |
| Methamphetamine (MET) | d-Methamphetamine |
| Methylenedioxymethamphetamine (MDMA) | d,l-Methylenedioxymethamphetamine |
| Opiates 300 (OPI300) | Morphine |
| Opiates 2000 (OPI2000) | Morphine |
| Oxycodone (OXY) | Oxycodone |
| Phencyclidine (PCP) | Phencyclidine |

The cutoff of each drug test was determined by the lowest concentration of drug which produces at least 50% positive results in total numbers of determinations. 20 replicates were run at each drug concentration from 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. The results are summarized below:

| Analyte | Drug-free Urine | -50% Cutoff | -25% Cutoff | Cutoff | +25% Cutoff | +50% Cutoff |
|-----------------|-----------------|-------------|-------------|--------|-------------|-------------|
| Amphetamine | 100% | 100% | 10% | 85% | 100% | 100% |
| Barbiturates | 100% | 100% | 15% | 95% | 100% | 100% |
| Benzodiazepine | 100% | 100% | 100% | 60% | 90% | 100% |
| Cocaine | 100% | 100% | 15% | 95% | 100% | 100% |
| Methamphetamine | 100% | 100% | 10% | 100% | 100% | 100% |
| MDMA | 100% | 100% | 100% | 55% | 80% | 100% |
| Opiates 300 | 100% | 100% | 15% | 95% | 100% | 100% |

| Analyte | Drug-free Urine | -50% Cutoff | -25% Cutoff | Cutoff | +25% Cutoff | +50% Cutoff |
|---------------|-----------------|-------------|-------------|--------|-------------|-------------|
| Opiates 2000 | 100% | 100% | 15% | 100% | 100% | 100% |
| Methadone | 100% | 100% | 100% | 70% | 95% | 100% |
| Oxycodone | 100% | 100% | 25% | 100% | 100% | 100% |
| Phencyclidine | 100% | 100% | 10% | 95% | 100% | 100% |
| Cannabinoid | 100% | 100% | 10% | 90% | 100% | 100% |

The data presented in this section is consistent with the results from the precision study. Based on the above data, sensitivity of the assay for the 12 analytes is as follows:

| | |
|-------------------------------|---------------------------------|
| Amphetamine (AMP) 1000ng/mL | Methamphetamine (MDMA) 500ng/mL |
| Barbiturate (BAR) 300ng/mL | Methamphetamine (MET) 1000ng/mL |
| Benzodiazepine (BZD) 300ng/mL | Opiates (OPI 300) 300ng/mL |
| Cannabinoid (THC) 50ng/mL | Opiates (OPI 2000) 2000ng/mL |
| Cocaine (COC) 300ng/mL | Oxycodone (OXY) 100ng/mL |
| Methadone (MTD) 300ng/mL | Phencyclidine (PCP) 25ng/mL |

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine/a negative control. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the tables below:

| Amphetamine | |
|--|--|
| Drug Compound | Response equivalent to cutoff in ng/mL |
| d-amphetamine | 1000 |
| d,l-amphetamine | 2500 |
| l-amphetamine | 50,000 |
| (+)methamphetamine | >100,000 |
| 3,4-Methylenedioxyethylamphetamine(MDMA) | >100,000 |
| Pseudoephedrine | 200,000 |
| 3,4-Methylenedioxyamphetamine (MDA) | 2,000 |
| (±) Phenylpropanolamine (PPA) | 75,000 |
| Ephedrine | 350,000 |

Methamphetamine and MDMA

| Drug Compound | Response equivalent to cutoff in ng/mL |
|--|--|
| d-amphetamine | >100,000 for both |
| l-amphetamine | >100,000 and n/a |
| (+/-)methamphetamine | 2,000 and >100,000 |
| (+)methamphetamine | 1,000 and >100,000 |
| 3,4-Methylenedioxyethylamphetamine(MDEA) | 35,000 and 300 |
| 3,4-Methylenedioxymethamphetamine (MDMA) | 2,000 and 500 |
| 3,4-Methylenedioxyamphetamine (MDA) | >100,000 and 50,000 |
| (+) Phenylpropanolamine (PPA) | 75,000 and not reported |
| Ephedrine | 50,000 and not reported |

Opiates 300 and 2000

| Drug compound | Response equivalent to cutoff in ng/mL |
|----------------------------------|--|
| 6-monoacetylmorphine | 600 and 5000 |
| Codeine | 300 and 2,000 |
| Normorphone | 100,000 for both |
| Hydrocodone | 75,000 for both |
| Hydromorphone | 3,500 and 7,000 |
| Oxycodone | 10,000 and 20,000 |
| Morphine | 300 and 2,000 |
| Morphine-3- β -glucuronide | 300 and 2,000 |
| Oxymorphone | 50,000 and 100,000 |
| Thebaine | 7,000 and 70,000 |

Cocaine

| Compound | Response equivalent to cutoff in ng/mL |
|------------------|--|
| Benzoyllecgonine | 300 |
| Ecgonine HCl | 35,000 |
| Cocaine | >100,000 |

Cannabinoids (THC)

| Compound | Response equivalent to cutoff in ng/mL |
|--|--|
| Cannabinol | 10,000 |
| 11-Nor- Δ^8 -Tetrahydrocannabinol carboxylic acid | 50 |
| 11-Nor- Δ^9 -Tetrahydrocannabinol carboxylic acid | 50 |
| Δ^8 -Tetrahydrocannabinol | 8,000 |
| Δ^9 -Tetrahydrocannabinol | 10,000 |
| Cannabidiol | 100,000 |

Phencyclidine

| Compound | Response equivalent to cutoff in ng/mL |
|------------------------|--|
| 4-hydroxyphencyclidine | 15,000 |
| Phencyclidine | 25 |

Barbiturates

| Compound | Response equivalent to cutoff in ng/mL |
|--------------------|--|
| Secobarbital | 300 |
| Alphenal | 400 |
| Phenobarbital | 300 |
| Butalbital | 500 |
| Pentobarbital | 600 |
| Amobarbital | 600 |
| Aprobarbital | 300 |
| Barbital | 300 |
| Butabarbital | 300 |
| Butethal | 200 |
| Cyclopentobarbital | 600 |

Benzodiazepines

| Compound | Response equivalent to cutoff in ng/mL |
|------------------|--|
| Alprazolam | 1000 |
| Chlordiazepoxide | 800 |
| Diazepam | 300 |
| Oxazepam | 300 |
| Clonazepam | 2500 |
| Flunitrazepam | 750 |
| Nitrazepam | 400 |
| Bromazepam | 25,000 |
| Clobazam | 400 |
| Estazolam | 500 |
| Flurazepam | 1000 |
| Lorazepam | 3000 |
| Lormetazepam | 10,000 |
| Medazepam | 50,000 |
| Nordiazepam | 800 |
| Prazepam | 5000 |
| Temazepam | 200 |

Methadone

| Compound | Response equivalent to cutoff in ng/mL |
|--|--|
| Methadone | 300 |
| Doxylamine | 50,000 |
| (±)-2-Ethyl-1,5-dimethyl-3,3-diphenylpyrrolinium | 50,000 |

Oxycodone

| Compound | Response equivalent to cutoff in ng/mL |
|----------------------------|--|
| Oxycodone | 100 |
| Morphine | 50,000 |
| Codeine | 25,000 |
| Morphine 3-β-D glucuronide | 50,000 |
| Hydromorphone | 15,000 |
| Normorphine | 100,000 |
| Oxymorphone | 1500 |

The following list of substances showed no interference at a concentration of 100 ug/mL in either drug-free or drug positive urines:

| Common Substances: | |
|------------------------------|---|
| Acetaminophen | Aspirin |
| Acetylsalicylic Acid | Atropine |
| Amikacin | Benzoic Acid |
| Amitriptyline | Oxalic Acid |
| Ampicillin | Caffeine |
| Arterenol | Methanol |
| Ethanol | Penicillin-G |
| Lidocaine | Phenylpropanalamine |
| Thioridazine | Ranitidine |
| Trifluoperazine | Salicylic Acid |
| Biological Materials: | |
| Albumin | Vitamin (L-Ascorbic Acid) |
| Bilirubin | Uric Acid |
| Creatine | Urine pH (4.5-9.0) |
| Hemoglobin | Urine Specific Gravity (1.002-1.035g/mL) |
| Glucose | |

f. Assay cut-off:

The identified cutoff concentrations for amphetamine, cocaine, methamphetamine (MDMA), opiates 2000, Phencyclidine and THC are those recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). Analytical performance of the device around the cutoff is described in Section 1.M.d above. The test will yield a positive result when a given drug exceeds this concentration in the urine sample.

2. Comparison studies:

a. Method comparison with predicate device:

128 unaltered clinical urine samples per drug type were evaluated. Specimens obtained from reference laboratories were tested using the predicate device and the Gas Chromatography/Mass Spectrometry (GC/MS). For each drug test, approximately 10% of samples had drug concentration between 50% below the cutoff and the cutoff concentration, another 10% of samples had drug concentrations between the cutoff and 50% above the cutoff concentration. The study was performed at the sponsor's facility by one member of the sponsor's staff.

Comparison of UCP Rapid™ Drug Screening Test to the Predicate

| | | Predicate | | | | | | | |
|--------------------------------|----------|-----------|-----|-----|-----|-----|-----|------|------|
| | | AMP | | BAR | | BZO | | COC | |
| | | pos | neg | pos | neg | pos | neg | pos | neg |
| UCP Rapid™ Drug Screening Test | Positive | 64 | 0 | 63 | 1 | 62 | 2 | 64 | 0 |
| | Negative | 1 | 63 | 1 | 63 | 2 | 62 | 0 | 64 |
| %Agreement among Positive | | 100% | | 98% | | 97% | | 100% | |
| % Agreement among Negative | | | 98% | | 98% | | 97% | | 100% |

| | | Predicate | | | | | | | |
|--------------------------------|----------|-----------|-----|------|-----|---------|------|----------|------|
| | | THC | | MDMA | | OPI 300 | | OPI 2000 | |
| | | pos | neg | pos | neg | pos | neg | pos | neg |
| UCP Rapid™ Drug Screening Test | Positive | 64 | 0 | 62 | 2 | 64 | 0 | 64 | 0 |
| | Negative | 1 | 63 | 2 | 62 | 0 | 64 | 0 | 64 |
| %Agreement among Positive | | 100% | | 97% | | 100% | | 100% | |
| % Agreement among Negative | | | 98% | | 97% | | 100% | | 100% |

| | | Predicate | | | | | | | |
|--------------------------------|----------|-----------|-----|------|-----|-----|-----|-----------|-----|
| | | MET | | PCP | | OXY | | METHADONE | |
| | | pos | neg | pos | neg | pos | neg | pos | neg |
| UCP Rapid™ Drug Screening Test | Positive | 64 | 0 | 64 | 0 | 63 | 1 | 63 | 1 |
| | Negative | 1 | 63 | 1 | 63 | 1 | 63 | 02 | 62 |
| %Agreement among Positive | | 100% | | 100% | | 98% | | 98% | |
| % Agreement among Negative | | | 98% | | 98% | | 98% | | 97% |

Candidate Device Results vs. stratified GC/MS Values

| | Candidate Device Results | Negative by the predicate device or less than half the cutoff concentration by GC/MS analysis | Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration) | Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration) | High Positive (greater than 50% above the cutoff concentration) | % Agreement (among positives and negatives) |
|-----------------|--------------------------|--|---|---|--|---|
| AMP | Positive | 0 | 0 | 11 | 52 | 100% |
| | Negative | 52 | 12 | 1 | 0 | 98% |
| BAR | Positive | 0 | 1 | 11 | 52 | 98% |
| | Negative | 52 | 11 | 1 | 0 | 98% |
| BZD | Positive | 0 | 2 | 10 | 52 | 97% |
| | Negative | 52 | 10 | 2 | 0 | 97% |
| COC | Positive | 0 | 0 | 12 | 52 | 100% |
| | Negative | 52 | 12 | 0 | 0 | 100% |
| MET | Positive | 0 | 0 | 11 | 52 | 100% |
| | Negative | 52 | 12 | 1 | 0 | 98% |
| MDMA | Positive | 0 | 2 | 10 | 52 | 97% |
| | Negative | 52 | 10 | 2 | 0 | 97% |
| MTD | Positive | 0 | 1 | 10 | 52 | 98% |
| | Negative | 52 | 11 | 2 | 0 | 97% |
| OPI 300 | Positive | 0 | 0 | 12 | 52 | 100% |
| | Negative | 52 | 12 | 0 | 0 | 100% |
| OPI 2000 | Positive | 0 | 0 | 12 | 52 | 100% |
| | Negative | 52 | 12 | 0 | 0 | 100% |
| OXY | Positive | 0 | 1 | 11 | 52 | 98% |
| | Negative | 52 | 11 | 1 | 0 | 98% |
| PCP | Positive | 0 | 0 | 11 | 52 | 100% |
| | Negative | 52 | 12 | 1 | 0 | 98% |
| THC | Positive | 0 | 0 | 11 | 52 | 100% |
| | Negative | 52 | 12 | 1 | 0 | 98% |

Comparison testing was performed between the test strip device and the cassette device. Normal human urine known to be drug-free was spiked with commercially available drug standard to the following levels: 0, 50% below cutoff, 25% below cutoff, cutoff, 25% above cutoff and 50% above cutoff. Testing was performed using the same lot number, 20 samples were run at each of the concentrations for each drug. For each drug at each drug concentration the results were identical.

b. Matrix comparison:

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

3. Clinical studies:
 - a. *Clinical Sensitivity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - b. *Clinical specificity:*
Not applicable. Clinical studies are not typically submitted for this device type.
 - 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:
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.