

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

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

k050878

**B. Purpose for Submission:**

New Device

**C. Measurand:**

Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Ecstasy (MDMA), Opiates (OPI), and Phencyclidine (PCP)

**D. Type of Test:**

One-step lateral flow immunoassay with visual, qualitative screening results

**E. Applicant:**

Acon Laboratories Corporation

**F. Proprietary and Established Names:**

On Call™ Multi Drug Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates and Phencyclidine

**G. Regulatory Information:**

Regulation section:

| Regulation Number | Standard Product Nomenclature                       | Panel           | Product Code | Class |
|-------------------|---|-----------------|--------------|-------|
| 862.3870          | Enzyme Immunoassay Cannabinoids                     | Toxicology (91) | LDJ          | II    |
| 862.3250          | Enzyme Immunoassay, Cocaine and Cocaine Metabolites | Toxicology (91) | DIO          | II    |
| 862.3100          | Enzyme Immunoassay, Amphetamine                     | Toxicology (91) | DKZ          | II    |
| 862.3610          | Thin Layer Chromatography, Methamphetamine          | Toxicology (91) | LAF          | II    |
| 862.3650          | Enzyme Immunoassay, Opiates                         | Toxicology (91) | DJG          | II    |
| Unclassified      | Enzyme Immunoassay, Phencyclidine                   | Toxicology (91) | LCM          |       |

**H. Intended Use:**

1. Intended use(s):

Refer to Indications for use

2. Indication(s) for use:

The On-Call™ Multi-Drug Home Test Cup is a screening test for the rapid detection of drugs in urine at a designated cut-off concentration of 50 ng/mL for Marijuana, 300 ng/mL for Cocaine, 1,000 ng/mL for Amphetamine, 1,000 ng/mL for Methamphetamine, 500 ng/mL for Ecstasy, 2,000 ng/mL for Opiates, and 25 ng/mL for phencyclidine. The test is intended for over-the-counter (OTC) consumer use.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

3. Special condition for use statement(s):

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**The test is intended for over-the-counter (OTC) consumer use.**

The materials necessary for confirmation testing are provided with the screening device. Materials, as well as confirmation testing are provided to the consumer at no additional charge.

Tests for opiates cannot distinguish between abused drugs and certain prescribed medications.

Certain foods or medications may interfere with tests for amphetamines and opiates and cause false positive results.

4. Special instrument Requirements:

Not applicable. The device is a visually read single-use device.

**I. Device Description:**

The product is a single-use device utilizing a cup format. Test strips are incorporated into the sides of a sample cup.

After urine is added to the test cup, operators replace the cup lid. The operator then inserts a Key into the opening on the side of the cup as far as it will go. This will allow the urine to pass into the test chamber to begin the test. The operator will then peel off the privacy label to view the results. The results are read at 5 minutes. Results are not to be read after 10 minutes.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

The test card assembled with the On-Call™ Multi-Drug Home Test Cup is identical to the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated E-Z Split Key Cup (K031759) in terms of product design, performance characteristics, construction materials, manufacturing process, and use. The On-Call™ Multi-Drug Home Test Cup is also similar to the Pharmatech At Home™ Drug Cup for Amphetamine, Methamphetamine, Ecstasy, Marijuana, Cocaine, and Opiates (K030447) as well as to other commercially available drug screening test cups, which quantitatively measure the presence or absence of target drugs and their metabolites by one-step lateral flow immunoassay.

2. Predicate K number(s):

K031759  
k030447

3. Comparison with predicate:

Both devices are for the qualitative determination of the same analytes in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

**Comparison of On-Call™ Multi-Drug Home Test Cup to Other Commercially Available Products**

| <b>Item</b>                        | <b>On-Call™ Multi-Drug Home Test Cup</b>   | <b>ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cup (k031759)</b> | <b>Pharmatech At Home™ Drug Cup (k030447)</b>  |
|------------------------------------|--|--|--|
| <b>Intended Use</b>                | Preliminary one-step rapid screen for detection of THC, COC, AMP, mAMP, MDMA, OPI, PCP and their metabolites in urine.                               | Identical  | Identical  |
| <b>Product Design</b>              | Application of specific amount of urine sample to cassette (housing test strip)  | Identical  | Identical  |
| <b>Mechanism of action</b>         | Immunochromatographic lateral flow assay with visual, qualitative screening result   | Identical  | Identical  |
| <b>Performance Characteristics</b> | Cut-off concentrations:<br>THC 50 ng/mL<br>COC 300 ng/mL<br>AMP 1,000 ng/mL<br>mAMP 1,000 ng/mL<br>MDMA 500 ng/mL<br>OPI 2,000 ng/mL<br>PCP 25 ng/mL | Identical  | OPI 300 ng/mL, MDMA drug specific only with GC/MS Testing of mAMP which has Cut-off of 500 ng/mL |
| <b>Target User Population</b>      | OTC  | Professional   | OTC  |

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

The sponsor referenced the same guidance document(s) from their previous submission (k031759) since the test card assembled with the On-Call™ Multi-Drug Home Test Cup is identical to the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated E-Z Split Key Cup.

**L. Test Principle:**

The test employs lateral flow immunochromatographic technology. Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds

at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

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

##### 1. Analytical performance:

###### *a. Precision/Reproducibility:*

The sponsor indicated that the On-Call™ Multi-Drug Home Test Cup is identical to the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with integrated EZ Split Key Cup marketed under 510(k) K031759, and the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated E-Z Split Key Cup a modified device derived from two preciously cleared ACON devices (k020313 and k023946). The performance characteristics concerning sensitivity, accuracy, reproducibility, stability, precision, cut-off concentration, and specificity apply to the ACON On-Call Multi-Drug Home Test Cup.

The ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated Cup was marketed for in vitro diagnostic professional use. ACON Laboratories conducted a clinical study using the ACON Multi-Drug Multi-Line Screen Test Card with Integrated cup at four (4) different sites, to include physicians' offices and testing laboratory. This previous study demonstrated that both professional and laboratory personnel could use the test to obtain visual, qualitative results.

#### **Consumer Study**

The objective of the study was to evaluate the ability of lay users to correctly follow test instructions, visualize the test line, and obtain acceptable results. The studies were conducted at four (4) separate geographical regions, with multiple sites in each region.

Six hundred nineteen (619) consumers participated in the study for the On-Call™ Multi-Drug Home Test Cup. Consumers were selected based on age, gender, and educational variation.

#### **Sample Preparation**

Fresh, drug free normal human urine was added to filtered urine and drug standard solutions. Solutions were prepared for each of the

studies by spiking the drug free urine with THC, COC, AMP, mAMP, OPI, and PCP to the concentrations of 50% below SAMHSA cut-off, 25% below cut-off, 25% above cut-off, 50% above cut-off and 100% above cut-off. Solutions with out drug added were also prepared (0% cut-off).

Concentrations of the prepared drug samples were quantitated by GC/MS analysis by and independent SAMHSA certified facility. 40 mL aliquots were dispensed in vials according to the aliquot scheme, and a minimum number of assays targeted for each solution were determined.

**Aliquot Scheme: percent of cut-off by target drug**

| Standard Solution ID | THC  | COC  | AMP  | mAMP | OPI  | PCP  | MDMA | n (min) |
|----------------------|------|------|------|------|------|------|------|---------|
| A                    | 125% | 125% | 0%   | --   | 0%   | 0%   | --   | 30      |
| B                    | 0%   | 75%  | --   | 75%  | 0%   | 0%   | 0%   | 30      |
| C                    | 0%   | 0%   | --   | 125% | 125% | --   | 0%   | 30      |
| D                    | 0%   | 0%   | 0%   | --   | 75%  | 75%  | --   | 30      |
| E                    | 75%  | 0%   | --   | 0%   | 0%   | 125% | --   | 30      |
| F                    | 0%   | 0%   | --   | 0%   | 75%  | --   | 75%  | 30      |
| G                    | 0%   | 0%   | 125% | --   | 125% | 0%   | --   | 30      |
| H                    | 50%  | 150% | 0%   | --   | 0%   | --   | 125% | 30      |
| I                    | 0%   | 50%  | --   | 150% | 0%   | 0%   | 0%   | 30      |
| J                    | 0%   | 0%   | --   | 50%  | 150% | --   | 0%   | 30      |
| K                    | 0%   | 0%   | --   | 0%   | 50%  | 150% | --   | 30      |
| L                    | 150% | 0%   | 75%  | --   | 0%   | 59%  | --   | 30      |
| M                    | 150% | 0%   | 0%   | --   | 0%   | --   | 50%  | 30      |
| N                    | 0%   | 0%   | 0%   | --   | 59%  | --   | 150% | 30      |
| O                    | 0%   | 0%   | 50%  | 0%   | 159% | --   | 0%   | 30      |
| P                    | 0%   | 50%  | 150% | --   | 0%   | 0%   | --   | 30      |
| Q                    | 200% | 200% | 200% | --   | 0%   | 0%   | --   | 20      |
| R                    | 0%   | 0%   | --   | 200% | 0%   | 200% | --   | 20      |
| S                    | 0%   | 0%   | 0%   | --   | 200% | --   | 200% | 20      |
| T                    | 0%   | 0%   | --   | 0%   | 0%   | 0%   | --   | 20      |
| U                    | 0%   | 0%   | 0%   | --   | 0%   | --   | 0%   | 20      |

The consumers performed a total of 619 assays for the On-Call™ Multi-Drug Home Test Cup for Marijuana, Cocaine, Amphetamine, Methamphetamine, Ecstasy, Opiates, and Phencyclidine. The tables below displays the results obtained by the consumer as a comparison to the negative or positive results based on the cut-off level and GC/MS data of the spiked samples.

**THC Test Result**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| Q               | 200% THC (+)  | 22          | 22 (100)     | 0 (100)      |
| M               | 150% THC (+)  | 30          | 30 (100)     | 0 (100)      |
| A               | 125% THC (+)  | 30          | 28 (93.3)    | 2            |
| E               | 75% THC (-)   | 34          | 0 (100)      | 34 (100)     |
| H               | 50% THC (-)   | 32          | 0 (100)      | 32 (100)     |
| T               | 0% THC (-)    | 43          | 0 (100)      | 43 (100)     |
| Total Tests     |               | 191*        |              |              |

**COC Test Result**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| Q               | 200% COC (+)  | 22          | 22 (100)     | 0 (100)      |
| H               | 150% COC (+)  | 32          | 32 (100)     | 0 (100)      |
| A               | 125% COC (+)  | 30          | 29 (96.6)    | 1            |
| B               | 75% COC (-)   | 33          | 1            | 32 (97.0)    |
| P               | 50% COC (-)   | 30          | 1            | 29 (96.6)    |
| T               | 0% COC (-)    | 43          | 0 (100)      | 43 (100)     |
| Total Tests     |               | 190*        |              |              |

**AMP Test Results**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| Q               | 200% AMP (+)  | 22          | 22 (100)     | 0 (100)      |
| P               | 150% AMP (+)  | 30          | 29 (96.6)    | 1            |
| G               | 125% AMP (+)  | 31          | 30 (100)     | 1            |
| L               | 75% AMP (-)   | 34          | 0 (100)      | 34 (100)     |
| O               | 50% AMP (-)   | 30          | 0 (100)      | 30 (100)     |
| U               | 0% AMP (-)    | 20          | 0 (100)      | 20 (100)     |
| Total Tests     |               | 167*        |              |              |

**mAMP Test Results**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| R               | 200% mAMP (+) | 20          | 20 (100)     | 0 (100)      |
| I               | 150% mAMP (+) | 30          | 30 (100)     | 0 (100)      |
| C               | 125% mAMP (+) | 30          | 29 (96.7)    | 1            |
| B               | 75% mAMP (-)  | 33          | 1            | 32 (97.0)    |
| J               | 50% mAMP (-)  | 30          | 0 (100)      | 30 (100)     |
| T               | 0% mAMP (-)   | 42          | 0 (100)      | 43 (100)     |
| Total Tests     |               | 186*        |              |              |

**OPI Test Result**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| S               | 200% OPI (+)  | 20          | 30 (100)     | 0 (100)      |
| O               | 150% OPI (+)  | 30          | 30 (100)     | 0 (100)      |
| C               | 125% OPI (+)  | 30          | 30 (100)     | 0 (100)      |
| D               | 75% OPI (-)   | 30          | 1            | 29 (96.7)    |
| N               | 50% OPI (-)   | 30          | 0 (100)      | 30 (100)     |
| T               | 0% OPI (-)    | 43          | 0 (100)      | 43 (100)     |
| Total Tests     |               | 183*        |              |              |

**PCP Test Result**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| R               | 200% PCP (+)  | 20          | 20 (100)     | 0 (100)      |
| K               | 150% PCP (+)  | 30          | 30 (100)     | 0 (100)      |
| E               | 125% PCP (+)  | 34          | 33 (97)      | 1            |
| D               | 75% PCP (-)   | 30          | 1            | 29 (96.7)    |
| L               | 50% PCP (-)   | 34          | 0 (100)      | 34 (100)     |
| T               | 0% PCP (-)    | 43          | 0 (100)      | 43 (100)     |
| Total Tests     |               | 191*        |              |              |

**MDMA Test Result**

| Sample Solution | Concentration | (n) Studies | Positive (+) | Negative (-) |
|-----------------|---------------|-------------|--------------|--------------|
| S               | 200% MDMA (+) | 20          | 20 (100)     | 0 (100)      |
| N               | 150% MDMA (+) | 30          | 30 (100)     | 0 (100)      |
| H               | 125% MDMA (+) | 32          | 30 (93.8)    | 2            |
| F               | 75% MDMA (-)  | 30          | 0 (100)      | 30 (100)     |
| M               | 50% MDMA (-)  | 30          | 0 (100)      | 30 (100)     |
| U               | 0% MDMA (-)   | 20          | 0 (100)      | 20 (100)     |
| Total Tests     |               | 162*        |              |              |

Percentage of correct results in parenthesis

Overall percentage of correct results: 605/619 (97.7%)

\* Many solutions were spiked with more than one drug therefore a higher total number of studies is indicated when totaling each individual drug. The total number of unique studies is 619.

*b. Linearity/assay reportable range:*

Not applicable.

c. *Traceability (controls, calibrators, or method):*

Device results were compared to GCMS.

d. *Detection limit:*

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. The On-Call™ Multi-Drug Home Test Cup follows SAMHSA cutoff recommendations. This information appears in the table below.

**Cut-off Levels for the On-Call™ Multi-Drug Home Test Cup**

|      |                                 |             |
|------|---------------------------------|-------------|
| THC  | Marijuana/ tetrahydrocannabinol | 50 ng/mL    |
| COC  | Cocaine                         | 300 ng/m    |
| mAMP | Methamphetamine                 | 1,000 ng/mL |
| OPI  | Opiates/morphine/heroin         | 2,000 ng/mL |
| PCP  | Phencyclidine                   | 25 ng/mL    |
| AMP  | Amphetamine                     | 1,000 ng/mL |
| MDMA | Ecstasy                         | 500 ng/mL   |

e. *Analytical specificity:*

Analytical specificity was established with the clearance of the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with integrated EZ Split Key Cup marketed under 510(k) K031759, and the ACON Spectrum Multi-Drug Multi-Line Drug Screen Test Card with Integrated E-Z Split Key Cup a modified device derived from two preciously cleared ACON devices (k020313 and k023946).

f. *Assay cut-off:*

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

2. Comparison studies:

a. *Method comparison with predicate device:*

Because the candidate device was compared to a reference method, GC/MS, it was not compared to a predicate device. According to the sponsor, accuracy was determined by analyzing spiked samples containing THC, COC, AMP, mAMP, MDMA, OPI, and PCP. See consumer study above.

*b. Matrix comparison:*

Not applicable. The assay is intended for only one sample matrix.

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):*

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.