

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

A. 510(k) Number:

k050050

B. Purpose of the Submission:

New device

C. Analyte:

Amphetamine, Cannabinoids, Cocaine, Methamphetamine, Opiates (Morphine) and Phencyclidine.

A. Type of Test:

Qualitative Lateral Flow Immunochromatographic Test

B. Applicant:

ACON Laboratories, Inc.

C. Proprietary and Established Names:

ACON On Call Multi-Drug Home Test

D. Regulatory Information:

1. Regulation section:

21 CFR 862.3100, Enzyme Immunoassay, Amphetamine

21 CFR 862.3870, Enzyme Immunoassay, Cannabinoids

21 CFR 862.3250, Enzyme Immunoassay, Cocaine and Cocaine
Metabolites

21 CFR 862.3610, Thin Layer Chromatography, Methamphetamine

21 CFR 862.3650, Enzyme Immunoassay, Opiates

Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product Code:

DKZ, LDJ, DIO, LAF, DJG and LCM, respectively.

4. Panel:

Toxicology (91)

E. Intended Use:

1. Intended use(s):

Refer to Indications for use below

2. Indication(s) for use:

The On Call™ Multi-Drug Home Test for Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, and Phencyclidine is a screening test for the rapid detection of Marijuana, Cocaine, Amphetamine, Methamphetamine, Opiates, and Phencyclidine 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, 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):

The On Call™ Multi-Drug Home Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

This assay is for OTC use.

The materials necessary for confirmational testing are provided with the screening device. Materials, as well as confirmational testing, are provided to the consumer at no additional cost. The consumer pays for shipment of the sample to the laboratory.

4. Special instrument Requirements:

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

F. Device Description:

The product is a single-use visually read cassette device. It has a plastic housing that contains the test strip. A plastic sample dropper is also provided with the device. Several drops of urine are added to start the test which employs traditional immunochromatographic technology.

G. Substantial Equivalence Information:

1. Predicate device name(s):

ACON Multi-Drug Multi-line Test Device, First Check Home Drug Test, Pharmatech at Home Drug Test and Accu-Stat™ Home Drug Test.

2. Predicate K number(s):
k020313, k993852, k003858 and k040629
3. Comparison with predicate:
This device and the predicate cleared under k020313 are identical in product design, performance characteristics, materials, manufacturing, matrix used and are intended for use as an initial screening method subject to confirmation. The proposed device is intended to be sold over the counter (OTC) while the device cleared under k020313 is prescription use only. Predicates cleared under k993852, k003858 and k040629 are all OTC products.

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

The sponsor did not reference any standards or guidance documents in their pre-market submission.

I. Test Principle:

The device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the control region and the test region. If the sample contains drugs above the cutoff level, a colored line will not appear in the strips test region. Formation of a colored line in the control region indicates that the proper volume of urine has been added. If a colored line does not appear in the control region, the test result is inconclusive and should be repeated. The absence or presence of the line is determined visually by the operator.

J. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

The accuracy and precision of the test was demonstrated in a consumer study. 503 unique tests were performed by consumers using drug-free urine that had been spiked with various concentrations and combinations of drugs. Each drug was tested at 0%, 50%, 75%, 125%, 150%, and 200% of the target concentration. Some samples contained as many as three drugs; there were combinations that contained no drugs at all. At least 21 but not more than 34 tests were performed for each combination. Drug concentrations were confirmed by GC/MS; recovery ranged between 81 to 116% of the target concentration. Approximately 10% of the consumers had used a home drug kit before. 98% reported that they were high-school graduates and the ratio of female to male was approximately 1:1. Four geographic locations were cited but the settings were not specified.

The results of the study are summarized in the table below:

Drug	Cutoff Concentration (ng/ml)	Number of Studies	Correctly Interpreted	Incorrectly Interpreted*
THC	50	169	167	2
COC	300	165	163	2
AMP	1000	165	161	4
mAMP	1000	163	161	2
OPI	2000	161	161	2
PCP	25	167	165	2

* All samples that were interpreted incorrectly were $\pm 25\%$ of the cutoff value (75% or 125% of target).

A consumer questionnaire was administered to evaluate labeling effectiveness. It asked only one question: “Was the test easy to interpret?” Thus it did not determine whether the labeling adequately alerted users to the limitations of home use testing devices. Only one participant of 503 responded that the test was not easy to interpret.

b. Linearity/assay reportable range:

Not applicable for a qualitative assay.

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

The device has an internal process control. Users are informed that the control indicates that sufficient urine was added to the test. This is typical of OTC tests. Users are also informed not to interpret the test if the control line does not form.

d. Detection limit:

Performance Characteristics have been addressed in k020313 (ACON Multi-Drug Multi-line Test Device).

e. Analytical specificity:

Performance Characteristics have been addressed in k020313 (ACON Multi-Drug Multi-line Test Device).

f. Assay cut-off:

The identified cutoff concentrations are those recommended by the Substance Abuse and Mental Health Services Administration

(SAMHSA). Analytical performance of the device around the cutoff is described in the precision section above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable.

b. *Matrix comparison:*

Not applicable as the device is only intended for use with urine.

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. Clinical studies are not typically submitted for this device type.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

K. Conclusion:

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