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

A. 510(k) Number:

k050936

B. Purpose for Submission:

New Device

C. Measurand:

Marijuana, or Marijuana and Cocaine

D. Type of Test:

Qualitative

E. Applicant:

ACON Laboratories, Inc.

F. Proprietary and Established Names:

On Call® Home Drug Test for Marijuana
On Call® Home Drug Test for Marijuana and Cocaine

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3870 – Cannabinoid test system
   21 CFR 862.3250 – Cocaine and cocaine metabolite test system

2. Classification:

   Class II

3. Product code:

   LDJ, DIO

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

   The On Call™ Home Drug Test for Marijuana (THC) is only the first step in a two-step process for determining the presence of the THC in human urine.

   The On Call™ Home Drug Test for Marijuana (THC) and Cocaine (COC) is only the first step in a two-step process for determining the presence of the marijuana and cocaine in human urine.

2. Indication(s) for use:

   The On Call Home Drug Test for Marijuana is a screening test for the rapid detection of Marijuana (THC) and its metabolites in urine at a designated cut-off concentration of 50 ng/mL for Marijuana (THC). The test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers with information concerning the presence of THC or its metabolites in a urine sample. Information, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

   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 On Call Home Drug Test for Marijuana & Cocaine is a screening test for the rapid detection of Marijuana (THC), Cocaine (COC) and their metabolites in urine at a designated cut-off concentration of 50 ng/mL for Marijuana (THC) and 300 ng/mL for Marijuana & Cocaine (THC, COC). The test is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers with information concerning the presence of THC, COC or their metabolites in a urine sample. Information, along with the materials for shipping a portion of the urine specimen to the laboratory for confirmation testing of a preliminary positive result, the second step in the process, is provided.

   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 conditions for use statement(s):

   The On Call Home Drug Test for Marijuana and the On Call Home Drug Test for Marijuana & Cocaine are for OTC use.

   These assays provide only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. The materials necessary for confirmation testing and the confirmation testing itself are provided to the consumer at no additional cost. The consumer, however, pays for shipment of the sample to the laboratory.

4. Special instrument requirements:

   None

I. Device Description:

The On Call® Home Drug Test kits include the following materials: 1 drug test with dropper, 1 instructional booklet, 1 urine collection cup with confirmation label, 1 shipping box, and 1 shipping bag with absorbent. The test device is composed of a test strip, containing mouse monoclonal antibody, enclosed in plastic housing.

With the exception of the brand name, the On Call® Home Drug Tests for Marijuana or Marijuana and Cocaine are identical to the Accu-Stat™ Home Drug Test for Marijuana (THC) and the Accu-Stat™ Home Drug Test for Marijuana & Cocaine (THC, COC) (k040327), the ACON THC One Step Marijuana Test Device (k003557), and the ACON One Step Multi-Drug Multi-Line Screen Test Card/Device (k020313).

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Accu-Stat™ Home Drug Test for Marijuana (THC), or Marijuana & Cocaine (THC, COC), ACON THC One Step Marijuana Test Device, First Check® Home Drug Test for THC, and Phamatech Quick Screen THC Drug Screening Tests

   ACON Multi-Drug Multi-Line Test Device, First Check® Home Drug Test for Marijuana & Cocaine, and Phamatech At Home™ Drug Test for Marijuana & Cocaine

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

   k040327, k003557, k993663, and k973122, respectively

k020313, k994139, and k991641, respectively

3. Comparison with predicate:

Similarities		
Item	Device	Predicates
Intended Use	Qualitative detection of marijuana or both marijuana and cocaine	Same
Specimen	Urine	Same
Test Principle	Immunochromatographic lateral flow assay	Same
Cut-off	50 ng/mL (THC) 300 ng/mL (COC)	Same
Target User Population	OTC / laypersons	Same (k040327, k993663, k973122, k994139, and k991641)

Differences		
Item	Device	Predicate
Target User Population	OTC / laypersons	Professionals (k003557 & k020313)

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

None referenced

L. Test Principle:

The tests employ lateral flow immunochromatographic technology, which involves the recognition and formation of a specific antibody/target drug complex.

Drug in the sample and drug-labeled conjugate compete for antibody binding sites. Absence of a line in the test area is a presumptive positive result, and the presence of a line in the test area is a negative result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Refer to the consumer study data provided in k040327.

b. Linearity/assay reportable range:

Not applicable

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

Not applicable

d. Detection limit:

This was addressed in the previous Acon submissions listed in Section I.

e. Analytical specificity:

This was addressed in the previous Acon submissions listed in Section I.

f. Assay cut-off:

See "Detection limit" above.

2. Comparison studies:

a. Method comparison with predicate device:

Refer to the consumer study data provided in k040327.

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):

See Method comparison with predicate device section for information on consumer studies.

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:

   The expected values were based on literature.

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.