

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

A. 510(k) Number:

K040629

B. Purpose for Submission:

Remarketing of previously approved product for OTC use

C. Analyte:

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

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Accu-Stat Diagnostics

F. Proprietary and Established Names:

Accu-Stat Home Drug Test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Opiates (OPI), and Phencyclidine (PCP)

G. Regulatory Information:

1. Regulation section:

Unclassified, Test Kit, Multiple Drugs of Abuse, Over the Counter
862.3870, Enzyme Immunoassay, Cannabinoids
862.3250, Enzyme Immunoassay, Cocaine and Cocaine Metabolites
862.3100, Enzyme Immunoassay, Amphetamine
862.3610, Enzyme Immunoassay, Methamphetamine
862.3650, Enzyme Immunoassay, Opiates
Unclassified, Enzyme Immunoassay, Phencyclidine

2. Classification:

Class II

3. Product Code:

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

4. Panel:

Toxicology (91)

H. Intended Use:

1. Indication(s) for use:

“The Accu-Stat™ Home Drug Test for Marijuana (THC), Cocaine (COC), Amphetamine (AMP), Methamphetamine (mAMP), Opiates (OPI), and Phencyclidine (PCP) is a single-unit screening test for the rapid detection of

two to six of the above drugs in human urine. The designated cut-off concentrations for these drugs are as follows: Marijuana at 50 ng/ml, Cocaine at 300 ng/ml, Amphetamine at 1000 ng/ml, Methamphetamine at 1000 ng/ml, Opiates at 2000 ng/ml, and Phencyclidine at 25 ng/ml. The tests are intended for over-the-counter (OTC) consumer use as the first step in a two step process that includes confirmatory testing of preliminary positive results. Information, along with the materials for shipping a portion of the urine specimen to the laboratory is provided.”

2. Special condition for use statement(s):

This device only provides a preliminary analytical test result. A more specific alternative chemical method must be used to obtain confirmed analytical results. Gas chromatography/mass spectroscopy is the preferred confirmatory method but other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test, particularly when preliminary positive results are used.

The assay is for OTC 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 cost. The consumer pays for shipment of the sample to the laboratory.

3. Special instrument Requirements:

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

I. Device Description:

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

J. Substantial Equivalence Information:

1. Predicate device name(s):

Acon Multi-Drug Multi-Line Test Device

2. Predicate K number(s):

K020313

3. Comparison with predicate:

Both devices 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 predicate is for prescription use only.

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

The sponsor did not reference any standards or guidance documents in the pre-market notification.

L. 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 antibody-coated particles in the device. The antibody-coated particles will then be captured by immobilized drug-specific conjugate and a colored line will appear in the test line region. The colored line will not form if the sample contains drug in excess of the cutoff level because the drug will saturate all the binding sites of the drug-specific antibody. Each strip in the device contains a procedural control that appears in the control line region indicating that the proper volume of urine has been added and membrane wicking has occurred.

M. 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:*
Issues were addressed in the predicate submission.
 - e. *Analytical specificity:*
Issues were addressed in the predicate submission.
 - 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.

N. Conclusion:

The submitted information in this pre-market notification is complete and supports a substantial equivalence decision