

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

A. 510(k) Number:

k053035

B. Purpose for Submission:

New device

C. Measurand:

Benzoyllecgonine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid Benzoyllecgonine (Cocaine) Urine Test

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3250 Cocaine and Cocaine metabolite test system

2. Classification:

Class II

3. Product code:

DIO

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

Acro Rapid Benzoyllecgonine (Cocaine) Urine test is a lateral flow, one-step immunoassay for the qualitative detection of benzoyllecgonine in human urine at a cutoff of 300 ng/mL. The test is used to obtain a visual qualitative result and is intended for laboratory use only.

This assay provides only preliminary result. Clinical consideration and professional judgment must be applied to a drug test result, particularly in evaluating a preliminary positive result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) analysis is preferred.

3. Special conditions for use statement(s):
For prescription use
4. Special instrument requirements:
Not applicable. The device is a visually read single-use device.

I. Device Description:

The Acro Rapid Benzoyllecgonine (Cocaine) Urine Test is a one-step immunoassay in which a chemically labeled drug (benzoyllecgonine-BSA conjugate) competes with Cocaine and its metabolite, benzoyllecgonine, in urine for limited antibody binding sites. The test device contains a membrane strip, which is pre-coated with benzoyllecgonine-BSA conjugate at the test band region of the membrane strip. A wicking pad containing anti-benzoyllecgonine monoclonal antibody-colloidal gold conjugate is placed at one end of the membrane. The device contains a control region which has a different antigen/antibody from the test region. The device is for single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):
Syntron QuickPac II OneStep Benzoyllecgonine test
2. Predicate 510(k) number(s):
k992990
3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Principle	Qualitative, immunochromatographic assay	Same
Intended Use	Detection of benzoyllecgonine in human urine	Same

Differences		
Item	Device	Predicate
Cutoff concentration	300 ng/mL	150 ng/mL
Read time	Read result after 5-10 minutes	Read result after 5 minutes

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

Draft Guidance for Industry and FDA Staff: Premarket Submission and Labeling Recommendations for Drugs of Abuse Screening Tests (December 2, 2003)

L. Test Principle:

The Acro Rapid Benzoyllecgonine (Cocaine) test is based on the principle of competitive immunochemical reaction between an immobilized drug-protein conjugate and the drug or drug metabolites, which may be present in the urine sample for limited binding sites of a labeled drug antibody. When sample is applied to the test device, the sample migrates by capillary action through the device. When benzoyllecgonine is absent in the urine or is present at a concentration below the cutoff level (300 ng/mL), the anti-benzoyllecgonine antibodies in the colloidal gold conjugate will bind to the benzoyllecgonine-BSA conjugate in the test region of the device to form a line, indicating a negative result. No line will form if the sample contains benzoyllecgonine at the cutoff level or higher, because it will compete with the benzoyllecgonine-BSA for antibody binding sites on the antibody colloidal gold conjugate, indicating a preliminary positive result. Each device contains a procedural control which generates a visible line to indicate that the correct amount of sample was added. If the device is functioning correctly, a line in the control region should always appear regardless of the presence or absence of drug or drug metabolite in the urine specimen.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

The reproducibility of the device was evaluated at four different sites. The samples were prepared from fresh drug-free normal human urine specimens collected from non-user volunteers and pooled. Test samples were prepared by spiking the pooled urine with benzoyllecgonine to concentrations of 150 ng/mL (50% below cutoff), 225 ng/mL (25% below cutoff), 375 ng/mL (25% above cutoff), 450 ng/mL (50% above cutoff) and 600 ng/mL (100% above cutoff). The testing was performed in one day by one operator at each site. Each sample was tested n=15.

The study data is presented below:

Test sites	0 ng/mL		150 ng/mL		225 ng/mL		375 ng/mL		450 ng/mL		600 ng/mL	
	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.	Neg.	Pos.
1	15	0	15	0	11	4	3	12	0	15	0	15
2	15	0	15	0	11	4	4	11	0	15	0	15
3	15	0	15	0	10	5	4	11	0	15	0	15
4	15	0	15	0	12	3	4	11	0	15	0	15
Total	60	0	60	0	44	16	15	45	0	60	0	60

b. *Linearity/assay reportable range:*
Not applicable.

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

Controls:

A procedural control is included in the test strip of the device. A line appears in the control region (C) with every test as long as a sufficient specimen volume was added to the device. If the line does not form, the test is considered invalid.

External control materials are not supplied with this test however, the labeling includes a recommendation that external controls be tested to ensure proper kit performance. Users are instructed to follow local, state and federal guidelines for testing QC material.

Stability:

The manufacturer claims an expiration date of 24 months when the devices are stored at 2-30 °C. Accelerated studies are being used by the sponsor to estimate the shelf-life of the device, however, on-going real time studies are being performed. Protocols and acceptance criteria were provided by the sponsor.

d. *Detection limit:*
See 1(f) Assay Cut-off

e. *Analytical specificity:*

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentrations 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 the studies appear in the table below:

Compound	Response equivalent to cutoff
Benzoylecgonine	300 ng/mL
Cocaethylene	600 ng/mL
Cocaine	800 ng/mL

The following list of structurally unrelated substances showed no interference at concentrations of 100 µg/mL in normal urine spiked with 150 and 450 ng/mL benzoylecgonine. Ascorbic acid, glucose, hemoglobin, ibuprofen, and sodium chloride were tested at higher concentrations (listed below) and each showed no interference as well.

Acetaminophen	Ibuprofen (200 µg/mL)
Acetone	(+/-)-Isoproterenol
Albumin	Ketamine
Ampicillin	Levorphanol
Ascorbic Acid (500 µg/mL)	Lidocaine
Aspartame	(+)-Naproxen
Aspirin	Niacinamide
Atropine	Nicotine
Benzocaine	(+/-)-Norephedrine
Bilirubin	Oxalic Acid
Caffeine	Penicillin-G
Chloroquine	Pheniramine
(+)-Chlorpheniramine	Phenothiazine
(+/-)-Chlorpheniramine	1-Phenylephrine
Creatine	β -Phenylethylamine
Dexbrompheniramine	Procaine
Dextromethrophan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride (10,000 µg/mL)
Erythromycin	Sulindac
Ethanol (0.2%)	Theophylline
Furosemide	Tyramine
Glucose (500 µg/mL)	4-Dimethylaminoantipyine
Guaiacol Glyceryl Ether	(1R, 2S)-(-)-N-Methyl-
Hemoglobin (500 µg/mL)	Ephedrine

Aliquots of test samples with concentrations of benzoylecgonine 50% below and 50% above the cutoff were adjusted to pH 4 to 9 in 1 pH unit increments and evaluated. Altering the pH of the sample did not affect the expected

results of the test.

The effect of specific gravity on test results was evaluated. Aliquots of test samples with concentrations of benzoylecgonine 50% below and 50% above the cutoff were adjusted to specific gravities ranging from 1.003-1.04. Altering the specific gravity of the sample did not affect the expected results of the test.

f. Assay cut-off:

The cutoff of the device is stated to be 300 ng/mL. The cutoff was determined by repetitive assaying of six levels of benzoylecgonine controls. The study was performed as part of the reproducibility study in section 1.a. of this template.

The results of the cut-off study are summarized in the following table:

Benzoylecgonine Conc.	# Tested	# Positive (+)	# Negative (-)
0 ng/mL	60	0	60
150 ng/mL	60	0	60
225 ng/mL	60	16	44
300 ng/mL	60	40	20
375ng/mL	60	45	15
450 ng/mL	60	60	0
600 ng/mL	60	60	0

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 60 self-declared non-drug users and were tested using the Acro Rapid Benzoylecgonine Urine Test and the predicate device. **Note:** The cutoff concentration of the candidate device is 300 ng/mL and the cutoff concentration of the predicate device is 150 ng/mL.

Additionally, seven (7) drug-negative samples were tested on the candidate device and a reference method, Gas Chromatography/Mass Spectrometry GC/MS. The results are summarized in the table below.

Sixty (n=60) clinical drug positive urine specimens were pre-screened by GC/MS and then assayed on the Acro Rapid Benzoylecgonine Urine Test. Approximately 10% of these study samples were evenly distributed between minus and plus 50% of the claimed cutoff concentration, 150 ng/mL and 450 ng/mL respectively,

The results are summarized in the table below:

Candidate Device Results vs. stratified GC/MS Values (Cut-off 300 ng/mL)

Candidate Device Results	Negative by the predicate device*	Near Cutoff Negative (150-300 ng/mL)	Near Cutoff Positive (300-450 ng/mL)	High Positive (>450 ng/mL)
Positive	0	3	7	40
Negative	60	7	3	0

* Drug-negative samples were tested by predicate with 150 ng/mL cut-off. These samples were *not* confirmed by GC/MS

** Additionally, 7 drug-negative urines were tested on candidate device and GC/MS. All were negative with both methods.

% Agreement to GC/MS among positives is 47/50 =94%

% Agreement to GC/MS among negatives is 14/17 =82%

b. Matrix comparison:

Not applicable; this device is only for use with urine samples

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):

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.