

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

A. 510(k) Number:

k053037

B. Purpose for Submission:

New device

C. Measurand:

Opiates

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid Opiate Urine Test

G. Regulatory Information:

1. Regulation section:

862.3650, Opiate Test System

2. Classification:

Class II

3. Product code:

DJG

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Acro Biotech LLC Rapid Opiate Urine test is a lateral flow, rapid immunoassay for the qualitative detection of opiate in human urine at a cutoff of 2000 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 professional 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.

4. Special instrument requirements:

Not applicable, as the device is a visually-read single-use device

I. Device Description:

Acro Rapid Opiate Urine Test is a one-step immunoassay in which a chemically labeled drug (Morphine-BSA conjugate) competes with opiate and its metabolites in urine for limited antibody binding sites. The test device contains a membrane strip, which is pre-coated with Morphine-protein conjugate at the test band region of the membrane strip. A wicking pad containing anti-Morphine 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 QuickStrip II OneStep Opiate test

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

k993491

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Principle	Immunochromatographic Assay	Immunochromatographic Assay
Tracer	Antibody-Colloidal Gold Conjugate	Antibody-Colloidal Gold Conjugate
Intended Use	To detect opiates in human urine	To detect opiates in human urine

Differences		
Item	Device	Predicate
Cutoff concentration	2000 ng/mL	300 ng/mL
Incubation Time	5-10 minutes @ Room Temperature	5-8 minutes @ Room Temperature
Separation System	BSA Conjugate	BTG Conjugate

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

None referenced

L. Test Principle:

The Acro Rapid Opiate Urine 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 for the drug/drug metabolites of a labeled drug antibody. When sample is applied to the test device, the sample migrates by capillary action through the device. Opiate, if present in concentration below the cutoff level, the anti-drug antibodies in colloidal gold conjugate will bind to the drug-protein conjugate coated in the test line (in the test region) to form a line, a negative result. No line will form if the sample contains drug at the cutoff level or higher, because it will compete with drug-protein conjugate with colloidal gold conjugate (a preliminary positive result). Each device contains a procedural control which indicated that the correct volume of sample was added. Formation of a line in the control region should always appear if the proper volume is added 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. Each site tested the device against blind-labeled urine controls contain 0, 1000, 1500, 2500, 3000 and 4000 ng/mL morphine. A total number of 60 determinations were made for each concentration spread over the four sites. Reproducibility study data is presented below:

Test Sites	0 ng/mL		1000ng/mL		1500ng/mL		2500ng/mL		3000ng/mL		4000ng/mL	
	#	Result	#	Result	#	Result	#	Result	#	Result	#	Result
1	15	15-	15	15-	15	4+, 11-	15	11+, 4-	15	15+	15	15+
2	15	15-	15	15-	15	4+, 11-	15	12+, 3-	15	15+	15	15+
3	15	15-	15	15-	15	3+, 12-	15	11+, 4-	15	15+	15	15+
4	15	15-	15	15-	15	4+, 11-	15	10+, 5-	15	15+	15	15+
Total	60	60-	60	60-	60	15+, 45-	60	44+, 16-	60	60+	60	60+

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

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

Procedural controls are included in the test strip of the device. A line appearing in the control region (C) is considered as an internal procedural control. It confirms sufficient specimen volume was added to the device.

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

Stability:

Accelerated studies have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 15 – 30 °C product is good until expiration date which is 24

months.

Real time studies have been conducted and are on-going.

d. Detection limit:

See the Precision/Reproducibility section (1a) above.

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug into drug-free normal urine. The following structurally related compounds produced positive results when tested at levels equal to or greater than the concentrations listed below.

Compound	Concentration	
	ng/ml	Relative to Cutoff
Morphine	2,000	1 x
Codeine	2,000	1 x
Ethylmorphine	1,000	0.5 x
Heroin	5,000	2.5 x
Hydrocodone	4,000	2 x
Hydromorphone	5,000	2.5 x
Morphine-3-glucuronide	2,500	1.25 x
Nalorphine	5,000	2.5 x

Substances unrelated to Opiates were first added to a pool of drug free urine samples to concentrations of 10 µg/mL and 100 µg/mL, levels that are not likely to be found in urine. Samples containing the following substances were negative with the rapid test device.

In addition, the same substances were added to two specimens of pooled drug free urine and with spiked morphine at 1000ng/ml and 4000ng/ml and tested with the rapid test device. Samples prepared in 1000ng/ml morphine specimen all tested negative and those prepared in 2000ng/ml morphine specimen all tested positive. The results show that these substances do not interfere with the assay.

<i>Acetaminophen</i>	<i>Hemoglobin</i>
<i>Acetone</i>	<i>Ibuprofen</i>
<i>Albumin</i>	<i>(+/-)-Isoproterenol</i>
<i>Ampicillin</i>	<i>Ketamine</i>
<i>Ascorbic Acid</i>	<i>Levorphanol</i>
<i>Aspartame</i>	<i>Lidocaine</i>
<i>Aspirin</i>	<i>(+)-Naproxen</i>
<i>Atropine</i>	<i>Niacinamide</i>
<i>Benzocaine</i>	<i>Nicotine</i>

<i>Bilirubin</i>	<i>(+/-)-Norephedrine</i>
<i>Caffeine</i>	<i>Oxalic Acid</i>
<i>Chloroquine</i>	<i>Penicillin-G</i>
<i>(+)-Chlorpheniramine</i>	<i>Pheniramine</i>
<i>(+/-)-Chlorpheniramine</i>	<i>Phenothiazine</i>
<i>Creatine</i>	<i>1-Phenylephrine</i>
<i>Dexbrompheniramine</i>	<i>β-Phenylethylamine</i>
<i>Dextromethrophan</i>	<i>Procaine</i>
<i>Diphenhydramine</i>	<i>Quinidine</i>
<i>Dopamine</i>	<i>Ranitidine</i>
<i>(+/-)-Epinephrine</i>	<i>Riboflavin</i>
<i>Erythromycin</i>	<i>Sodium Chloride</i>
<i>Ethanol</i>	<i>Sulindac</i>
<i>Furosemide</i>	<i>Theophylline</i>
<i>Glucose</i>	<i>Tyramine</i>
<i>Guaiacol Glyceryl Ether</i>	<i>4-Dimethylaminoantipyrine</i>
	<i>(1R, 2S)-(-)-N-Methyl-Ephedrine</i>

Drug sample solutions with 50% below and 50% above the cutoff concentration were adjusted to a range of 4 to 9 in 1 pH unit increments. Each sample was run ten times at each concentration with the Acro Rapid Opiate Urine Test. Altering the pH of the sample did not affect the expected results of the test.

Drug sample solutions with 50% below and 50% above the cutoff concentration were adjusted to a specific gravity ranging from 1.003-1.04. Each sample was run ten times at each concentration with the Acro Rapid Opiate Urine Test. Altering the specific gravity of the sample did not affect the expected results of the test.

f. Assay cut-off:

Analytical performance of the device around the cutoff is described in Section M.1., above.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 60 presumed non-user volunteers and were tested using the Acro Rapid Opiate Urine Test and the predicate. Sixty clinical drug positive urine specimens were pre-screened by Gas Chromatography/Mass Spectrometry (GC/MS) and then assayed on the Acro Rapid Opiate Urine Test and the predicate device. The study also included 10 additional samples that were diluted with drug-free urine to concentrations between -50% and the cutoff and concentrations between the cutoff and

+50%. The results are presented in the tables below:

New Device	GC/MS, Cutoff 2000 ng/mL			% Agreement with GC/MS
	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (>+50%)	
Positive	3	8	40	48/50=96%
Negative	7	2	0	7/10 =70%
% Total Agreement				55/60 =92%

		Predicate Device 300 ng/mL cutoff	
		Negative	Positive
Acro Amphetamine 1000 ng/mL cutoff	Positive	0	53
	Negative	60	7
% Agreement with Predicate Device		100%	88%

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.