

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

A. 510(k) Number:

k053032

B. Purpose for Submission:

New device

C. Measurand:

Amphetamine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid Amphetamine Urine Test

G. Regulatory Information:

1. Regulation section:

862.3100, Amphetamine Test System

2. Classification:

Class II

3. Product code:

DKZ

4. Panel:

91, Toxicology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

Acro Rapid Amphetamine Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of Amphetamine in human urine at a cutoff of 1000 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 and Laboratory use only

4. Special instrument requirements:

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

I. Device Description:

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

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

k971109

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 Amphetamine in human urine	To detect Amphetamine in human urine

Differences		
Item	Device	Predicate
Cutoff concentration	1000 ng/mL	500 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 Amphetamine 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. Amphetamine, 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 amount of sample was added. Formation of 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. Each site tested the device against blind-labeled urine controls contain 0, 500, 750, 1250, 1500 and 2000 ng/mL Amphetamine. A total number of 68 determinations were made for each concentration spread over the four sites. Reproducibility study data is presented below:

Test Site	1		2		3		4		Total	
# tested	20		16		16		16		68	
conc. ng/mL	neg	pos	neg	Pos	neg	Pos	neg	pos	# correct results	% correct results
0	20	0	16	0	16	0	16	0	68/68	100
500	20	0	16	0	16	0	16	0	68/68	100
750	16	4	12	4	12	4	11	5	51/68	75
1250	6	14	3	13	4	12	4	12	51/68	75
1500	0	20	0	16	0	16	0	16	68/68	100
2000	0	20	0	16	0	16	0	16	68/68	100

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. Results of the study appear in the table below:

Compound	Concentration		Test results
	ng/mL	Relative to Cutoff	
d-Amphetamine	1000	1x	+
dl-Amphetamine	2500	2.5x	+
(+/-)3,4-MDA	1250	1.25x	+
d-Methamphetamine	50,000	50x	+
(+/-)3,4-MDMA	50,000	50x	+

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 Amphetamine 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 Amphetamine Urine Test. Altering the specific gravity of the sample did not affect the expected results of the test.

The following list of unrelated substances showed no interference at concentrations of 10 ug/mL and 100 ug/mL in either drug-free or drug positive urines:

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

f. Assay cut-off:

The identified cutoff concentration for amphetamine is the one recommended by the Substance Abuse and Mental Health Services Administration (SAMHSA). Analytical performance of the device around the cutoff is described in Section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 62 presumed non-user volunteers and were tested using the Acro Rapid Amphetamine Test Device 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 Amphetamine Test Device and the predicate device. The study also included 12 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 (Acro)	GC/MS, Cutoff 1000 ng/mL			% Agreement with GC/MS
	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)	
Positive	3	13	45	58/59 =98%
Negative	10	0	1	10/13 =77%
% Total Agreement				68/72 =94%

Comparison with the predicate:

		Predicate Device 500 ng/mL cutoff	
		Negative	Positive
Acro Amphetamine 1000 ng/mL cutoff	Positive	0	59
	Negative	62	1
% Agreement with Predicate Device		100%	98%

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.