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

A. 510(k) Number:

k053033

B. Purpose for Submission:

New device

C. Measurand:

Methamphetamine

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Rapid Methamphetamine Urine Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.3610, Methamphetamine Test System

2. Classification:

   Class II

3. Product code:

   DJC

4. Panel:

   91, Toxicology

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   Acro Rapid Methamphetamine Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of Methamphetamine in human urine at a cutoff of 500 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 device consists of a strip within a cassette. (See Test Principle, below.)

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Ameditech Immutest Drug Screen Methamphetamine

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

   k012585

3. Comparison with predicate:

   The intended use and general methodology is similar for both devices. The cutoff concentration is lower for this device (500 ng/mL) than for the predicate device (1000 ng/mL).

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

None referenced

L. Test Principle:

The Acro Rapid Methamphetamine 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 of a labeled antibody. The test contains a nitrocellulose membrane strip pre-coated with drug-protein conjugate in the test region and a wicking pad containing colored antibody-colloidal gold conjugate. During the test, the urine sample migrates on the strip and hydrates the antibody-colloidal gold conjugate. The mixture then migrates along the membrane chromatographically by capillary action to the immobilized drug-protein band in the test region. When drug is absent in the urine, the colored antibody-colloidal gold conjugate and immobilized drug-protein bind specifically to form a visible line in the test region (test line). When methamphetamine is present in the urine sample, it will compete with the drug-protein for the limited antibody binding sites. When the drug is present in sufficient concentration in the urine sample, it will fill the limited antibody binding sites, which will inhibit attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate in the test region. Therefore the presence of the test line indicates a negative result for methamphetamine and the absence of the test line indicates a preliminary positive result for methamphetamine.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

   The reproducibility of the device was evaluated at multiple biotech company sites, and one hospital site. Each site tested the device against masked urine control samples containing 0, 250, 375, 625, 750 and 1000 ng/mL Methamphetamine. Similar performance was observed at the various sites. Composite results are shown below:

Results with samples containing 0 ng/mL	Results at 250 ng/mL	Results at 375 ng/mL	Results at 625 ng/mL	Results at 750 ng/mL	Results at 1000 ng/mL
0+, 60-	0+, 60-	14+, 46-	44+,16-	62+, 0-	60+, 0-

   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 confirms that 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. Users should follow local, state and federal guidelines for testing QC material.

d. *Detection limit:*

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

e. *Analytical specificity:*

The following compounds were serially diluted 1:1 and added to methamphetamine-negative urine. They produced positive results with the Acro Rapid Methamphetamine Urine Test at the concentrations indicated in the table below:

Compound	Concentration (ng/mL)
d-Methamphetamine	500
d-Amphetamine	50,000
l-Amphetamine	>100,000
(+/-)3,4-MDEA	50,000
(+/-)3,4-MDA	100,000
(+/-)3,4-MDMA	2,000
l-Methamphetamine	10,000
Ephedrine	100,000
Mephentermine	50,000

Note: Drugs or drug metabolites not listed may interfere with methamphetamine assays and cause false results.

The compounds listed below were added to a pool of urine samples containing amphetamine spiked to 250 ng/mL, and 1000 ng/mL. These substances did not alter expected results at the indicated concentrations.

Acetaminophen (100 ug/mL)	Hemoglobin (500 ug/mL)
Acetone (100 ug/mL)	Ibuprofen (200 ug/mL)
Albumin (500 ug/mL)	(+/-)-Isoproterenol (100 ug/mL)
Ampicillin (100 ug/mL)	Ketamine (100 ug/mL)

Ascorbic Acid (500 ug/mL)	Levorphanol (100 ug/mL)
Aspartame (100 ug/mL)	Lidocaine (100 ug/mL)
Aspirin (100 ug/mL)	(+)-Naproxen (100 ug/mL)
Atropine (100 ug/mL)	Niacinamide (100 ug/mL)
Benzocaine (100 ug/mL)	Nicotine (100 ug/mL)
Bilirubin (100 ug/mL)	(+/-)-Norephedrine (100 ug/mL)
Caffeine (100 ug/mL)	Oxalic Acid (100 ug/mL)
Chloroquine (100 ug/mL)	Penicillin-G (100 ug/mL)
(+/-)-Chlorpheniramine (100 ug/mL)	Pheniramine (100 ug/mL)
	Phenothiazine (100 ug/mL)
Creatine (500 ug/mL)	1-Phenylephrine (100 ug/mL)
Dexbrompheniramine (100 ug/mL)	β -Phenylethylamine (100 ug/mL)
Dextromethrophan (100 ug/mL)	Procaine (100 ug/mL)
Diphenhydramine (100 ug/mL)	Quinidine (100 ug/mL)
Dopamine (100 ug/mL)	Ranitidine (100 ug/mL)
(+/-)-Epinephrine (100 ug/mL)	Riboflavin (100 ug/mL)
Erythromycin (100 ug/mL)	Sodium Chloride (10 mg/mL)
Ethanol (0.2%)	Sulindac (100 ug/mL)
Furosemide (100 ug/mL)	Theophylline (100 ug/mL)
Glucose (500 ug/mL)	Tyramine (100 ug/mL)
Guaiacol Glyceryl Ether (100 ug/mL)	4-Dimethylaminoantipyine
	(1R, 2S)-(-)-N-Methyl-Ephedrine (100 ug/mL)

f. *Assay cut-off:*

The identified cutoff concentration (500 ng/mL) 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 1.a., above.

2. Comparison studies:

a. *Method comparison with predicate device:*

Negative specimens: 70 urine specimens were donated by sixty self-declared non-drug users and were tested with the predicate device. In addition, 60 urine specimens pre-screened by GC/MS, which contained methamphetamine were evaluated. Results are shown below.

	Ameditech Immutest	GC/MS		
Acro	Negative	Near Cutoff Negative (– 50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	Positive (> +50%)
Positive	0	3	9	40
Negative	70	7	1	0

   b. *Matrix comparison:*

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

3. Clinical studies:

   a. *Clinical Sensitivity:*

   Not applicable. Clinical studies are not typically provided for this type of device.

   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.