

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

A. 510(k) Number:

k060355

B. Purpose for Submission:

New device

C. Measurand:

Methylenedioxyamphetamine (MDMA)

D. Type of Test:

Qualitative lateral flow immunochromatographic test

E. Applicant:

Acro Biotech, LLC

F. Proprietary and Established Names:

Acro Biotech LLC Rapid MDMA 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 Biotech LLC Rapid MDMA Urine Test is a lateral flow, rapid immunoassay for the qualitative detection of MDMA 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 Professional and Laboratory use only

4. Special instrument requirements:

Not applicable.

I. Device Description:

Acro Rapid MDMA Urine Test is a single-use immunochromatographic test in a cassette format. Users add urine to a test well to initiate the reaction, and visually read the results.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Microgenics CEDIA DAU Amphetamine/Ecstasy

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

k010496

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Test Principle	Immunochemical Assay	Immunochemical Assay
Tracer	Antibody-Colloidal Gold Conjugate	Antibody-Colloidal Gold Conjugate
Intended Use	To detect MDMA in human urine	To detect MDMA in human urine
Cutoff Concentration	500 ng/mL	500 ng/mL

Differences		
Item	Device	Predicate
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 MDMA 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. MDMA, 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:*

Reproducibility and performance around the cutoff concentration of the device was characterized by analyzing blind-labeled drug-free urine controls containing MDMA. The study was conducted at four sites by four operators using one lot of product. Results at each site were similar. Pooled results are

presented below.

Reproducibility at Concentrations Near the Cutoff Concentration

MDMA Concentration (ng/mL)	# Tested	# Positive	# Negative
0	60	0	60
250	60	0	60
375	60	12	48
500	60	42	18
625	60	45	15
750	60	60	0
1000	60	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 (C) is considered as an internal procedural control. It confirms that a sufficient volume of sample 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.

Stability: A summary of stability studies to establish expiration dating was provided. Replicates at concentrations -50% and +50% of the cutoff concentration are periodically tested. Accelerated and Real time studies are described.

d. Detection limit:

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

e. Analytical specificity:

Cross-Reactivity Testing: Cross-reactivity was established by spiking various concentrations of similarly structured drug into drug-free normal urine. These samples were analyzed, and the results appear in the table below:

Cross-Reactivity

Drug Compound	Amount of compound needed to provide a positive response (in ng/mL)
d-amphetamine	10,000
l-amphetamine	10,000
d-methamphetamine	10,000
l-methamphetamine	10,000
3,4-Methylenedioxyethylamphetamine(MDEA)	450
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	4000

Interference Testing: The following list of unrelated compounds showed no interference when added to drug-free urine or drug-free urine spiked with MDMA (1000 ng/mL). All results remained the same as the control sample (a urine containing no potentially interfering compound). Compounds were added to the urines at concentrations of 10 ug/mL and 100 ug/mL. *It should be noted that testing was not performed near the cutoff concentration of the assay.*

Compounds Having No Affect on Test Results

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-Dimethylaminoantipyrine
Guaiacol Glyceryl Ether	(1R,2S)-(-)-N-Methyl-Ephedrine
Hemoglobin	Pseudoephedrine

Affects from pH and Specific Gravity

Drug-free urine samples were spiked with MDMA to concentrations 50% below and 50% above the cutoff concentration. The pH in each sample was adjusted (in 1 pH increments) over a range of 4 to 9. Each sample was run ten times at each concentration with the Acro Rapid MDMA Urine Test. Altering the pH of the samples did not affect the expected results of the test.

Drug-free urine samples were spiked with MDMA to concentrations 50% below and 50% above the cutoff concentration. The specific gravity in each sample was adjusted to span a range of 1.003-1.04. Each sample was run ten times at each concentration with the Acro Rapid MDMA Urine Test. Altering the specific gravity of the samples did not affect the expected results of the test.

f. Assay cut-off:

The identified cutoff concentration for MDMA is the one currently 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., above.

2. Comparison studies:

a. Method comparison with predicate device:

Urine samples were collected from 60 presumed non-drug-using volunteers and were tested using the Acro Rapid MDMA Test Device and the predicate. All were negative.

Sixty clinically unaltered drug positive urine samples were pre-selected for testing by Gas Chromatography/Mass Spectrometry (GC/MS). Samples were assayed using the Acro Rapid MDMA device, and results from the study are presented below:

Method Comparison Test Results, Acro MDMA Results compared to GC/MS

Acro MDMA Result	MDMA Concentration, GC/MS		
	259-485 ng/mL	508-747 ng/mL	> 747 ng/mL
Positive	7	8	26
Negative	8	6	0

It should be noted that the presence or concentrations of other methamphetamine or amphetamine in the sample are not known.

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):

None

4. Clinical cut-off:

Not applicable. Optimal cutoff concentrations are recommended by SAMHSA.

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.