

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

A. 510(k) Number:

k060353

B. Purpose for Submission:

New device

C. Measurand:

Phencyclidine (PCP)

D. Type of Test:

Qualitative immunoassay

E. Applicant:

Acro Biotech LLC

F. Proprietary and Established Names:

Acro Rapid Phencyclidine Urine Test

G. Regulatory Information:

1. Regulation section:
Unclassified
2. Classification:
Unclassified, 510(k) required
3. Product Code:
LCM, Enzyme Immunoassay, PCP
4. Panel:
Toxicology (91)

H. Intended Use:

1. Intended use(s):
Refer to Indications for use.
2. Indication(s) for use:
The Acro Rapid Phencyclidine Urine Test is a lateral flow, one step immunoassay for the qualitative determination of phencyclidine in human urine at a cutoff of 25 ng/mL. The test is used to obtain a visual qualitative result and is intended for central laboratory use only.

This assay provides only a 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.

1. Special condition for use statement(s):

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This assay provides only a 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

The device is for in vitro diagnostic use.

For central laboratory use only.

2. Special instrument Requirements:

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Not applicable. The device is a visually read single-use device.

F. Device Description

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The product is a single-use device in a cassette format. Operators add several drops of the sample to the sample well. The test reaction is initiated by movement of the sample through the test strip.

Description of the test antibody: monoclonal mouse antibody against phencyclidine.

Description of the control line antibody: polyclonal goat anti-mouse.

G. Substantial Equivalence Information:

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1. Predicate device name(s):
Ameditech ImmuTest Drug Screen PCP
2. Predicate K number(s):
k012582
3. Comparison with predicate:

Both devices are for the qualitative determination of the same analyte in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices.

The reagent formulations vary between the two devices.

Similarities		
Item	Device	Predicate
Target User Population	Professional Users	Same
Cutoff	25 ng/mL	Same
Matrix	Urine	Same

Similarities		
Item	Device	Predicate
Methodology	Qualitative Lateral Flow Immunochromatographic	Same
Internal Control	Included; indicates adequate sample volume and integrity of test strip	Same
Differences		
Item	Device	Predicate
Test Line Antibodies	Mouse anti-PCP	Mouse anti-PCP and rabbit antibodies
Control Line Antibodies	Goat anti-mouse	Goat anti-rabbit

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

The sponsor did not reference any standards in their submission.

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I. Test Principle:

The test employs lateral flow immunochromatographic technology.

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Drug in the sample and drug-labeled conjugate (containing a chromagen) compete for antibody binding sites in the test area of the test strip. Binding of drug in the sample causes the absence of a line at the test area, i.e., a positive result. When drug is not present in the sample, the drug-labeled conjugate binds at the test line, resulting in formation of a line, i.e., a negative result. The absence or presence of the line is determined visually by the operator.

The device also has an internal process control which indicates that an adequate volume of sample has been added and that the immunochromatographic strip is intact.

J. Performance Characteristics (if/when applicable):

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1. Analytical performance:

a. *Precision/Reproducibility:*

Although this assay is intended for central laboratory use only, the sponsor collected precision data at four sites including a hospital laboratory and three biotechnology companies. Phencyclidine was spiked into drug free urine at the concentrations listed below. There was one operator per site and all 60 results (4 levels X 15 replicates per level) were run in one day by that operator.

Lots of product used: four

Operator: the sponsor states that all operators had at least one year of experience in research and development of immunoassays. One operator was an employee of the sponsor, one was a laboratorian, and two were employees of biotechnology companies.

Results of the study are presented below:

Site 1

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
12.5	15	15/0
18.75	15	11/4
25	15	7/8
31.25	15	8/7
37.5	15	0/15
50	15	0/15

Site 2

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
12.5	15	15/0
18.75	15	13/2
25	15	6/9
31.25	15	5/10
37.5	15	0/15
50	15	0/15

Site 3

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
12.5	15	15/0
18.75	15	10/5
25	15	8/7
31.25	15	1/14
37.5	15	0/15
50	15	0/15

Site 4

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	15	15/0
12.5	15	15/0
18.75	15	13/2
25	15	5/10
31.25	15	1/14
37.5	15	0/15
50	15	0/15

Combined data from all four sites

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	60	60/0
12.5	60	60/0
18.75	60	47/13
25	60	26/34
31.25	60	15/45
37.5	60	0/60
50	60	0/60

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

Control materials are required but are not specifically identified in the labeling.

The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. Detection limit

Sensitivity of this assay is characterized by validating performance around the claimed cutoff concentration of the assay, including a determination of the lowest concentration of drug that is capable of producing a positive result. In addition to the precision study in section M.1.a above, the sponsor performed an in-house study using spiked samples at concentrations of 0, 12.5, 18.75, 25, 31.25, 37.5, and 50 ng/mL. Results were as follows:

Phencyclidine Conc.	# Tested	# Positive (+)	# Negative (-)
0	60	0	60
12.5 ng/mL	60	0	60
18.75 ng/mL	60	13	47
25 ng/mL	60	34	26
31.25 ng/mL	60	45	15
37.5 ng/mL	60	60	0
50 ng/mL	60	60	0

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine /a negative control. By analyzing various concentration 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 those studies appear in the table(s) below:

Phencyclidine

Compound	Response equivalent to cutoff in ng/mL
Phencyclidine	25
4-hydroxyphencyclidine	12,500
Phencyclidine Morpholine	12.5

The following compounds were evaluated for potential positive or negative interference with the assay. To evaluate for interference the sponsor prepared three control samples: one consisted of drug-free urine only, one consisted of drug-free urine spiked with PCP at 12.5 ng/mL, and one consisted of drug-free urine spiked with PCP at 50 ng/mL. Potentially interfering substances were added to the three control samples at concentrations of 10 and 100 µg/mL to test for positive or negative interference. No deviations from the expected results were observed.

(+)-Chlorpheniramine	Diphenhydramine
(+)-Naproxen	Dopamine
(+/-) - Norephedrine	Erythromycin
(+/-)-Chlorpheniramine	Ethanol
(+/-)-Epinephrine	Furosemide
(+/-)-Isoproterenol	Glucose
/3 -Phenylethylamine	Guaiacol Glyceryl Ether
1-Phenylephrine	Hemoglobin
4-Dimethylaminoantipyrine	Ibuprofen
(1 R, 2S)-(+N-Methyl- Ephedrine	Ketamine
Acetaminophen	Levorphanol
Acetone	Lidocaine
Acetylsalicylic Acid	Niacinamide
Albumin	Nicotine
Ampicillin	Oxalic Acid
Ascorbic acid	Penicillin-G
Aspartame	Pheniramine
Atropine	Phenothiazine
Benzocaine	Procaine
Bilirubin	Quinidine
Caffeine	Ranitidine
Chloroquine	Riboflavin
Creatine	Sodium Chloride
Dexbrompheniramine	Sulindac
Dextromethorphan	Theophylline
Dextromethorphan	Tyramine

There is the possibility that other substances and/or factors not listed above may interfere with the test and cause false results, e.g., technical or procedural errors.

To test for potential positive or negative interference from endogenous conditions the sponsor prepared study control samples. The control samples consisted of drug-free urine spiked with phencyclidine at 50% above and below the cutoff. Aliquots of the control sample were then altered to span the following ranges of conditions, analyzed, and compared to the unaltered control samples:

4-9 pH

1.005 to 1.030 specific gravity

No deviations from the expected results were observed.

f. Assay cut-off:

The identified cutoff concentration of the assay is recommended for use by the Substance Abuse and Mental Health Services Administration (SAMHSA).

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

a. Method comparison with predicate device:

The candidate device was compared both to a reference method, GC/MS, and to the predicate device.

A total of 130 samples (81 negative and 49 positive) were evaluated by the candidate device and by GC/MS and/or the predicate device.

Sample description: Unaltered clinical urine samples were evaluated.

Sample selection: seventy presumed zero concentration samples were collected from self-declared non-drug users. All 70 samples were compared to the predicate device and 19% of these samples were confirmed by GC-MS. The remainder of the samples all contained phencyclidine (some below and some above the cutoff) and were compared to GC-MS.

The study included an adequate number of samples that contained drugs near to the cutoff concentration of the assay. Approximately 10% of the study samples are evenly distributed between plus and minus 50% of the claimed cutoff concentration.

Number of study sites: two

Type of study site(s): one biotechnology company, one clinical setting

Operator description: one manufacturer's staff, one clinical site staff

Candidate Device Results vs. stratified GC/MS Values

Candidate Device Results	Less than half the cutoff concentration by GC/MS analysis or negative by the predicate device*	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	3	7	37
Negative	71	7	5	0

*57 of these samples were from self-declared non-drug users but were not confirmed by GC-MS.

GC/MS values used to categorize samples in this table are based on the concentration of phencyclidine found in the sample.

% Agreement among positives is 90%

% Agreement among negatives is 96%

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:

a. Clinical sensitivity:

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

b. Clinical specificity:

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

c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

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L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

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