

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

A. 510(k) Number:

k080431

B. Purpose for Submission:

New device

C. Measurand:

Phencyclidine (PCP)

D. Type of Test:

Qualitative immunoassay

E. Applicant:

QuantRx Biomedical Corporation

F. Proprietary and Established Names:

RapidSense Drugs of Abuse Phencyclidine (PCP) 25 Device

G. Regulatory Information:

1. Regulation section:

Unclassified, PCP Test System

2. Classification:

Unclassified, 510(k) required

3. Product Code:

LCM

4. Panel:

Toxicology (91)

H. Intended Use:

1. Intended use(s):

Refer to Indications for use.

2. Indication(s) for use:

The RapidSense Drugs of Abuse Phencyclidine (PCP) 25 Device is a lateral flow competitive immunoassay for the qualitative detection of phencyclidine in human urine at a cutoff concentration of 25 ng/mL. The assay is intended for use in professional laboratories by healthcare professionals. For in vitro diagnostic use.

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternative chemical method is needed. Gas chromatography/Mass spectroscopy (GC/MS) is the recommended confirmatory method.

3. Special condition for use statement(s):

This assay provides only a preliminary result. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternative chemical method is needed. Gas chromatography/Mass spectroscopy (GC/MS) is the recommended confirmatory method.

The assay is not designated for use in point-of-care settings.

The assay is for prescription use only.

4. Special instrument Requirements:

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

I. Device Description:

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: mouse monoclonal antibody against protein A (Protein A binds with the colloidal gold)

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON PCP One Step Phencyclidine Test Strip and Test Device

2. Predicate K number(s):

k011730

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 devices differ in interpretation of the test line. The presence of the test line indicates a negative result for the predicate and a positive result for the new device.

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

The sponsor referenced the following guidance document(s) in their submission:

CEN 13640, Stability Testing of In Vitro Diagnostic Reagents

L. Test Principle:

The test employs lateral flow immunochromatographic technology.

The QuantRx assay is a positive read type test with a differential migration mechanism. The free analyte runs ahead of and continuous with the blue colored latex labeled antigen conjugates and reacts with the antibody immobilized in the primary capture zone. The primary capture zone is located under the top of the cassette, not visible to the user. When analyte is at or above the cutoff concentration, less antibody in the primary capture zone is available to bind with the latex-analyte conjugate. Thus more latex-analyte conjugate migrates beyond the primary capture zone to the secondary capture zone where it forms a test line visible to the reader. When the drug analyte is absent or below the cut off, the latex-conjugate binds with the antibody in the primary capture zone and no line forms at the secondary capture zone (T) resulting in a negative result (no test line).

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

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Specimen description: commercially available drugs of abuse controls containing PCP

Number of days: ten

Replicates per day: two

Lots of product used: three

Number of operators: three

Operator: manufacturer staff

Testing Facility: manufacturer

Results of the study are presented below:

PCP Precision Study Results

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
0	20	20/0
12.5	20	20/0
18.75	20	14/6
25	20	4/16
31.25	20	2/18
37.5	20	0/20

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 government regulations 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. This information appears in the precision section, above.

e. Analytical specificity:

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. 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 below:

Compound	Response equivalent to cutoff in ng/mL
TCP, 1-[1-(2-thienyl)-cyclohexyl]-piperidine or thienylcyclohexylpiperidine	100
Venlafaxine hydrochloride	>15,000

The following compounds were evaluated for potential positive and/or negative interference with the assay. To evaluate for interference the sponsor prepared two control samples that consisted of drug-free urine spiked with 12.5 and 30 ng/mL of phencyclidine. 100 µg/mL of potentially interfering compounds were then added to separate aliquots of the control samples and analyzed. No positive or negative interference was observed. The compounds tested were:

Acetaminophen	Chlorpheniramine	Hemoglobin
Acetone	Creatine	Imipramine
Albumin	Dextromethorphan	Isoproterenol
Amitriptyline	4-dimethylaminoantipyrine	Lidocaine
Aspartame	Erythromycin	Penicillin G
Aspirin	Ethanol	Pheniramine
Atropine	Furosemide	Quinidine
Benzocaine	Glucose	Sulindac
Caffeine	Guaiacol Glycerol Ether	Vitamin C

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 possible positive and/or negative interference from specific gravity, the sponsor prepared two study control samples. The control samples consisted of drug-free urine spiked with 12.5 ng/mL and 37.5 ng/mL of phencyclidine. Aliquots of the control samples were then altered to span the specific gravity range of 1.007 to 1.031. No positive or negative interference due to specific gravity was observed.

To test for potential negative interference from pH the sponsor prepared a study control sample consisting of drug-free urine spiked with 37.5 ng/mL of phencyclidine. Aliquots of the control samples were then added to urine samples with a pH range of 4 - 8 and analyzed. No negative interference due to pH was 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:

A total of 103 samples (45 negative and 58 positive) were evaluated by the candidate device and by GC/MS.

Sample description: Unaltered clinical urine samples were evaluated.

Sample selection: Samples were selected based on previous GC/MS values.

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 each plus and minus 50% of the claimed cutoff concentration.

Number of study sites: one

Type of study site: clinical setting

Operator description: clinical site staff

Candidate Device Results vs. stratified GC/MS Values

Candidate Device Results	Less than half the cutoff concentration by GC/MS analysis	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	2	10	46
Negative	37	6	0	2*

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 97%

% Agreement among negatives is 96%

* The GC-MS concentrations of these samples were 51 and 58 ng/mL

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.

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.