

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

A. 510(k) Number:

k080436

B. Purpose for Submission:

New Device

C. Measurand:

Cocaine

D. Type of Test:

Qualitative

E. Applicant:

Quantrx Biomedical Corporation

F. Proprietary and Established Names:

RapidSense™ Drugs of Abuse Cocaine (COC) 300 Device

G. Regulatory Information:

1. Regulation section:

21 CFR § 862.3250, Cocaine and cocaine metabolite test system

2. Classification:

Class II

3. Product code:

DIO - Cocaine and cocaine metabolite test system

4. Panel:

91 (Toxicology)

H. Intended Use:

1. Intended use(s):

See Indications for use below.

2. Indication(s) for use:

The RapidSense™ Drugs of Abuse Cocaine (COC) 300 Device is a lateral flow competitive immunoassay intended for the qualitative detection of the cocaine metabolite, benzoylecgonine, in human urine at a cut-off concentration of 300 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 alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

3. Special conditions 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.

For prescription use only.

The assay is not intended for Point of Care use.

4. Special instrument requirements:

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

I. Device Description:

The RapidSense™ Drugs of Abuse Assay is in a plastic cassette approximately 2" x 4" with a disposable pipette inserted. The cassette houses a 5 x 76 mm lateral flow strip made of nitrocellulose and other cellulose materials.

Each cassette is individually packaged in a moisture barrier foil pouch with desiccant. Each kit contains 25 individually pouched devices.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON COC One Step Test Strip & Test Device

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

k010841

3. Comparison with predicate:

The new and predicate devices have the same indications for use and same cut-off of 300 ng/mL. Both assays are lateral flow competitive immunoassays which provide a visual qualitative end point. Both assays are intended as a screening method that provides a preliminary test result.

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):

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 line read, competitive immunoassay 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:*

The sponsor conducted precision studies over ten days using six levels of commercially available drugs of abuse controls containing benzoylecgonine. The tests were run in replicates of two and using different lots of product by different operators at the manufacturer site.

Results of the study are presented below:

COC Precision Study Results:

Sample Concentration ng/mL	Percent Cut-off	# Observations	Results	
			# Negative	# Positives
0	0	20	20	0
150	-50%	20	20	0
225	-25%	20	14	6
300	Cut-off	20	7	13
375	+25%	20	2	18
450	+50%	20	0	20

b. *Linearity/assay reportable range:*

Not applicable. The assay is intended for qualitative use.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Control materials are required but are not specifically identified in the labeling. Users are instructed to follow government regulations when determining when to run external controls.

The device has an internal process control.

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 1.a., above.

e. *Analytical specificity:*

Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentrations 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
Cocaine	5,000
Benzoylcegonine	300
Ecgonine Methyl Ester	100,000
Ecgonine	>100,000

The sponsor conducted studies to determine the potential interference of the test with variety of endogenous and pharmaceutical substances. A positive (450 ng/mL, +50% of cut-off) and a negative urine pool (150 ng/mL, -50% of cut-off) were used and the potentially interfering compounds were spiked to a concentration of 100 µg/mL into each urine pool. The following compounds showed no interference when tested with the RapidSense™ COC Assay at a concentration of 100µg/mL.

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

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 150 ng/mL and 450 ng/mL of benzoylecgonine. 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 450 ng/mL of benzoylecgonine. 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:*
Not Applicable.

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision Section 1.a above.

2. Comparison studies:

a. *Method comparison with predicate device:*

A total of 87 samples (42 negative and 45 positive) were evaluated by the new 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.

The study was performed at a single study site by laboratory professionals. The results are summarized in the table below:

Number of study sites: one

Type of study site: clinical setting

Operator description: clinical site staff

New Device Results vs. stratified GC/MS Values

New 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	15	26
Negative	26	14	4	0

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

% Agreement among positives is 91%
% Agreement among negatives is 95%

b. *Matrix comparison:*
Not applicable

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.