

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY**

A. 510(k) Number:

k051958

B. Purpose for Submission:

New 510(k)

C. Measurand:

Buprenorphine

Oxycodone

D. Type of Test:

Qualitative immunochromatographic assay

E. Applicant:

Rapid Diagnostics (a division of MP Biomedicals, Inc.)

F. Proprietary and Established Names:

MP RapidBUP Test Strip

MP RapidOXY Test Strip

G. Regulatory Information:

1. Regulation section:
862.3650, Opiate test system

2. Classification:

Class II

3. Product code:
DJG

4. Panel:

91 (Toxicology)

H. Intended Use:

1. Intended use(s):

See indications for use.

2. Indication(s) for use:

The *MP RapidBUP Test Strip* is an immunochromatography based one step in vitro test. It is designed for qualitative determination of the major metabolite of buprenorphine, buprenorphine-3- β -d-glucuronide, in human urine specimens at cut-off level of 10 ng/ml.

The *MP RapidBUP Test Strip* may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

The *MP RapidOXY Test Strip* is an immunochromatographic one-step *in-vitro* test designed for qualitative determination of oxycodone in human urine specimens above a cut-off level of 100 ng/ml.

The *MP RapidOXY Test Strip* may be used in a point-of-care (POC) setting and will provide preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

3. Special conditions for use statement(s):

The device is for in vitro diagnostic prescription use.

4. Special instrument requirements:

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

I. Device Description:

The device is a one-step immunochromatographic test intended for the detection of major metabolite of buprenorphine, buprenorphine-3- β -d-glucuronide, or oxycodone in human urine. The test device contains a membrane strip, which is pre-coated with drug-protein

conjugate at the test band region of the membrane strip. A wicking pad containing anti-drug monoclonal antibody-colloidal gold conjugate is placed at one end of the membrane. The device contains a control region which has a different antigen/antibody from the test region. The device is for single-use and visually read.

J. Substantial Equivalence Information:

1. Predicate device name(s):

ACON[®] OXY One Step Oxycodone Test Strip
For Sure One Step Buprenorphine Test Strip

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

k033047 k042990

3. Comparison with predicate:

Both subject and predicate devices are qualitative immunochromatographic visually read single-use tests for measurement of the same analyte(s) in the same matrix. Both subject and predicate devices are competitive immunoassays.

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

The sponsor did not reference any guidance documents or standards.

L. Test Principle:

The MP RapidBUP Test Strip and MP RapidOXY Test Strip are based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug that may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate.

When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line regardless the presence of drug or metabolite.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*
MP RapidBUP Test Strip

A precision study was conducted to assess the precision at the cut-off level for the *MP RapidBUP Test Strip* in a point-of-care setting. The control materials used in the study were commercially purchased, aqueous-based controls (GC/MS calibrated), spiked with the targeted drug. The precision study was designed to evaluate the random error of visual interpretation by multiple observers (2 per site) at 3 different point of care settings (total=3 sites/6 observers) over a period of two (2) days.

Each site tested 60 samples for the presence of buprenorphine using GCMS calibrated urine controls at three levels: above cutoff, near cutoff, and below cutoff; results are listed below. Note that samples at the cut-off level were all reported as “POS” or “+”.

NOTE: Samples at <25% of cut-off will give negative results, samples at cut-off level may give either positive or negative results, samples at >25% cut-off level will give positive results.

CONTROL	#NO	# +	# +	# -	# +	# +	# -	# +	# +	# -
ng/ml		Site 1	Site 1	Site 1	Site 2	Site 2	Site 2	Site 3	Site 3	Site 3
7.5 ng/ml	20			20			20			20
10 ng/ml	20		20			20			20	
12.5 ng/ml	20	20			20			20		

MP RapidOXY Test Strip

A precision study was conducted to assess the precision at the cut-off level for the *MP RapidOXY Test Strip* in a point-of-care setting. The control materials used in the study were commercially purchased, aqueous-based controls (GC/MS calibrated), spiked with the targeted drug. The precision study was designed to evaluate the random error of visual interpretation by multiple observers (2 per site) at 3 different point of care settings (total=3 sites/6 observers) over a period of two (2) days.

Each site tested 60 samples for the presence of oxycodone using GCMS calibrated urine controls at one level of above cutoff, near cutoff, and below cutoff values; results are listed below. Note that samples at the cut-off level were all reported as “POS” or “+”.

NOTE: Samples at <25% of cut-off will give negative results, samples at cut-off level may give either positive or negative results, samples at >25% cut-off level will give positive results.

CONTROL	#NO	# +	# +	# -	# +	# +	# -	# +	# +	# -
ng/ml		Site 1	Site 1	Site 1	Site 2	Site 2	Site 2	Site 3	Site 3	Site 3
75 ng/ml	20			20			20			20
100 ng/ml	20		20			20			20	
125 ng/ml	20	20			20			20		

b.

Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

The sponsor did not indicate any degree of traceability for their devices.

Control materials are required but are not specifically identified in the labeling. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

The device has an internal process control which indicates whether an adequate volume of sample was added and whether the membrane strip is intact.

No calibrators are required. The device is calibrated during the manufacturing process.

Stability studies are summarized for the devices:

The device should be stored at 2 – 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be destroyed.

d. Detection limit:

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

e. Analytical specificity:

MP RapidBUP Test Strip

The specificity for MP RapidBUP Test Strip was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

MP RapidBUP Test Strip

The MP RapidBUP Test Strip performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 8.0 and 1.005 to 1.035. The following substances were tested and confirmed not to interfere with the test at the listed concentrations.

Glucose 2000 mg/dl,

Human albumin 2000 mg/dl

Human hemoglobin 10 mg/dl

Urea 4000 mg/dl

Uric acid 10 mg/dl

2. Specificity

The following table lists compounds that are detected by MP RapidBUP Test Strip which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Concentration	Cross reactivity
Buprenorphine-3- β -d-glucuronide	10 ng/ml	100%
Buprenorphine	200 ng/ml	5%

Each listed substance was evaluated and indicated negative results at a concentration of 100 μ g/ml.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital	Amphetamine	Arterenol
Aspartame	Ascorbic acid	Atrophine	Caffeine
Camphor	Chloroquine	Chlopheniramine	Cortisone
deoxyephedrine	Dextromethorphan	Digitoxin	Digoxin
Diphenhydramine	Ecgonine	Ecgonine methyl ester	Ephedrine
Epinephrine	Gentisic	Guaicol glycer ester	Histamine
Hydrochlorothiazide	Homatrophine	Imipramine	Ibuprofen
Isoproterenol	Ketamine	Lidocaine	Meperidine
Methadone	Methamphetamine	3,4 \pm MDMA	Methaqualone
Methylphenidate	Neomycin	Niacinamide	Norbuprenorphine
Oxazepam	Norbuprenorphine-3- β -D-Glucoronide		
Perphenazine	Penicillin G	Phencyclidine	Phenylethylamine- \square
Phenylpropanolamine	Promethazine	Pseudoephedrine	Quinine antidine
Salicylic acid	Tetracycline	Tetrahydrozoline	Theophyline
11-nor- Δ 8 –THC-9-COOH (10 μ g/ml)		11-nor- Δ 8 –THC-9-COOH (10 μ g/ml)	
Thioridazine	Trifluoperazine	Tryptophan	Tyramine

MP RapidOXY Test Strip

The specificity for MP RapidOXY Test Strip was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference testing

The MP RapidOXY Test Strip performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035. The following substances were tested and confirmed not to interfere with the test at the listed concentrations.

Glucose 2000 mg/dl,
 Human albumin 2000 mg/dl
 Human hemoglobin 10 mg/dl
 Urea 4000 mg/dl
 Uric acid 10 mg/dl

2. Specificity

The following table lists compounds that are detected by MP RapidOXY Test Strip which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds Concentration

Oxycodone	100 ng/ml	Acetylmorphine	> 100 µg/ml
Dihydrocodeine	20 µg/ml	Morphine	> 100 µg/ml
Codeine	100 µg/ml	Buprenorphine	> 100 µg/ml
Hydromorphone	100 µg/ml	Ethylmorphine	> 100 µg/ml

Each listed substance was evaluated and indicated negative result at a concentration of 100 µg/ml.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital	Amphetamine	Arterenol
Aspartame	Ascorbic acid	Atrophine	Caffeine
Camphor	Chloroquine	Chlopheniramine	Cortisone
Deoxyephedrine	Dextromethorphan	Digitoxin	Digoxin
Diphenhydramine	Ecgonine	Ecgonine methyl ester	Ephedrine
Epinephrine	Gentisic	Guaiacol glycer ester	Histamine
Hydrochlorothiazide	Homatrophine	Imipramine	Ibuprofen
Isoproterenol	Ketamine	Lidocaine	Meperidine
Methadone	Methamphetamine	3,4±MDMA	Methaqualone
Methylphenidate	Neomycin	Niacinamide	Oxazepam
Perphenazine	Penicillin G	Phencyclidine	Phenylethylamine-á
Phenylpropanolamine	Promethazine	Pseudoephedrine	Quinine antidine
Salicylic acid	Tetracycline	Tetrahydrozoline	Theophyline
11-nor- Δ^8 -THC-9-COOH (10 µg/ml)		11-nor- Δ^8 -THC-9-COOH (10 µg/ml)	
Thioridazine	Trifluoperazine	Tryptophan	Tyramine

f. Assay cut-off:

The stated cutoff of MP RapidBUP Test Strip is 10 ng/mL. The stated cutoff of MP RapidOXY Test Strip is 100 ng/mL. Characterization of how the device performs analytically around the claimed cutoff concentration appears in the detection limit section, above.

2. Comparison studies:

a. Method comparison studies:

MP RapidBUP Test Strip

The accuracy of the MP RapidBUP Test Strip was tested for buprenorphine (buprenorphine-3- β -d-glucuronide) at 10 ng/ml and compared to the GC/MS method. This product was also evaluated in a point-of-care setting and excellent performance was observed. Ninety-eight (98) specimens with GC/MS confirmed buprenorphine concentration (+ or -) were evaluated in this study.

The MP RapidBUP Test Strip results are summarized and presented below in following table:

	(-)		(+)		
<i>MP RapidBUP Test Strip</i>	Negative by GC/MS	Near Cutoff NEG (-25% to C/O)	Near Cutoff POS (C/O to +25%)	GC/MS POS (> +25% C/O)	% Agreement with GC/MS
Positive	0	1	12	34	97.9%
Negative	42	8	1	0	98.0%
Total	42	9	13	34	N=98

Positive agreement % = true positive results/total positive results = 97.9%

Negative agreement % = true negative results total negative results = 98%

MP RapidOXY Test Strip

The accuracy of the MP RapidOXY Test Strip was tested for oxycodone at 100 ng/ml and compared to the GC/MS method. One-hundred eight (108) specimens with GC/MS confirmed oxycodone concentration (+ or -) were evaluated in this study. The results are summarized and presented below in following table:

	(-)		(+)		
<i>MP RapidOXY Test Strip</i>	Negative by GC/MS	Near Cutoff NEG (-25% to C/O)	Near Cutoff POS (C/O to +25%)	GC/MS POS (> +25% C/O)	% Agreement with GC/MS
Positive	0	1	5	53	98.3%
Negative	45	4	0	0	100%
Total	45	5	5	53	N=108

Positive agreement % = true positive results/total positive results = 98.3%

Negative agreement % = true negative results total negative results = 100%

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 and matrix.

b. Clinical specificity:

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

matrix.

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

None provided

4. Clinical cut-off:

Validation of the clinical appropriateness of the cutoff is not typically submitted for this device type and matrix.

5. Expected values/Reference range:

Not applicable

N. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:

O. Proposed Labeling:

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

P. Conclusion:

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