

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

A. 510(k) Number:

k043051

B. Purpose for Submission:

New submission

C. Measurand:

Oxycodone

D. Type of Test:

Lateral Flow Immunoassay Methodology

E. Applicant:

Pharmatech, Inc.

F. Proprietary and Established Names:

QuickScreen Oxycodone Test Model 9120 Strip, 9120T Dip Card, 9120X Cup, and 9121 Cassette.

G. Regulatory Information:

1. Regulation section:

862.3650, Enzyme Immunoassay, Opiates

2. Classification:

Class II

3. Product code:

DJG

4. Panel:

91 (Toxicology)

H. Intended Use:

1. Intended use(s):

The QuickScreen Oxycodone Test is a rapid qualitative immunoassay for the detection of Oxycodone in human urine. The cutoff concentration for this test is 100 ng/mL. This test is intended for professional use only.

2. Indication(s) for use:

The QuickScreen Oxycodone Test is an in-vitro diagnostic screen for the detection of oxycodone in urine. This kit provides a preliminary result for the detection/presence of oxycodone in urine. It is intended for professional use only.

3. Special conditions for use statement(s):

The QuickScreen Oxycodone Test provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are observed.

4. Special instrument requirements:

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

I. Device Description:

The product #9120 is a single-use dip-strip device. The operators dip the test strip into the urine and the reaction is initiated by movement of the sample through the test strip.

The product #9120T is a single-use Dip Card device in a cassette format. The operator inserts the absorbent end of the device in the urine sample to the maximum level indicated by the line on the device label. The test reaction is initiated by movement of the sample through the test strip.

The product #9120X is a single-use device utilizing a cup format. The donor collects urine in the cup to the recommended volume. The reaction is initiated by movement of the sample through the test strip. Test strips are incorporated into the sides of a sample cup.

The product #9121 is a single-use Cassette Version device. The operator lays the cassette on a level surface and adds 4 drops of urine to the Sample Well with the provided sample pipette. The reaction is initiated by movement of the sample through the test strip.

J. Substantial Equivalence Information:

1. Predicate device name(s):

American BioMedica Corporation RapidOne OXY Test

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

k014101

3. Comparison with predicate:

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

	ABMC Oxycodone Test	QuickScreen Oxycodone Test Model 9120	QuickScreen Oxycodone Test Model 9120T	QuickScreen Oxycodone Test Model 9120X	QuickScreen Oxycodone Test Model 9121
Format	Dip Card	Dip Strip	Dip Card	Cassette	Cup Version
In Vitro Diagnostic Use	Yes	Yes	Yes	Yes	Yes
Intended Use	Detection of Oxycodone or Oxycodone Metabolites in Urine	Detection of Oxycodone or Oxycodone Metabolites in Urine	Detection of Oxycodone or Oxycodone Metabolites in Urine	Detection of Oxycodone or Oxycodone Metabolites in Urine	Detection of Oxycodone or Oxycodone Metabolites in Urine
Specimen	Urine	Urine	Urine	Urine	Urine
Methodology	Lateral Flow Immunoassay				
Qualitative	Yes	Yes	Yes	Yes	Yes
Antibodies	Monoclonal Polyclonal				
Analyte	Oxycodone	Oxycodone	Oxycodone	Oxycodone	Oxycodone
Cutoff	100 ng/mL				
Control Feature	Procedural Control Line				
End User	Health Care Professional				

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

None referenced.

L. Test Principle:

The QuickScreen™ Oxycodone Test is a competitive immunoassay that is used to screen for the presence of Oxycodone and its metabolites in urine. It is a chromatographic absorbent device in which drugs or drug metabolites in the sample compete with drug/ protein conjugate on a porous membrane for a limited number of antibody/ dye conjugate binding sites. The test device employs a unique combination of monoclonal and polyclonal antibodies to selectively identify Oxycodone and its metabolites.

In the procedure, the absorbent end of the device is inserted in the urine sample. Urine is absorbed into the device by capillary action, mixes with the antibody/ dye conjugate and flows across the pre-coated membrane. When sample Oxycodone levels are below 100 ng/mL (the detection sensitivity of the test) antibody/ dye conjugate binds to the drug / protein conjugate immobilized in the Test Region (T) of the device. This produces a colored Test Band that regardless of its intensity indicates a negative result.

When sample Oxycodone levels are at or above 100 ng/mL, the free drug in the sample binds to the antibody/ dye conjugate, preventing the antibody/ dye conjugate from binding to the drug/ protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band, indicating a potentially positive sample.

In either case, a colored Control Band is produced in the Control Region (C) by a non-specific antibody-dye/ conjugate reaction. This band serves as a built in quality control device, demonstrating migration of the urine sample across the membrane as well as confirming that the test is complete.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

To determine the precision of the QuickScreen™ Oxycodone Test within and between assays, eight separate normal urine pools were spiked with Oxycodone metabolites as follows:

	Concentration (ng/mL)
<1% to 25% of cutoff	20
26% to 50% of cutoff	31
51% to 75% of cutoff	62
76% to cutoff	77
Cutoff to 125% of cutoff	105
126% to 150% of cutoff	152
151% to 175% of cutoff	173
176% to 200% of cutoff	199

One replicate of each level was assayed twice a day for twenty days, in accordance with package insert instructions using two lots of the QuickScreen Oxycodone Test. The interpretations of either negative or positive result was recorded in each case and used to evaluate precision. The results of this evaluation are listed in the table below.

Percent Correct

	Test 1	Test 2	Overall	Percent Correct
Day	8/8	8/8	16/16	100%
1	8/8	8/8	16/16	100%
2	8/8	8/8	16/16	100%
3	8/8	8/8	16/16	100%
4	8/8	8/8	16/16	100%
5	8/8	8/8	16/16	100%
6	8/8	8/8	16/16	100%
7	8/8	8/8	16/16	100%
8	8/8	8/8	16/16	100%
9	8/8	8/8	16/16	100%
10	8/8	8/8	16/16	100%
11	8/8	8/8	16/16	100%
12	8/8	8/8	16/16	100%
13	8/8	8/8	16/16	100%
14	8/8	8/8	16/16	100%
15	8/8	8/8	16/16	100%
16	8/8	8/8	16/16	100%
17	8/8	8/8	16/16	100%
8	8/8	8/8	16/16	100%
19	8/8	8/8	16/16	100%
20	8/8	8/8	16/16	100%

b. Linearity/assay reportable range:

Not applicable. The assay is intended for qualitative use.

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

There are no controls or calibrators provided with or specifically identified for use in the package insert.

STABILITY

The sponsor specifies the method used to analyze the material, environmental storage conditions, frequency of testing, baseline against which measurements are compared, and acceptance criteria for the study. Accelerated studies are being used by the sponsor to estimate the expiration date, however, on-going real time

studies are being performed.

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.

QuickScreen™ and ABMC RapidOne Oxy compared to GC/MS Method
Correlation around Cut-off

QuickScreen	18	22
RapidOne Oxy	18	22
GCMS	18	22

Sample range across assay range: quantification by GC/MS

ng/mL	75-80	81-85	86-90	91-95	96-100	101-105	106-110	111-115	116-125
Sample n	8	4	1	6	4	3	3	4	7
Pharmatech	8 neg	4 neg	1 neg	6 neg	3 neg 1 pos	3 pos	3 pos	4 pos	7 pos
ABMC	8 neg	4 neg	1 neg	6 neg	3 neg 1 pos	3 pos	3 pos	4 pos	7 pos

All results indicating a positive sample were confirmed by GC/MS testing. All samples which were confirmed to be Oxycodone positive were confirmed to be positive at a level > 100ng/mL.

e. Analytical specificity:

Specificity studies included testing of cross-reacting metabolites, potential exogenous interferences and potential endogenous interferences. Each chemical or biological analyte was spiked into aliquots of a normal urine pool. The pools were tested for possible interference in the assay in accordance with the package insert procedure. The chemical/agent and the concentration (in µg/mL) at which tested is recorded. Any chemical/agent producing a result equivalent to the cutoff (i.e.: positive) is noted in the following table. No compound tested at the level indicated exhibited any sign of interference in the test.

Chemical Analytes	µg/mL	Test Result	Chemical Analysis	µg/mL	Test Result
Acetone	10,000	Neg	Mephentermine	100	Neg
4-Aceamidophenol	1,000	Neg	Meprobamate	100	Neg
6-Acetylmorphine	100	Neg	Mescaline	100	Neg
6-Acetylcodeine	100	Neg	Metanephine DL	100	Neg
Albumin	100	Neg	(±) Methadone	100	Neg

Chemical Analytes	µg/mL	Test Result	Chemical Analysis	µg/mL	Test Result
Acetylsalicylic Acid	2,000	Neg	(+) Methamphetamine	100	Neg
N-Acetylprocainamide	100	Neg	Methaqualone	100	Neg
Alphenal	100	Neg	(±) 3,4-Methylenedioxy-methamphetamine	100	Neg
Alprazolam	100	Neg	Methylphenidate	1,000	Neg
Amantadine	100	Neg	Methyprylon	100	Neg
(+) Amethopterin	100	Neg	Metoclopramide	100	Neg
Amikacin	200	Neg	(±) Metoprolol	100	Neg
DL-Aminoglutethimide	100	Neg	Morphine	0.30	Neg
Amino pyrene	100	Neg	Morphine 3-β-D Glucuronide	0.30	Neg
Amitriptyline	100	Neg	2-Methyl-3-(3,4Dihydrophenly) DL & L Alanine	100	Neg
Amobarbital	100	Neg	(±) Methylenedioxy meth-amphetamine	100	Neg
Amoxicillin	300	Neg	6-Methylenedioxymeth-amphetamine	100	Neg
Ampicillin	100	Neg	Nafcillin	100	Neg
D-Amphetamine	100	Neg	Nalorphine	0.50	Neg
DL-Amphetamine	100				
L-Amphetamine	100				
Apomorphine	100	Neg	Naloxone	0.40	Neg
Ascorbic Acid	60,000	Neg	Naltrexone	5.00	Neg
Aspartame	100	Neg	Naphazoline	100	Neg
Aspartic Acid D, L, & DL	100	Neg	α Naphthaleneacetic Acid	100	Neg
Atropine	100	Neg	β Naphthaleneacetic Acid	100	Neg
Barbital	100	Neg	Naproxen	1,000	Neg
Barbituric Acid	100	Neg	Netilmicin	100	Neg
Benzoic Acid	100	Neg	Niacinamide	100	Neg
Benzoylcegonine	100	Neg	Nialamide	100	Neg
Benzphetamine	100	Neg	Nicotinic Acid	100	Neg
Benztropine methane sulfonate	100	Neg	Nifedipine	100	Neg
Bilirubin	100	Neg	Nitrazepam	100	Neg
Bromazepam	100	Neg	Nomifensine	100	Neg
2-Bromo-α	100	Neg	Norcodeine	100	Neg

Chemical Analytes	µg/mL	Test Result	Chemical Analysis	µg/mL	Test Result
Ergocryptine					
(+)-Brompheniramine	100	Neg	11 Nor Δ^8 THC Carboxylic Acid	10	Neg
Butabarbital	100	Neg	11 Nor Δ^9 THC Carboxylic Acid	5	Neg
Butalbital	100	Neg	NOR doxepin	100	Neg
Butethal	100	Neg	Norethindrone	100	Neg
Caffeine	20,000	Neg	Normorphine	10	Neg
Cannabidiol	100	Neg	Nortriptyline	100	Neg
Cannabinol	100	Neg	Noscapine	200	Neg
Carbamazepine	100	Neg	Nylidrin	100	Neg
Cephalexin	100	Neg	Orphenadrine	1,000	Neg
Chloramphenicol	100	Neg	Oxalic Acid	1,000	Neg
Chlordiazepoxide	100	Neg	Oxazepam	100	Neg
Chloroquine	200	Neg	Oxycodone	0.45	Neg
Chlorpropamide	100	Neg	Oxymetazoline	100	Neg
(+) and (\pm) Chlorpheniramine	100	Neg	Papaverine	100	Neg
Chlorpromazine	100	Neg	Penicillin G	100	Neg
Chlorpropamide	100	Neg	Pentazocine	100	Neg
Chlorprothixene	100	Neg	Pentobarbital	100	Neg
Cimetidine	100	Neg	Phencyclidine	100	Neg
Clemastine	100	Neg	Phenelzine	100	Neg
Clonazepam	100	Neg	Pheniramine	100	Neg
Clonidine	100	Neg	Phenobarbital	100	Neg
Clomipramine	100	Neg	Phenothiazine	100	Neg
Cocaine	100	Neg	Phterminine	100	Neg
Codeine	100	Neg	Phenyl acetone	100	Neg
(-)- Cotinine	100	Neg	Phenylbutazone	100	Neg
Creatinine	10,000	Neg	trans 2 phenyl cyclopropylamine	100	Neg
Cyclobenzaprine	100	Neg	L-Phenylephrine	100	Neg
Cyclizine	100	Neg	(R) (+) α Phenylethylamine	100	Neg
Cyproheptadine	100	Neg	(\pm) α Phenylethylamine	100	Neg
Cyclosporin A	100	Neg	β Phenylethylamine	100	Neg
Cyproheptadine	100	Neg	(\pm) phenylpropanolamine	100	Neg
Deoxyephedrine	100	Neg	Piroxicam	100	Neg
Desmethyldiazepam	100	Neg	Potassium Chloride	500	Neg
Dextromethorphan	0.50	Neg	Prazepam	100	Neg

Chemical Analytes	µg/mL	Test Result	Chemical Analysis	µg/mL	Test Result
5,5 Diallylbarbituric Acid	100	Neg	Prednisolone	100	Neg
Diazepam	100	Neg	Primidone	100	Neg
Diflunisal	100	Neg	Procainamide	100	Neg
Digoxin	100	Neg	Procaine	100	Neg
Dihydrocodeine	100	Neg	Prochlorperazine	100	Neg
4-Dimethylaminoantipyrine	100	Neg	Promazine	100	Neg
Diphenhydramine	100	Neg	Promethazine	100	Neg
Diphenoxylate	100	Neg	(+) propoxyphene	100	Neg
Diphenylhydantoin 5,5	100	Neg	2-propylpantoic Acid	100	Neg
Disopyramide	100	Neg	Protriptyline	100	Neg
Doxepin	100	Neg	Pyrilamine	100	Neg
Doxylamine	100	Neg	Quinidine	100	Neg
2 Ethylidene-1,5 Dimethyl-3,3 Diphenyl pyrrolidine	100	Neg	Quinine	100	Neg
Ψ Ephedrine (+)(±) and (-)	1,000	Neg	Ranitidine	100	Neg
Ephedrine (+) (±) and (-)	1,000	Neg	Riboflavin	750	Neg
Epinephrine (±) and (-)	1,000	Neg	(-) Scopolamine	100	Neg
Erythromycin	100	Neg	Secobarbital	100	Neg
Estriol	100	Neg	Sodium Chloride	60,000	Neg
Estrone 3 Sulfate	100	Neg	Sulindac	100	Neg
Ethanol	10,000	Neg	Temazepam	100	Neg
Ethosuximide	100	Neg	Terbutaline	100	Neg
Ethyl-p-Aminobenzoate	100	Neg	Tetracycline	200	Neg
Ethylmorphine	0.35	Neg	Tetraethylthiuram Disulfide	100	Neg
Fenfluramine	100	Neg	Δ ⁸ Tetrahydrocannabinol	100	Neg
Fenoprofen	100	Neg	Δ ⁹ Tetrahydrocannabinol	100	Neg
Fentanyl	10	Neg	Tetrahydrozoline	100	Neg
Flunitrazepam	100	Neg	Theophylline	100	Neg
Flurazepam	100	Neg	Thioridazine	100	Neg
Furosemide	100	Neg	cis- Thiothixene	100	Neg
Gentamicin	100	Neg	Tobramycin	100	Neg

Chemical Analytes	µg/mL	Test Result	Chemical Analysis	µg/mL	Test Result
Gentisic Acid	100	Neg	Triamterene	100	Neg
Glucose	60,000	Neg	Triazolam	100	Neg
DL Glutethimide	100	Neg	Trifluoperazine	200	Neg
Griseofulvin	100	Neg	Triflupromazine	100	Neg
Guaiacol glyceryl Ester	100	Neg	DL Trihexyphenidyl	100	Neg
Hemoglobin, human	100	Neg	Trimethobenzamide	100	Neg
Heroin	100	Neg	Trimethoprim	100	Neg
Hexobarbital	100	Neg	Trimipramine	300	Neg
Hydrochlorothiazide	100	Neg	Tripolidine	100	Neg
Hydrocodone	0.40	Neg	Tyramine	100	Neg
5 Hydroxyindol-3 Acetic Acid	100	Neg	Urea	60,000	Neg
o Hydroxy hippuric Acid	2,000	Neg	Uric Acid	100	Neg
5 Hydroxyindole-2 Carboxylic Acid	100	Neg	Vancomycin	100	Neg
11 Hydroxy ⁹ THC	5	Neg	(±) Verapamil	1,000	Neg
3 Hydroxytyramine	100	Neg	Zomepirac	100	Neg
Levorphanol	0.5	Neg			
Lidocaine	100	Neg			
Lithium Carbonate	100	Neg			
(±) Lorazepam	100	Neg			
Lormetazepam	100	Neg			
Lysergic Acid Diethylamide	2.5	Neg			
Medazepam	100	Neg			
Melanin	100	Neg			
Meperidine	100	Neg			

Interference and cross reactivity studies were performed by testing the drug analytes in the QuickScreen™ Oxycodone Test with other biological compounds found in urine as well as various chemical agents. Below is a list of drugs which yield a positive result at or above the concentration (ng/mL) stated:

Analyte	Concentration (ng/mL)
Hydrocodone	25,000 ng/mL
Hydromorphone	50,000 ng/mL
Norcodeine	100,000 ng/mL
Oxycodone	100 ng/mL
Oxymorphone	100 ng/mL

a. Assay cut-off:

The assay cutoff was determined using spiked urine samples in a controlled study. The assay cutoff for the Pharmatech, Inc. QuickScreen™ Oxycodone Test is 100 ng/mL.

2. Comparison studies:
 - a. *Method comparison with predicate device:*

To compare the accuracy of the QuickScreen™ Oxycodone Test to detect the presence or absence of Oxycodone in urine samples to results obtained with the American Biomedica RapidOne Oxy Test (ABMC) (k014101) predicate device. A total of one hundred and ninety two (192) samples obtained from clinical sites were used. All sample collection was performed at these clinical sites. Testing was performed at Pharmatech. Immediately upon completion of the assays, results were visually scored as “negative” (absence of Oxycodone metabolites in concentrations of 100 ng/mL or greater) or “positive” (presence of Oxycodone or Oxycodone metabolites in concentrations of 100 ng/mL or greater) by the technician. Quality assurance personnel then verified all results. After all in-house testing was completed the samples were analyzed by gas chromatography / mass spectrometry. Test results were recorded in the equivalency summary protocol by QC personnel.

Results

Of the 192 urine samples collected 192 were tested. The performance characteristics of the QuickScreen™ Oxycodone Test to the ABMC RapidOne assay are presented in the table below.

QuickScreen™ versus ABMC Uncorrected Clinical Correlation

	Positive	Negative
QuickScreen	98	94
RapidOne Oxy	98	94
Sensitivity	98/98	= 100%
Specificity	94/94	= 100%
Accuracy	192/192	= 100%

ABMC			
QuickScreen		+	-
	+	98	0
	-	0	94

As presented in the above chart one hundred ninety two (192) urine samples evaluated in the ABMC – QuickScreen comparison study, ninety eight (98) were positive and ninety four (94) were negative by the ABMC RapidOne Oxy test. The QuickScreen test identified 98 positive and 94 negative samples.

Lastly, the performance characteristics of the QuickScreen™ Oxycodone Test, ABMC RapidOne Oxy Test are compared to the GC/MS method presented in the table below.

**QuickScreen™ and ABMC RapidOne Oxy compared to GC/MS Method
Combined Correlation**

QuickScreen	80	72
RapidOne Oxy	80	72
GC/MS	80	72

Sample range across assay range: quantification by GC/MS

Ng/mL	0-100	101-200	201-300	301-400	401-500	501-800	801-1000	1001-2000	>2000
Sample n =	72	16	13	8	7	8	11	10	7

All results indicating a positive sample were confirmed by GC/MS testing. All samples which were confirmed to be Oxycodone positive were confirmed to be positive at a level >100 ng/mL

Overall the QuickScreen™ Oxycodone Test obtained an accuracy of 100% when compared to the ABMC predicate device. The QuickScreen™ test correctly detected 100% of the positive samples and 100% of the negative samples.

b. Matrix Comparison

Not applicable since this test is for Oxycodone in Urine samples only.

3. Clinical studies:

a. Clinical sensitivity:

Clinical studies are not typically submitted for this device type.

b. Clinical specificity:

Clinical studies are not typically submitted for this device type.

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

Not applicable

4. Clinical cut-off:

Not applicable for this device type.

5. Expected values/Reference range:

Not applicable for this device type.

N. Conclusion:

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