

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

A. 510(k) Number:

k181945

B. Purpose for Submission:

Modification of a previously cleared device to add Imipramine and Buprenorphine to the test panel.

C. Measurand:

Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy (MDMA), Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Marijuana, Imipramine, Buprenorphine

D. Type of Test:

Qualitative lateral flow immunoassay

E. Applicant:

Phamatech, Inc.

F. Proprietary and Established Names:

QuickScreen Pro Multi Drug Screening Test, Model 9395Z

G. Regulatory Information:

1. Regulation section:

Product Code	Regulation Number	Regulation Description
DKZ	862.3100	Amphetamine test system
DIS	862.3150	Barbiturate test system
JXM	862.3170	Benzodiazepine test system
DIO	862.3250	Cocaine and cocaine metabolite test system
DJC	862.3610	Methamphetamine test system
DJR	862.3620	Methadone test system
DJG	862.3650	Opiate test system

Product Code	Regulation Number	Regulation Description
LCM	Unclassified	Phencyclidine
LDJ	862.3870	Cannabinoid test system
LFG	862.3910	Tricyclic antidepressant drugs test system

2. Classification:

Class II

4. Panel:

Toxicology

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The QuickScreen™ Pro Multi Drug Screening Test Model 9395Z is a screening test for the qualitative detection of amphetamines, barbiturates, benzodiazepines, cocaine, ecstasy (MDMA), methadone, methamphetamine, opiates, oxycodone, phencyclidine, marijuana, tricyclic antidepressants (Imipramine) and buprenorphine in urine at the cut-off concentrations listed below. Test for barbiturates, benzodiazepine, oxycodone, buprenorphine and tricyclic antidepressants (Imipramine) cannot distinguish between abused drugs and certain prescription medications. The test is intended for professional use only.

Analyte	Abbreviation	Cut-off Concentration (ng/ml)
Amphetamines	AMP	1000
Barbiturates	BAR	200
Benzodiazepines	BZD	200
Cocaine	COC	300
Ecstasy	MDMA	500
Methadone	MTD	300
Methamphetamine	MET	500
Opiates	OPI	300
Oxycodone	OXY	100
Phencyclidine	PCP	25
Marijuana	THC	50

Analyte	Abbreviation	Cut-off Concentration (ng/ml)
Tricyclic Antidepressants (Imipramine)	TCA (Imipramine)	1000
Buprenorphine	BUP	10

This test provides only a preliminary test result. A more specific alternate testing method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Other 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.

3. Special conditions for use statement(s):

For prescription use only

4. Special instrument requirements:

Not applicable. These devices are single use and disposable.

I. Device Description:

The QuickScreen™ Pro Multi Drug Screening Test, Model 9395Z is a competitive immunoassay that is used to screen for the presence of the following drugs of abuse in urine: Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, Marijuana, Imipramine, and Buprenorphine. The device is single-use utilizing a cup format. Each kit consists of the following materials:

- Twelve separate test strips for the 13 target drugs. Each test strip device includes monoclonal anti-drug antibody/colloidal gold conjugate specific to each drug coated in the sample path, drug derivative/protein conjugate immobilized as a line in the Test Region (T), and goat anti-rabbit antibody immobilized as a line in the Control Region (C).
- Instructional insert
- Urine sample collection cup
- Built-in timer to identify when test results should be read

J. Substantial Equivalence Information:

1. Predicate device name(s):

At Home Drug Test 12: Model 9308Z

2. Predicate 510(k) number(s):
k070009

3. Comparison with predicate:

Similarities		
Item	QuickScreen™Pro Multi Drug Screening Test, Model 9395Z	At Home Drug Test 12: Model 9308Z (k070009) Predicate Device
Indications for use	The QuickScreen™Pro Multi Drug Screening Test Model 9395Z is an screening test for the qualitative detection of amphetamines, barbiturates, benzodiazepines, cocaine, ecstasy, methadone, methamphetamine, opiates, oxycodone, phencyclidine, marijuana, tricyclic antidepressants (Imipramine) and buprenorphine in urine at the cut-off concentrations listed.	Same
Methodology	Lateral flow immunoassay based on the principle of antigen and antibody immunochemistry	Same
Results	Qualitative	Same
Analyte Cut-off	Amphetamines (AMP): 1000 ng/ml Barbiturates (BAR): 200 ng/ml Benzodiazepines: (BZD): 200 ng/ml Cocaine (COC): 300 ng/ml Ecstasy (MDMA): 500 ng/ml Methadone (MTD): 300 ng/ml Methamphetamine (MET): 500 ng/ml Opiates (OPI): 300 ng/ml Oxycodone (OXY): 100 ng/ml Phencyclidine (PCP): 25	Same for shared analytes

Similarities		
Item	QuickScreen™Pro Multi Drug Screening Test, Model 9395Z	At Home Drug Test 12: Model 9308Z (k070009) Predicate Device
	ng/ml Marijuana (THC): 50 ng/ml Tricyclic Antidepressants (TCA): 1000 ng/ml Buprenorphine (BUP): 10 ng/ml	
Configuration	Cup	Same
Specimen Type	Urine	Same
Use	Single-use	Same

Differences		
Item	QuickScreen™Pro Multi Drug Screening Test Model 9395Z	At Home Drug Test 12: Model 9308Z (k070009) Predicate Device
Use Setting	Prescription	OTC

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

None referenced.

L. Test Principle:

The QuickScreen™ Pro Multi Drug Screening Test, Model 9395Z device employs lateral flow immunochromatographic technology, which involves the recognition and formation of a specific antibody/target drug complex. Drug in the sample and drug-labeled conjugate compete for antibody binding sites. During testing, a urine specimen migrates upward by capillary action. If target drugs present in the urine specimen are below the cut-off concentration, it will not saturate the binding sites of its specific monoclonal mouse antibody coated on the particles. The antibody-coated particles will then be captured by immobilized drug-conjugate and a visible colored line will show up in the test line region (T). The colored line will not form in the test line region if the target drug level exceeds its cutoff-concentration because it will saturate all the binding sites of the antibody coated on the particles. The control line (C) serves as an internal quality control to ensure proper sample volume has been added to the test and that the sample has correctly migrated up the test strip.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

A precision/reproducibility study was performed using the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device at three separate point of care (POC) sites. Multiple replicates of each of the nine drug concentrations (prepared by spiking negative urine samples with buprenorphine or TCA (Imipramine)) was assayed over a minimum of 5 days. The tests were done in accordance with the package insert instructions using one lot of the device, and a summary of the results are provided in the table below. Precision performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

Test Results for BUP				
Level	BUP Conc. (ng/ml)	% of cutoff	Result (Neg/Pos)	% Correct
1	0.00	0	80/0	100%
2	2.58	- 75%	80/0	100%
3	5.62	- 50%	80/0	100%
4	7.13	- 25%	80/0	100%
5	10.42	cutoff	0/80	100%
6	12.27	+ 25%	0/80	100%
7	16.83	+ 50%	0/80	100%
8	17.69	+ 75%	0/80	100%
9	20.43	+100%	0/80	100%

Test Results for TCA (Imipramine)				
Level	TCA Conc. (ng/ml)	% of cutoff	Result (Neg/Pos)	% Correct
1	0.00	0	80/0	100%
2	249.53	- 75%	80/0	100%
3	547.65	- 50%	80/0	100%
4	767.56	- 25%	80/0	100%
5	1026.32	cutoff	0/80	100%
6	1267.91	+ 25%	0/80	100%
7	1589.23	+ 50%	0/80	100%
8	1789.60	+ 75%	0/80	100%
9	2089.3	+100%	0/80	100%

b. *Linearity/assay reportable range:*

Not applicable.

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

There are no external controls supplied with the device.

Real time stability tests were conducted over 24 months. Protocol and acceptance criteria were found to be acceptable. The manufacturer claims that the devices are stable for 22 months.

d. *Detection limit:*

See precision data in Section M.1.a., above, for assay performance around the claimed cutoff concentrations.

e. *Analytical specificity:*

Cross-reactivity: Cross-reactivity studies for BUP and Imipramine were conducted for the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device (BUP and TCA) by testing structurally similar compounds. The compounds in the below table were tested for cross reactivity, and the lowest concentration causing a positive result was determined to calculate the percentage of cross-reactivity. Cross-reactivity performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

BUP Cross Reactivity		
Compound	Lowest conc. resulting in positive result	% cross reactivity
Norbuprenorphine	20 ng/ml	50%
Morphine	N/A	<0.01%
Buprenorphine-3-β-D-Glucuronide	10 µg/ml	0.1%
Norbuprenorphine-3-β-D-Glucuronide	20 µg/ml	0.2%
Oxymorphone	N/A	<0.01%
Hydromorphone	N/A	<0.01%
TCA Cross Reactivity		
Compound	Lowest conc. resulting in positive result	% cross reactivity
Amitriptyline	250 ng/ml	400%
N-Desmethyldomipramine	100 mg/ml	1%
N-Desmethyldomipramine-maleate	100 mg/ml	1%
Cyclobenzaprine	500 ng/ml	200%
Cyproheptadine	100 mg/ml	1%
Desipramine	250 ng/ml	400%
Doxepin	100 ng/ml	1000%

Imipramine	1000 ng/ml	100%
Maprotiline	N/A	<0.01%
Nordoxepin	N/A	<0.01%
Nortriptyline	100 mg/dl	1%
Promazine	N/A	<0.01%
Promethazine	N/A	<0.01%
Protryptiline	100 mg/dl	1%

Interference: The following compounds did not show interference with the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device (for BUP and Imipramine) when tested at BUP and Imipramine concentration of 50% and 150% of cut-off values. Interference performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

Compound	Conc. tested (µg/ml)	Compound	Conc. tested (µg/ml)
6-Acetylcodeine	100	Ketamine	100
6-Acetylmorphine	100	Levallorphan Tartrate	100
Acetaminophen	100	Lidocaine	100
Acetaminophen	500	Lormetazepam	100
Acetylsalicylic Acid (Aspiring)	500	Lysergic Acid Diethylamide	100
Acetylsalicylic Acid (Aspiring)	1000	MDEA	100
Alprazolam	100	d-Methamphetamine	100
α-Hydroxyalprazolam	100	l-Methamphetamine	100
Aminogluthethimide	100	Metanphrine	100
Amobarbital	100	Methaqualone	100
S(+) Amphetamine	100	Metoprolol	100
Aprobarbital	100	Methylenedioxyamphetamine (MDA)	100
Apromorphine	100	Methylphenidate	100
Ascorbic Acid	10,000	Methylphenidate	500
Ascorbic Acid	15,000	Methylphenidate	1000
Ampicillin	100	Metoclopramide	150
Amoxicillin	100	Metoclopramide	300
Barbituric Acid	100	Morphine	100
Benzoylcegonine	100	Morphine-3-β-D Glucuronide	100
Oxalic Acid	100	Nafcillin	100
Benzphetamine	100	Nalbuphine	100
Benztrapine Methane Sulfonate	100	Naloxone	100
Bilirubin	100	Naltrexone	100

Compound	Conc. tested (µg/ml)	Compound	Conc. tested (µg/ml)
Bromazepam	100	Naphazoline	100
Brompheniramine	100	Netilmicin	100
Butabarbital	100	Nifedipine	100
Butabital	100	Nitrazepam	100
Butalbital	100	Norbuprenorphine	100
N-Desmethylimipramine	100	Norcodeine	100
Caffeine	100	Nordoxepin	100
Caffeine	500	Normorphine	100
Cannabidiol	100	Noroxymorphone	100
Cannabidiol	100	Nylidren	100
Cannabinol Delta 9	5	Oxazepam	100
Chlordiazepoxide	100	Oxycodone	100
Chlorpropamide	100	Oxymetazoline	100
Chlorprothixene	100	Penicillin-G	100
Chloroquine	100	Pentazocine	100
Chlorpheniramine	100	Pentobarbital	100
Clamastine	100	Phencyclidine	100
Clorimpramine	100	Phenylephrine	100
Clonazepam	100	Phenylbutazone	100
Codeine	100	Phenylcyclopropylamine HCl	100
Cotinine	100	Phenylethylamine	100
Creatinine	2500	Terbutaline	100
Creatinine	5000	Phenytoin	100
Cyclizine	100	Prazepam	100
Cyclosporin	100	Prednisolone	100
Desalkylflurazepam	100	Primadone	100
Dextromethorphan	100	Procainamide	100
Diazepam	100	Promethazine	100
Dihydrocodeine	100	Promazine	100
Dipehnylhydantoin	100	Propoxyphine	100
Dipehnylhydantoin	2500	S, S (+)-Pseudoephedrine	100
Dipehnylhydantoin	5000	Pyrilamine	100
Doxylamine	100	Quinidine	100
Ecgonine	100	Ranitidine	100
Ecgonine Methyl Ester	100	Salicylic Acid	100
Efavirenz	100	Scopolamine	100
Ephedrine	100	Secobarbital	100
Epinephrine	100	Temazepam	100
Erythromycin	100	Thioridazine	250
Ethanol	10,000	Thioridazine	500
Ethanol	25,000	Thiothixene	100
Ethanol	50,000	Traylcyromine	100

Compound	Conc. tested (µg/ml)	Compound	Conc. tested (µg/ml)
Ethylmorphine	100	Triamptere	100
Fenfluramine	100	Triazolam	100
Fentanyl	100	α-Hydroxytriazolam	100
Flunitrazepam	100	Triflupromazine	100
Griseofuvin	100	Trimipramine	100
Hydrocodone	100	Tyramine	100
Hydromorphone	100	Urea	10,000
Hexabarbital	100	Urea	30,000
Ibuprofen	50	Urea	60,000
Ibuprofen	100	Uric Acid	100
Indomethacin	100	Verapamil	100
Isoxsuprine	100	Verapamil	500
Kanamycin	100	Verapamil	1000
MDMA	100	Naproxime	100
Mephentermine	100		

pH sensitivity: Testing was conducted for BUP and Imipramine with the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device to determine the influence of sample pH on test results. Samples were tested in triplicate at a pH of 4.0, 4.5, 5.5, 6.5, 7.5, 8.5 and 9.0. No interference was observed for any pH test conditions. pH interference performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

Specific Gravity: Testing was conducted for BUP and Imipramine with the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device to determine the influence of sample specific gravity on test results. Four samples were tested, spanning a range of specific gravity from 1.002 to 1.040. All were tested in quadruplicate. No interference was observed for any specific gravity test conditions. Specific gravity interference performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

f. Assay cut-off:

Characterization of how the device performed analytically around the claimed cutoff concentration appears in the precision section M.1.a., above.

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison studies were conducted for BUP and Imipramine at four different

sites for the detection of BUP and two sites for the detection of Imipramine, using the QuickScreen™ Pro Multi Drug Screening Test Model 9395Z device. All tests were conducted using unaltered urine clinical samples. Accuracy performance for Amphetamines, Barbiturates, Benzodiazepines, Cocaine, Ecstasy, Methadone, Methamphetamine, Opiates, Oxycodone, Phencyclidine, and Marijuana, was reviewed in k070098.

Method Comparison Site #1

Candidate Device Results	Zero Value Samples by GC/MS	Below 50% cutoff by GC/MS	Near Cutoff Negative (Between 50% below cutoff and cutoff concentration) by GC/MS	Near Cutoff Positive (between cutoff and 150%) by GC/MS	High Positive (above 150%) by GC/MS
BUP					
QuickScreen					
Positive	0	0	3	5	35
Negative	40	32	5	0	0
TCA (Imipramine)					
QuickScreen					
Positive	0	0	1	23	17
Negative	22	20	19	0	0

Discrepant results

Sample	Analyte Detected	Subject Device Result	GC/MS Result (ng/ml)
82	Buprenorphine	Positive	8.21
40	Buprenorphine	Positive	9.04
17	Buprenorphine	Positive	9.29
62	Imipramine	Positive	995.9

Method Comparison POC Site 1

Candidate Device Results	Zero Value Samples	Below 50% cutoff	Near Cutoff Negative (Between 50% below cutoff and cutoff concentration)	Near Cutoff Positive (between cutoff and 150%)	High Positive (above 150%)
BUP					
QuickScreen					
Positive	0	0	3	5	35
Negative	40	32	5	0	0
TCA (Imipramine)					
QuickScreen					
Positive	0	0	1	23	17
Negative	22	20	19	0	0

Discrepant Results

Sample	Analyte Detected	Subject Device Result	GC/MS Result (ng/ml)
82	Buprenorphine	Positive	8.21
40	Buprenorphine	Positive	9.04
17	Buprenorphine	Positive	9.29
62	Imipramine	Positive	995.9

Method Comparison POC Site 2

Candidate Device Results	Zero Value Samples	Below 50% cutoff	Near Cutoff Negative (Between 50% below cutoff and cutoff concentration)	Near Cutoff Positive (between cutoff and 150%)	High Positive (above 150%)
BUP					
QuickScreen					
Positive	0	0	3	5	35
Negative	40	32	5	0	0

Discrepant Results

Sample	Analyte Detected	Subject Device Result	GC/MS Result (ng/ml)
82	Buprenorphine	Positive	8.21
40	Buprenorphine	Positive	9.04
17	Buprenorphine	Positive	9.29

Method Comparison POC Site 3

Candidate Device Results	Zero Value Samples	Below 50% cutoff	Near Cutoff Negative (Between 50% below cutoff and cutoff concentration)	Near Cutoff Positive (between cutoff and 150%)	High Positive (above 150%)
BUP					
QuickScreen					
Positive	0	0	4	5	35
Negative	40	32	4	0	0

Discrepant Results

Sample	Analyte Detected	Subject Device Result	GC/MS Result (ng/ml)
52	Buprenorphine	Positive	6.85
82	Buprenorphine	Positive	8.21
40	Buprenorphine	Positive	9.04
17	Buprenorphine	Positive	9.29

b. Matrix comparison:

N/A

3. Clinical studies:

a. Clinical Sensitivity:

N/A

b. Clinical specificity:

N/A

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

N/A

4. Clinical cut-off:

N/A

5. Expected values/Reference range:

N/A

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

O. Conclusion:

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