

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

**A. 510(k) Number:**

k070009

**B. Purpose for Submission:**

This submission is for the addition of four new analytes intended for over-the-counter (OTC) use; these devices have been previously cleared for prescription use.

**C. Measurand:**

Benzodiazepines, Barbiturates, Methadone and Oxycodone

**D. Type of Test:**

Qualitative Lateral Flow Immunoassay

**E. Applicant:**

Phamatech, Inc.

**F. Proprietary and Established Names:**

At Home Drug Test 12: Models 9308T and 9308Z

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.3150, Enzyme Immunoassay, Barbiturate

21 CFR 862.3170, Enzyme Immunoassay, Benzodiazepine

21 CFR 862.3620, Enzyme Immunoassay, Methadone

21 CFR 862.3650, Enzyme Immunoassay, Opiates

2. Classification:

Class II

3. Product Codes:

DIS, JXM, DJR, and DJG

4. Panel:

Toxicology (91)

**H. Intended Use:**

1. Intended use(s):

Refer to the Indications for use below.

2. Indication(s) for use:

The Phamatech At Home 12 Drug Test: Models 9308T and 9308Z for amphetamines (AMP), barbiturates (BAR), benzodiazepines (BZD), cocaine (COC), ecstasy (MDMA), methadone (MTD), methamphetamine (MET), opiates (OPI), oxycodone (OXY), phencyclidine (PCP) and marijuana (THC) is a screening test for the rapid detection of the drugs listed above in urine. The cut-

off concentrations (ng/ml) for these drugs are as follows: amphetamines (1000), barbiturates (200), benzodiazepines (200), cocaine (300), ecstasy (500), methadone (300), methamphetamine (500), opiates (300), oxycodone (100), phencyclidine (25) and marijuana (50).

The BAR, BZD and OXY assay will yield preliminary positive results when these drugs are ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturates, benzodiazepines or oxycodone in urine.

This test only identifies the presence of these drugs when present at or above the stated cut-off concentration.

This assay provides only a preliminary test result. A more specific alternate analytical method must be used in order to obtain a confirmed analytical result. Gas chromatography / Mass spectrometry (GC/MS) is the preferred confirmatory test method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

This device is not for professional or workplace testing. It is intended for Home Use.

This device is intended for over-the-counter (OTC) consumer use as the first step in a two step process to provide consumers with information concerning the presence or absence of the above stated drugs / drug metabolites in urine. Information regarding confirmation testing – the second step in the process, along with materials for shipping urine samples to the laboratory, are included.

3. Special conditions for use statement(s):

The BAR, BZD and OXY assay will yield preliminary positive results when these drugs are ingested at or above therapeutic doses. There are no uniformly recognized drug levels for barbiturates, benzodiazepines or oxycodone in urine. This test only identifies the presence of these drugs when present at or above the stated cut-off concentration.

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in a two step process to provide consumers with information concerning the presence or absence of the above stated drugs / drug metabolites in urine. Information regarding confirmation testing – the second step in the process, along with materials for shipping urine samples to the laboratory, are included.

4. Special instrument requirements:  
Not applicable.

**I. Device Description:**

The At Home Drug Test 12 Model 9308Z is a single use device utilizing a cup format. The user collects urine in the cup to the recommended volume and fills the labeled vial to two-thirds full. 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 kit includes the following materials: 1 instructional booklet, 1 urine collection cup, 1 labeled vial, 1 plastic pouch with absorbent pad, 1 pre-addressed mailer box and 1 personal identification label.

The At Home Drug Test 12 Model 9308T is a single use dip card device. The user 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 kit includes the following materials: 1 instructional booklet, 1 urine collection cup, 1 labeled vial, 1 plastic pouch with absorbent pad, 1 pre-addressed mailer box and 1 personal identification label.

The At Home Drug Test 12 devices detect up to twelve drugs of abuse. The table presented below lists the drugs of abuse that were previously cleared for OTC use, the 510(k) number they were cleared under and the device format (card or cup).

510(k) #	Device Name	Device Format	Analytes
k030447	At Home Drug Test Model 9150X	Cup	cocaine, THC, opiates, amphetamine/MDA, methamphetamine/MDMA
k010655	At Home Drug Test Model 9150T	Card	cocaine, THC, opiates, amphetamine/MDA, methamphetamine/MDMA
k010651	At Home Drug Test Model 9133T	Card	PCP

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
Quick Screen Pro Multi Drug Screening Test, Model 9153T  
Quick Screen Benzodiazepine (Models 9025, 9026, 9027T, 9153 and 9195X)  
Quick Screen Pro Drug Cup, Model 9195X  
Quick Screen Oxycodone, Model 9120X

2. Predicate K number(s):  
 k000131  
 k043167  
 k001397  
 k043051
3. Comparison with predicate:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	For the qualitative detection of drugs of abuse	Same
Specimen Type	Urine	Same
Principle	Immunochromatographic Lateral Flow Immunoassay	Same
Format	Cup and Card	Same

<b>Differences</b>		
Item	Device	Predicate
Analytes, OTC	Barbiturates, benzodiazepine, oxycodone, methadone, cocaine, THC, opiates, amphetamine/MDA, methamphetamine/MDMA, and PCP	Cocaine, THC, opiates, amphetamine/MDA, methamphetamine/MDMA, and PCP

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

None referenced.

**L. Test Principle:**

The tests employ 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. Absence of a line in the test area is a presumptive positive result, and the presence of a line in the test area is a negative result. 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:*  
 See Clinical Studies section 3c. below for performance data around the cutoffs.
  - b. *Linearity/assay reportable range:*  
 Not applicable.
  - c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*  
 This device has internal process controls. A colored line appearing in the

control region confirms that sufficient sample volume has been applied and that the sample has migrated correctly on the test strip. Users are informed not to interpret the test if a colored line failed to appear in the control region. External controls are not supplied with this device.

- d. *Detection Limit:*  
Performance characteristics have been addressed in k000131 (Phamatech QuickScreen Pro Multi Drug Screening Test), k043167 Phamatech QuickScreen Benzodiazepines Test), k001397 (Phamatech QuickScreen Pro Drug Cup) and k043051 (Phamatech QuickScreen Oxycodone Test).
  - e. *Analytical Specificity:*  
Performance characteristics have been addressed in k000131, k043167, k001397 and k043051.
  - f. *Assay cut-off:*  
Performance characteristics have been addressed in k000131, k043167, k001397 and k043051.
2. Comparison studies:
    - a. *Method comparison with predicate device:*  
Performance characteristics have been addressed in k000131, k043167, k001397 and k043051.
    - 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):*  
Three consumer studies were conducted to determine the device's performance when used by untrained users following the instructions in the labeling. Note: Study number three was performed only with sample solutions containing oxycodone at two concentrations: approximately 67 ng/mL and approximately 109 ng/mL. A questionnaire was used to determine if the untrained users understood the test instructions and the meaning of the results. Consumers were asked if they understood the best time to collect a sample, the directions for collecting a urine sample, performing the test and interpreting the test result. 180 consumers interpreted a total of 1,874 tests and 98% (1,844 of 1,874) were interpreted correctly. Approximately 50% of the participants were female and 50% were male ranging in age from 18 to >60 years of age. Approximately 25 of 180 had less than 12 years of education, approximately 42 of 180 were high school graduates, and approximately 109 of 180 had attended college or graduated from college. There was no

information on the educational background of approximately four consumers.

#### Study #1

109 consumers performed the tests using high clinical samples diluted in normal drug-free urine. Some samples contained as many as ten drugs; there were combinations that contained no drugs at all. Drug concentrations were confirmed by GC/MS. Consumers tested even numbered samples on the test cup device and odd numbered samples on the test card device. Each of the new drugs intended for OTC use, barbiturates, benzodiazepines, methadone and oxycodone, were tested at 0%, 50%, 75%, 125%, and 150% of the target concentration. The drugs previously cleared for OTC use, amphetamines, cocaine, methamphetamines, opiates, PCP, and THC were tested at various cutoff concentrations ranging from 0% to 150% of the target concentrations.

1,073 of 1,081 interpretations made by lay users were correct (99%). At 75% of the cutoff, 99 of the 100 test interpretations were scored as correct. There was one false positive for amphetamines. At  $\leq 50\%$  of the cutoff, 884 of the 891 test interpretations were scored as correct. There was 1 false positive for benzodiazepine and THC, 2 false positives for opiates and 3 false positives for PCP.

#### Study #2

760 unique tests with sample solutions containing amphetamines, methamphetamines, cocaine, benzodiazepine, barbiturates, oxycodone, methadone, opiates, THC and PCP were performed by 38 consumers using drug-free urine that had been spiked with various concentrations and combinations of drugs. Participants tested random coded samples with various combinations of drugs at 75%, 125% and 150% of the target concentrations. Drug concentrations were confirmed by GC/MS. Consumers performed the assays using the test card format.

750 of 760 interpretations (98%) made by lay users were correct. At 75% of cut-off, 229 of 235 interpretations were scored as correct results. There were 6 false positives for oxycodone; 1 false positive for benzodiazepines and 1 false positive for cocaine. At 125% of cut-off 268 of 270 interpretations were scored as correct results. There were 2 Invalid test results; i.e., control and/or test line did not develop. At 150% of cut-off 253 of 255 interpretations were scored as correct results. There was 1 false negative for PCP and 1 false negative for THC.

#### Study #3

Sample solutions containing oxycodone were performed by thirty-three consumers at two Phamatech locations. Thirty of the samples were clinical samples diluted in drug-free urine to an approximate concentration of 67 ng/mL. Three positive samples were Oxycodone 200 ng/ml control diluted to an approximate concentration of 109 ng/mL. Of the total thirty-three

interpretations made by lay users a total of 33 test results were correct. Consumers performed the assays using the test card format.

A total of 1,874 tests were interpreted by lay users and 1,844 tests were interpreted correctly. The sponsor pooled the results obtained by the test cup and test card formats because these formats were demonstrated to be equivalent in 510(k)s previously cleared for these analytes. The summary of the results for Studies 1, 2 and 3 is presented in the tables below:

Drug	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)
Amphetamine	Positive	0	1	27	31
	Negative	93	35	0	0
Methamphetamine	Positive	0	0	27	33
	Negative	93	34	0	0
Cocaine	Positive	0	4	27	33
	Negative	93	30	0	0
Benzodiazepine	Positive	1	1	27	30
	Negative	92	33	0	0
Barbiturate	Positive	0	0	36	32
	Negative	85	34	0	0
Oxycodone	Positive	0	6	30	36
	Negative	89	57	0	0

Drug	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)
Methadone	Positive	0	0	39	41
	Negative	68	34	0	0
Opiates	Positive	2	0	27	33
	Negative	90	33	0	0
THC	Positive	1	0	27	31
	Negative	92	23	0	1
PCP	Positive	3	0	27	25
	Negative	90	34	0	1

The results of the post-survey questionnaire are presented below:

<b>Question:</b>	Easy to Understand	Somewhat Difficult	Difficult
The section “What is the At Home Drug Test” instruction was	169/180	10/180	1/180
When is the best time to collect a sample was	174/180	4/180	2/180
Direction for collecting the urine and performing the test were	161/180	16/180	3/180
The “Interpretation of Your Test Result” section was	163/180	14/180	3/180
Actually reading the test result was	156/180	20/180	4/180
I found the test device format was	173/180	6/180	1/180
The Question and Answer section was	177/180	2/180	1/180

The reading level of the package inserts (less than 8th grade) was determined on MS Word.

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.