

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

A. 510(k) Number:

k070098

B. Purpose for Submission:

Change in the barbiturate cutoff concentration from 200 ng/mL to 300 ng/mL

C. Measurand:

Barbiturates

D. Type of Test:

Qualitative

E. Applicant:

Phamatech, Inc.

F. Proprietary and Established Names:

Phamatech QuickScreen™ Barbiturates Test Models 9019, 9018

Phamatech QuickScreen™ Pro Multi Drug Screening Test model 9317T and 9187Z

G. Regulatory Information:

1. Regulation section:

21 CFR 862.3150 Barbiturate test system

2. Classification:

II

3. Product code:

DIS

4. Panel:

H. Intended Use:

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

Phamatech QuickScreen™ Barbiturates Test Models 9019, 9018

The QuickScreen Barbiturates Test is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of barbiturates in urine. Tests for barbiturates cannot distinguish between abused drugs and certain prescribed medications. The cut-off concentration will be 300 ng/ml (secobarbital). It is intended for professional use only.

Phamatech QuickScreen™ Pro Multi Drug Screening Test Model 9317T

QuickScreen™ Pro Multi Drug Screening Test is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, barbiturates, benzodiazepines, methadone and THC in urine. Tests for prescription drugs cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

Amphetamine	1000 ng/ml
Cocaine	300 ng/ml
Methamphetamine	1000 ng/ml
Opiates	2000 ng/ml
PCP	25 ng/ml
Barbiturates (Secobarbital)	300 ng/ml
Benzodiazepines	200 ng/ml
Methadone	300 ng/ml
THC	50 ng/ml

Phamatech QuickScreen™ Pro Drug Cup Model 9187Z

QuickScreen™ Pro Drug Cup is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, Barbiturates, benzodiazepines, methadone and THC in urine. Tests for prescription drugs cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. It is intended for professional use only.

Amphetamine	1000 ng/ml
Cocaine	300 ng/ml
Methamphetamine	1000 ng/ml
Opiates	2000 ng/ml
PCP	25 ng/ml
Barbiturates (Secobarbital)	300 ng/ml
Benzodiazepines	200 ng/ml
Methadone	300 ng/ml
THC	50 ng/ml

3. Special conditions for use statement(s):

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.

4. Special instrument requirements:

Not applicable.

I. Device Description:

The single barbiturate test and multi drug test device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. The device is available in the cassette, dipstick and cup formats. Drugs, if present in concentrations below the cutoff level, will not saturate the binding sites of the antibody coated particles on the drug specific test strips. The goat-anti-rabbit IgG antibody-coated particles will then be captured by immobilized drug-specific conjugate. If the level of drug in the urine specimen is below the cutoff concentration, the T line appears as a visible burgundy line. If the level of drug in the urine specimen is above the cutoff, no T line develops. The control line (C line) serves as an internal quality control of the system. It should always appear as a burgundy-colored band regardless of the presence of the drug.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Phamatech QuickScreen Model 9026 and 9025 (Cassette and Dipstick)
Phamatech QuickScreen Pro Drug Cup Model 9195X and 9153 T (Integrated Cup and Dip Card).

2. Predicate K number(s):

k82152, k001397 and k043167

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Cup and Card		
Specimen	Urine	Urine
Methodology	Lateral flow immunoassay	Lateral flow immunoassay
Type	Qualitative	Qualitative
Analytes	Secobarbital	Secobarbital
User	Professional use	Professional Use
Cup and Dip card		
Methodology	Lateral flow immunoassay	Lateral flow immunoassay
Formats	Cup and Dip card	Cup and Dip card
Specimen	Urine	Urine
Type	Qualitative	Qualitative
Analytes	cocaine (benzoylecgonine) THC, opiates, amphetamine, methamphetamine, benzodiazepines, barbiturates, methadone PCP	cocaine (benzoylecgonine) THC, opiates, amphetamine, methamphetamine, benzodiazepines, barbiturates, methadone PCP

Differences		
Item	Device	Predicate
Cutoff	Secobarbital 300 mg/mL	Secobarbital 200 mg/mL

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

None were referenced.

L. Test Principle:

The QuickScreen™ Barbiturate tests are chromatographic absorbent devices in which drug metabolites in a sample compete with drug conjugate, immobilized on a porous support membrane, for a limited number of goat anti-rabbit IgG antibody binding sites. When a urine sample is applied to a test device, the barbiturates, if present in the test sample at a concentration of less than 300 ng/mL, will not block the binding sites of the immobilized antigen conjugate in the test region. The dye conjugate will migrate to the test region with the urine. There the dye conjugate will bind to barbiturate derivative immobilized in the test region of the membrane. As a result, a visible rose pink band will form in the test region, indicating a negative

result. Conversely, where barbiturate concentrations are 300 ng/mL or more the antibody - dye conjugate binds to free drug forming a complex that competes with the immobilized antigen conjugate in the test region. This prevents the development of a rose pink band, indicating a positive sample.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Eight normal urine pools were spiked with secobarbital to concentrations of 0, 122, 162, 274, 300, 400, 490 and 800 ng/mL and confirmed by GC/MS. One replicate per level was assayed five times per day for 10 days with the cassette format. The results are shown in the table below.

Phenobarbital Conc. (ng/mL)	% Cutoff Concentration	% Correct
0	<25% of cutoff	100
122	26% to 50% of cutoff	100
162	51% to 75% of cutoff	100
274	76% to cutoff	100
300	Cutoff to 125% of cutoff	100
400	126% to 150% of cutoff	100
490	151% to 175% of cutoff	100
800	>176% of cutoff	100

The sponsor conducted a bridging study to assess the equivalency of the 4 format types (dipstick, cassette and dip-card and cup). Fifty GC/MS confirmed urine samples that ranged from 50 to 2000 ng/mL were obtained from clinical sites and were tested in duplicates. The sponsor's results showed 100% agreement between formats.

b. Linearity/assay reportable range:

Not applicable. This assay is intended for qualitative use.

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

This device has an internal process control. A 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 line does not form in the control region. External controls are not supplied with this device but the manufacturer recommends the use of external controls in the labeling.

d. Detection limit:

See assay cutoff section below.

e. Analytical specificity:

To test the consistency of the test line and control line development, the sponsor tested four urine control pools and five patient samples. The pools and samples were analyzed in replicates of three using three lots of the QuickScreen Barbiturate 300 dipstick test. The results indicate that the development times were under the ten minutes given in the package insert.

The sponsor conducted a prozone study to test the effects of high barbiturate concentrations on the device. A GC/MS confirmed positive urine sample (>3000 ng/mL) was tested with three lots of the QuickScreen Barbiturate 300 test. The sponsor reported no interference with high barbiturate concentrations.

The sponsor conducted a prozone effect (hook-effect) study to evaluate the device's ability to detect high barbiturate concentrations. A GC/MS confirmed positive for barbiturate (concentration greater than 3000 mg/mL) was tested in three lots of the QuickScreen™ Test. All results for the barbiturates were positive and sponsor reports that there was no prozone effect observed.

The sponsor conducted a pH study to test for pH effects on the device. Three urine samples were aliquoted at barbiturate concentrations of 0, 835, and 3000 ng/mL. Each sample was then again aliquoted into five individual samples and each was adjusted to pH 4.5 to 8.5 (increments of 1 pH). The sponsor reports no adverse effect with varying pH levels.

The sponsor conducted a test strip flexibility study to determine the dip time for the strip test. Five urine samples were selected at random for this study. The samples had barbiturate concentrations of 0, 0, 449, 531 and 1146 ng/mL. The sample dip times were varied from 10 seconds to 600 seconds (10 minutes). The samples were run in three assays in triplicates. The samples produced 100% of the expected results.

The sponsor studied structurally related compounds to test for cross-reactivity in the QuickScreen Barbiturates 300 test. The compounds were prepared in normal human urine and the results (below) were expressed as the amount of compound capable of giving a result equivalent to 300 ng/mL secobarbital.

Alphenal 0.400 µg/mL	Butabarbital >0.800 µg/mL	Pentobarbital 0.250 µg/mL	Amobarbital 0.500 µg/mL
Butabital 0.125 µg/mL	Phenobarbital 0.050 µg/mL	Secobarbital 0.300 µg/mL	

A wide variety of compounds (n=167 see package insert for a complete list) were tested to 100,000 ng/mL and were found not to interfere or cross react. Additionally, the following compounds were tested to the stated concentration and were found not to cross react.

Alprazolam -25 µg/mL	Fentanyl- 10 µg/mL	LSD 2.5 µg/mL
Barbituric Acid 1000 µg/mL	Heroin – 10 µg/mL	Ethylmorphine- 10 µg/mL
11-Hydroxy Δ^9 HC- 5 µg/mL		

f. Assay cut-off:

The sponsor conducted a cutoff/sensitivity study on 80 assay urine samples. The results are presented below and support the sponsors claimed cutoff of 300 ng/mL.

% of the cutoff concentration	Result	N
0-20%	100% negative	10/10
26-50%	100% negative	10/10
51-75%	100% negative	10/10
76-100%	80% negative	8/10
101-125%	100% positive	10/10
126-150%	100% positive	10/10
151-175%	100% positive	10/10
176-200%	100% positive	10/10

2. Comparison studies:

a. Method comparison with predicate device:

The sponsor tested 152 GC/MS confirmed urine samples obtained from two clinical sites with two lots of BAR 300 (cassette and strip). QuickScreen test correctly detected >99% of the positive samples and >96% of the negative samples. The study included members of the barbiturate family that included amobarbital, pentobarbital, secobarbital, butalbital and alphenal, Test results

below were compared to their know GC/MS results. Samples were considered positive if they were at or higher than the cutoff of 300 ng/mL.

Quick Screen GC/MS		Specimen cutoff range by GC/MS results						
		0-150 ng/mL	151-225 ng/mL	226-300 ng/mL	300-375 ng/mL	375-450 ng/mL	>450 ng/mL	% Agreement
	-	19	42	36	0	0	0	96%
	+	0	0	2	31	6	16	99%

b. Matrix comparison:

Not applicable: this device is only for use with urine samples.

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.