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

A. 510(k) Number:

k103295

B. Purpose for Submission:

Device Modification: Change in the cocaine cutoff concentration from 300 ng/mL to 150 ng/mL for previously cleared devices (in single drug format and multi drug format)

C. Measurand:

Cocaine (benzoylecgonine)

D. Type of Test:

Qualitative, lateral flow immunoassay

E. Applicant:

Phamatech, Inc.

F. Proprietary and Established Names:

QuickScreen Cocaine 150 Test Dip Card Model 9050T
QuickScreen Cocaine 150 Test Cassette Model 9051
QuickScreen Multi Drug Screening Test Model 9339T
QuickScreen Drug Cup Model 9339Z

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
DIO	Class II	21 CFR § 862.3250	Toxicology (91)

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

QuickScreen Cocaine 150 Test Models 9050T, 9051

The QuickScreen Cocaine 150 Test is an in-vitro diagnostic test for the detection/presence of cocaine (benzoylecgonine) in urine. The cut-off concentration is 150 ng/mL. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

This test provides only 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.

QuickScreen Multi Drug Screening Test: Model 9339T

The QuickScreen 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 barbiturates cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

Analyte	Calibrator	Cutoff
Amphetamine	d amphetamine	1000 ng/ml
Cocaine	Benzoylecgonine	150 ng/mL
Methamphetamine	d methamphetamine	500 ng/mL
Opiates	Morphine	300 ng/mL
PCP	Phencyclidine	25 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	200 ng/mL
Methadone	Methadone	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
THC	Cannabinoids	50 ng/mL

This test provides only 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.

QuickScreen Drug Cup: Model 9339Z

An in-vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, PCP, barbiturates, benzodiazepines, methadone, oxycodone and THC in urine. Tests for barbiturates cannot distinguish between abused drugs and certain prescribed medications. Measurements obtained by this device are used in the diagnosis and treatment of drug abuse. This test is intended for point-of-care testing.

Analyte	Calibrator	Cutoff
Amphetamine	d amphetamine	1000 ng/ml
Cocaine	Benzoylecgonine	150 ng/mL
Methamphetamine	d methamphetamine	500 ng/mL
Opiates	Morphine	300 ng/mL
PCP	Phencyclidine	25 ng/mL
Barbiturates	Secobarbital	300 ng/mL
Benzodiazepines	Oxazepam	200 ng/mL
Methadone	Methadone	300 ng/mL
Oxycodone	Oxycodone	100 ng/mL
THC	Cannabinoids	50 ng/mL

This test provides only 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):

This test provides only 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.

For prescription and point-of-care use only

4. Special instrument requirements:

Not applicable

I. Device Description:

The single cocaine 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Acon One Step Cocaine 150 Test Strip
   Pharmatech At Home Drug Test

2. Predicate K number(s):

   k032903 and k070009, respectively

3. Comparison with predicate:

Item	Proposed Device QuickScreen Multi Drug Screening Test and QuickScreen Drug Cup	Proposed Device QuickScreen Cocaine 150 Test	Acon One Step Cocaine 150 Test Strip	Phamatech At Home Drug Test
Intended use	Qualitative detection of drugs of abuse in urine	Same	Same	Same
Analytes	cocaine (benzoylecgonine) THC, opiates, amphetamine, methamphetamine, benzodiazepines, barbiturates, methadone PCP and OXY	cocaine	cocaine	cocaine (benzoylecgonine) THC, opiates, amphetamine, ecstasy (MDMA), methamphetamine, benzodiazepines, barbiturates, methadone PCP and OXY

Item	Proposed Device QuickScreen Multi Drug Screening Test and QuickScreen Drug Cup	Proposed Device QuickScreen Cocaine 150 Test	Acon One Step Cocaine 150 Test Strip	Phamatech At Home Drug Test
Format	Integrated Cup/dip card/cassette	dip card/cassette	Dip strip	Dip card
Specimen	Urine	Same	Same	Same
Cutoff (cocaine)	150 ng/mL	150 ng/mL	150 ng/mL	300 ng/mL
End User	Professional	Professional	Professional	Home Use
Methodology	Lateral flow immunoassay	Same	Same	Same
Qualitative	Yes	Same	Same	Same

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

None were referenced

L. Test Principle:

The device employs lateral flow immunochromatographic technology and is based on the principle of competitive binding. 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 certain testing steps. It should always appear as a burgundy-colored band regardless of the presence of the drug if enough sample volume has been added to the test and if sample has correctly migrated up the test strip.

M. Performance Characteristics (if/when applicable):

1. <u>Analytical performance:</u>

   a. Precision/Reproducibility:

   Precision studies were performed using drug-free urine spiked to the following concentrations: cutoff, +/-25%, +/-50%, +/-75% and 200% of the cutoff. Also, a negative control was tested over the 20 days. The samples were aliquots, randomized and blinded. A total of 20 determinations were made at each concentration**.** Testing was performed once a day over 20 days by 3

operators at 4 point of care sites. One lot number of devices for each format was used in the study. Sample concentrations were confirmed by LC/MS or GC/MS. The results are displayed in the table below:

Conc.	Multi card		Cup		Cassette	
Site 1	Neg	Pos	Neg	Pos	Neg	Pos
Negative	10	0	10	0	10	0
-75%	20	0	20	0	20	0
-50%	20	0	20	0	20	0
-25%	20	0	20	0	20	0
Cutoff	0	20	0	20	0	20
125%	0	20	0	20	0	20
150%	0	20	0	20	0	20
175%	0	20	0	20	0	20
200%	0	20	0	20	0	20

Conc.	Multi card		Cup		Cassette	
Site 2	Neg	Pos	Neg	Pos	Neg	Pos
Negative	10	0	10	0	10	0
-75%	20	0	20	0	20	0
-50%	20	0	20	0	20	0
-25%	20	0	20	0	20	0
Cutoff	7	13	13	7	10	10
125%	0	20	0	20	0	20
150%	0	20	0	20	0	20
175%	0	20	0	20	0	20
200%	0	20	0	20	0	20

Conc.	Multi card		Cup		Cassette	
Site 3	Neg	Pos	Neg	Pos	Neg	Pos
Negative	10	0	10	0	10	0
-75%	20	0	20	0	20	0
-50%	20	0	20	0	20	0
-25%	20	0	20	0	20	0
Cutoff	5	15	8	12	5	15
125%	0	20	0	20	0	20
150%	0	20	0	20	0	20
175%	0	20	0	20	0	20
200%	0	20	0	20	0	20

Conc.	Multi card		Cup		Cassette	
Site 4	Neg	Pos	Neg	Pos	Neg	Pos
Negative	10	0	10	0	10	0
-75%	20	0	20	0	20	0
-50%	20	0	20	0	20	0
-25%	20	0	20	0	20	0
Cutoff	0	20	0	20	0	20
125%	0	20	0	20	0	20
150%	0	20	0	20	0	20
175%	0	20	0	20	0	20
200%	0	20	0	20	0	20

b. *Linearity/assay reportable range:*

Not applicable, the device is intended for qualitative use.

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

Procedural controls are included in the test strip and device. A colored line appearing in the control zone is considered as an internal procedural control. It confirms sufficient specimen volume and adequate membrane wicking. Users are informed not to interpret the test if no red line appears in the control zone.

Control standards are not supplied with these tests; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. User should follow local, state and federal guidelines for testing QC material.

Accelerated and real time studies for the device have been conducted. Protocols and acceptance criteria were described and found to be acceptable. The manufacturer claims the following expiration date:

When stored at 15–28 ºC product is good until expiration date which is 20 months.

Real time studies have been conducted and are on-going.

Read time Stability was performed for Quickscreen Drug Screen Dip Card, Cup and Cassette. Five urine samples containing drug at the following concentration (zero, +/-25% and +/-50% of the cutoff) were used to perform

the study. All samples were analyzed ten times at 1-5 minute intervals from 60 sec-20 minutes. Data supports the recommended read time of 5 minutes for each device.

d. Detection limit:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the assay cut-off section, M.1.a, above.

e. Analytical specificity:

Cross-reactivity was established by spiking structurally related compounds into drug-free urine and diluting each to obtain various concentrations. Results are expressed as a minimum concentration of metabolite or compound required to produce a response approximately equivalent to the cutoff concentration of the assay.

Structurally related:

Compound	**Tested Concentration (ug/mL)**	**Response equivalent to cutoff**
Benzoylecgtonine	150	Positive
Benxoylecgonine	300	Positive
Ecgonine	100	Negative
Ecgonine methyl ester	100	Negative
Ephedrine d,l	1000	Negative
Epinephrine	1000	Negative
Metoclopramide	300	Negative
Pyrilamine	100	Negative

Structurally un-related:

This study was performed by spiking structurally unrelated compounds and endogenous substances at a concentration of 100 or 1000 µg/mL into urine samples containing drug at +/-50% of the drug cutoff concentrations. The following compounds showed no interference when tested at the +/-50% drug concentration:

Acetaminophen	Diphenhydramine	(+) Norephedrin
Allobarbitol	5,5-Diphenylhydantoin	Normorphine
Alphenal	Doxepin	Noroxymorophine
Alprazolam	Doxylamine	Nortriptyline
Alprazolam α OH	EDDP	Nylidrin

Amenoglutetimide	Erythromycin	Orphenadrine
Amitriptyline	Ethanol	Oxazepam
Amobarbitual	Ethylmorphine	Oxycodone
Amphetamine d	Fenfluramine	Oxymetazoline
Amphetamine l	Fentanyl	Penicillin G
Apomorphine	Flunitrazepam	Pentazocine
Ampicillin	Flurazepam	Phentobarbital
Amoxicillin	Griseofluvin	Phencyclidine
Ascorbic Acid	Hexobarbital	Phenelzine
Asprin	Hydrocodone	Pheniramine
Barbital	Hydromorphine	Phenmetrazine
Barbituris Acid	Hydroxyzine	Phenobarbital
Benztropine methane sulfonate	Ibuprofen	Phenylethylamine
Bilirubin	Indomethacin	Phenylproanolamine
Bromazepam	Isoxsuprine	Phenytoin metabolite
Bropheniramine	Kanamycin	Prazepam
Buprenorphine	Ketamine	Protriptyline
Butabarbital	Levallorphan	(+) Propoxyphene
Butalbital	Levorphanol	d-Pseudophedrine
Butethal	Lidocane	S.S (-) Pseudoephedrine
Caffine	Lorazepam	R,R (-) Pseudoephedrine
Cannabidol	Lysergic Acid Diethylamine	Pyridium
Cannabinol	MDA	Pyrilamine
Cannabinol Δ 9	MDE	Quinidine
Chlordiazepoxide	MDEA	Ranitidine
Chlorpromazine	MDMA	Salicyluric Acid
Chlorprothixene	Medazepam	Scopolamine
Clemastine	Meperidine	Tabutal
Choripramine	Mephentermine	Temazepam
Chonazepam	Metanephrine	THC: 9 carboxy-11-nor Δ 8
Codeine	Methadone d,l	THC: 9 carboxy-11-nor Δ 9
(-)-Cotinine	Methamphetamine d	Thioridazine
Creatinine	Methamphetamine l	Theothixene
Cyclizine	Methaqualone	Tranylcyproamine
Cyclobenzaprine	Methylephedrine	Trimterene
	Methylphenidate	Triazolam
Cyclopentobarbital	Morphine	Triazolam α-OH
Cycosporin A	Morphine 3 β glucuronide	Triflupromazine
Cyprohaptadine	Nalorphine	Trihexyphenidyl
Demoxepam	Naloxone	Trimipramine
Desalkylflurazepam	Naltrexone	Triprolidine
Desipramine	Naphazoline	Tyramine
Dextromethorpham	Nefidipine	Urea
Dextropropoxyphene	Netilmicin	Uric Acid

Diacetylmorphine	Nitrazepam	Verapamil
Diazepam	Norcodeine	
Dihydrocodine	Nordoxepin	

Evaluation of SG and pH on test results:

To test for possible positive and/or negative interference drug free urine were adjusted to the following pH concentrations 4.0, 5.0. 6.0, 7.0, 8.0 and 9.0.

Each of these samples were divided into five aliquots: urine, containing drug at +/-25% and +/-50% of the cutoff. Each sample was assayed in triplicate. No negative or positive interference due to pH was observed.

To test for possible positive and/or negative interference from specific gravity 5 urine samples having specific gravity from 1.002-1.040 were used. These samples had GC/MS concentration at +/-25% and +/-50% of the cutoff.

Each sample was assayed in triplicate. No negative or positive interference due to specific gravity was observed.

The testing results demonstrate that varying pH's and specific gravities do not affect urine testing results around each analyte cut-off.

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, M1.a, above.

2. Comparison studies:

a. Method comparison with predicate device:

An in-house was conducted using 160 unaltered clinical samples tested on the dipcard device and compared to the GC/MS. Results are displayed below:

COC150		Negative (<50% cutoff concentration by GC/MS)	Near cutoff negative (-50% to the cutoff concentration)	Near cutoff positive (cutoff to 50%)	High Positive (>50% cutoff)	% Agreement
	Positive	0	1	17	79	98%
	Negative	29	32	2	0	98%

Cutoff Value	Pharmatech	Drug/Metabolite

(ng/mL)	Coc150 dipcard (POS/NEG)	GC/MS value (ng/mL)
150	Positive	143
150	Negative	158
150	Negative	154

Performance of the Quickscreen devices (dipcard, cup and cassette) was evaluated with 3 operators who are typical operators at this site. Operators tested 80 unaltered clinical urine samples (40 negative and 40 positive). The samples were blind labeled and sufficiently randomized and compared to GC/MS results. The results are presented in the tables below:

Quickscreen COC150		Negative (<50% cutoff concentration by GC/MS)	Near cutoff negative (-50% to the cutoff concentration)	Near cutoff positive (cutoff to 50%)	High Positive (>50% cutoff)	% Agreement
Dipcard	Positive	0	1	17	28	100%
	Negative	21	18	0	0	97%
Cup	Positive	0	1	17	28	100%
	Negative	21	18	0	0	97%
Cassette	Positive	0	1	17	28	100%
	Negative	21	18	0	0	97%

Cutoff Value (ng/mL)	Pharmatech Coc150 (POS/NEG)	Drug/Metabolite GC/MS value (ng/mL)
150	Positive (card)	144
150	Positive (cup)	144
150	Positive (cassette)	144

All study participants completed questionnaires after they performed the test and recorded their results. The questionnaires covered evaluation of the package insert regarding the directions for performing the test, the ease of performing the test, directions for interpreting the results, and ease of interpretation of the results. These questionnaires demonstrated that the test instructions were easy to understand and that the testing procedure was easy to perform and the results were easy to read.

b. Matrix comparison:

Not applicable. The assay is intended for only one sample matrix, urine

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.