

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

A. 510(k) Number:

k131069

B. Purpose for Submission:

Device Modification: Change in the amphetamine test strip cutoff concentration from 1000 ng/mL to 500 ng/mL for previously cleared devices. There were no modifications made to the following test strips; Cocaine, Methamphetamine, Opiates, Phencyclidine, Barbiturates, Benzodiazepines, Methadone, Oxycodone, and THC (Cannabinoids) which are contained within the QuickScreen Multi Drug Screening Test and QuickScreen Drug Cup, cleared under k103295.

C. Measurand:

Amphetamine

D. Type of Test:

Qualitative, lateral flow immunoassay

E. Applicant:

Phamatech Inc.

F. Proprietary and Established Names:

QuickScreen Amphetamine 500 Model 9058 (dip card)

QuickScreen Amphetamine 500 Test Model 9054 (cassette)

QuickScreen Multi Drug Screening Test Model 9346T (dip card)

QuickScreen Multi Drug Cup Model 9346Z

G. Regulatory Information:

1. Regulation section:

Product Code	Classification	Regulation Section	Panel
DKZ	II	21 CFR §862.3100, Amphetamine test system	Toxicology - 91

H. Intended Use:

1. Intended use(s):

See Indications for use below

2. Indication(s) for use:

QuickScreen™ Amphetamine 500 Test Model 9058 (dip card)

The QuickScreen Amphetamine 500 Test Model 9058 is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of Amphetamine in urine. The cut-off concentration is 500 ng/ml. It is intended for prescription point of care use only.

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.

QuickScreen™ Amphetamine 500 Test Model 9054 (cassette)

The QuickScreen Amphetamine 500 Test Model 9054 is a qualitative in-vitro diagnostic screen that provides a preliminary result for the detection/presence of Amphetamine in urine. The cut-off concentration is 500 ng/ml. It is intended for prescription point of care use only.

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.

QuickScreen™ Multi Drug Screening Test Model 9346T(dip card)

The QuickScreen™ Multi Drug Screening Test Model 9346T is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, oxycodone, PCP, Barbiturates, benzodiazepines, methadone and THC in urine. The test is available in any combination of the drugs or drug metabolites listed below. Tests for barbiturates, benzodiazepine and oxycodone cannot distinguish between abused drugs and certain prescribed medications. The test is intended for prescription point of care use only.

Amphetamine (d amphetamine) 500 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 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.

QuickScreen™ Drug Cup Model 9346Z

The QuickScreen™ Drug Cup Model 9346Z is an in vitro diagnostic test for the qualitative detection of amphetamine, cocaine, methamphetamine, opiates, oxycodone, PCP, barbiturates, benzodiazepines, methadone and THC in urine at the cut-off concentrations listed below. The test is available in any combination of the drugs or drug metabolites listed below. Tests for barbiturates, benzodiazepine and oxycodone cannot distinguish between abused drugs and certain prescribed medications. The test is intended for prescription point of care use only.

Amphetamine (d amphetamine) 500 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 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, point of care use only.

4. Special instrument requirements:

Not applicable; this is a visually read single use device

I. Device Description:

The QuickScreen™ test devices employ lateral flow immunochromatographic technology and are based on the principle of competitive binding. The devices are available in either the cassette, dipcard, or cup formats as indicated by the device names. The devices are for use with human urine and results are visually read as positive or negative for the detection/presence of drug(s) in urine.

J. Substantial Equivalence Information:

1. Predicate device name(s):

QuikStrip™ OneStep Amphetamine 500 Test

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

k971218

3. Comparison with predicate:

Similarities/Differences		
Item	Candidate Device	Predicate Device
Intended Use	Detection of drugs of abuse	Same
Format	Integrated Cup/Dip/Card/Cassette	Dip card
Specimen	Urine	Same
Methodology	Lateral flow Immunoassay	Same
Qualitative	Yes	Same
Antibodies	Monoclonal/Polyclonal	Same
Amphetamine Cutoff	500 ng/mL	Same
Sample Incubation Time	10 minutes	5 minutes
End User	Prescription Point-of-Care	Same

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

None referenced.

L. Test Principle:

The QuickScreen test devices are chromatographic absorbent devices in which drug or drug metabolite(s) in an urine sample compete with a drug-antigen conjugate, immobilized on a porous support membrane. When an urine sample is applied to the test device, if drug is present in the sample at a concentration less than the stated cut-off, it will not block the binding sites of the immobilized drug-antigen conjugate in the test region and the antibody-dye conjugate will migrate to the test region with the urine. As a result, a visible rose pink band will form in the test region, indicating a negative result. Conversely, where drug concentrations are equal to or greater than the stated cut-off, the antibody - dye conjugate binds to the free drug, forming a complex which competes with immobilized drug-antigen conjugate in the test region. This prevents the development of a rose pink band, indicating a positive sample.

To serve as a procedural control, a colored band will always appear in the control region regardless of the presence of drug(s) in the test sample. This verifies the device is functioning correctly.

M. Performance Characteristics (if/when applicable):

Performance testing was conducted on the amphetamine test strip only due to the change in cutoff for this drug analyte. The other drug analyte test strips in the QuickScreen Multi Drug Screening Test and QuickScreen Drug Cup have not been modified and were previously cleared (k103295).

1. Analytical performance:

a. Precision/Reproducibility:

Precision studies were performed using drug-free urine spiked to the following concentrations: cutoff, +/-25%, +/-50%, +/-75% and 100% of the cutoff. Also, negative urine was tested. For each device, sixty urine samples were assayed for each test concentration. The samples were aliquotted, randomized, and blinded prior to testing. Testing was performed at 3 point-of-care sites by 2 operators/site with each testing the 4 device formats (dipcard multi 9346T, cup 9346Z, cassette 9054, dipcard single 9058). Testing was performed once a day for 20 days. Results are shown in the tables below:

Dipcard multi 9346T

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	20	0	20	0	20	0	60	0
-50%	20	0	20	0	20	0	60	0
-25%	20	0	20	0	20	0	60	0
Cutoff	5	15	0	20	5	15	10	50
125%	0	20	0	20	0	20	0	60
150%	0	20	0	20	0	20	0	60
175%	0	20	0	20	0	20	0	60
200%	0	20	0	20	0	20	0	60

Cassette 9054

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	20	0	20	0	20	0	60	0
-50%	20	0	20	0	20	0	60	0
-25%	20	0	20	0	20	0	60	0
Cutoff	19	1	0	20	19	1	38	22
125%	0	20	0	20	0	20	0	60
150%	0	20	0	20	0	20	0	60
175%	0	20	0	20	0	20	0	60
200%	0	20	0	20	0	20	0	60

Cup 9346Z

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	20	0	20	0	20	0	60	0
-50%	20	0	20	0	20	0	60	0
-25%	20	0	20	0	20	0	60	0
Cutoff	19	1	0	20	19	1	38	22
125%	0	20	0	20	0	20	0	60
150%	0	20	0	20	0	20	0	60
175%	0	20	0	20	0	20	0	60
200%	0	20	0	20	0	20	0	60

Dipcard single 9058

Conc.	Site 1		Site 2		Site 3		Combined	
	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos
Negative	20	0	20	0	20	0	60	0
-75%	20	0	20	0	20	0	60	0
-50%	20	0	20	0	20	0	60	0
-25%	20	0	20	0	20	0	60	0
Cutoff	19	1	0	20	19	1	38	22
125%	0	20	0	20	0	20	0	60
150%	0	20	0	20	0	20	0	60
175%	0	20	0	20	0	20	0	60
200%	0	20	0	20	0	20	0	60

b. *Linearity/assay reportable range:*

Not applicable, the device is intended for qualitative use.

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

Control standards are not supplied with this device; however the labeling states that it is good laboratory practice to confirm the test procedure and to verify proper test performance. Users should follow all applicable guidelines for testing QC materials.

Stability:

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

“When stored at 15–30°C, the product is stable until the expiration date which is 20 months.”

d. *Detection limit:*

Not applicable, the device is intended for qualitative use

e. *Analytical specificity:*

Cross-reactivity was established by spiking structurally related compounds into drug-free urine. Results are expressed as a minimum concentration of compound required to produce a response approximately equivalent to the cutoff concentration of the assay. Testing was performed on three devices (dipcard- multi 9346T, cup 9346Z, cassette 9054). All devices produced similar results. The percent cross-reactivity of those compounds are presented below:

Structurally related:

Substances	Concentration (ng/mL)	% Cross-reactivity
d-amphetamine	500	100%
l-amphetamine	10,000	5.0%
Methylenedioxyamphetamine (MDA)	1000	50%
Methylenedioxymethamphetamine (MDMA)	100,000	0
Norephedrin	>10,000	>5.0%
Tyramine	5000	10%

Structurally un-related:

This study was performed by spiking structurally unrelated compounds and endogenous substances at a concentration of 100 µg/mL into urine samples containing drug at +/- 50% respective drug cutoff concentrations. Testing was performed on three devices (dipcard- multi 9346T, cup 9346Z, cassette 9054). The following compounds showed no interference when tested at the +/-50% drug concentration:

Acetaminophen	5,5-Diphenylhydantoin	Oxalic Acid
Acetylsalicylic Acid	Dopamine	Papaverine
6-Acetylmorphine	(-)-ephedrine	Perphenazine
Amoxicillin	l-Erythromycin	Phenelzine
R-(-)-Apomorphine	Estradiol	L-Phenylephrine
L-Ascorbic Acid	Estrone	Phenylethylamine
Atropine	Ethanol	Phenylproanolamine
Baclofen	Fenofibrate	Prednisone
Benzocaine	Fentanyl	Promazine
Benzoic Acid	Fotemustine	Promethazine
Bilirubin	Furosemide	D-Propoxphene
Buprenorphine	Gemfibrozil	d,l Propranolol
Cannabidiol	Gentisic acid	d-Pseudophedrine
Carisoprodol	Glucose	Pyridoxal-5-phosphate
Cholesterol	Guaiacol glyceryl ether	Pyridoxine
Chloral hydrate	Hemoglobin	Pyrilamine
Chloramphenicol	Hydralazine	Pyrogallol
Chlordiazepoxide	Hydrocortisone	Quinidine
(+)-Chlorpheniramine	3-Hydroxytyramine	Quinine
Chlorpromazine	(+/-)-Isoproterenol	Quinolinic Acid
Chlorprothixene	Ketamine	Riboflavin
Clofibrate	Meprobamate	Salicylic Acid
Clonidine	Methapyrilene	Sodium Chloride
Cortisone	Methylphenidate	Sulfamethazine
(-)-Cotinine	Nalidixic Acid	Sulindac

Creatine Hydrate	Naloxone	Tetracycline
Creatinine	Naltrexone	Tetrahydrozoline
Cyclobenzaprine	(+)-Naproxen	Thiamine
Cyclodextrin-r	Niacinamide	Thioridazine
Cyproheptadine	Nicotinic Acid	Tramadol
Deoxycorticosterone	Nifedipine	Trifluoperazine
Dextromethorphan	19-Norethindrone	Tryptamine
Diclofenac	Norpropoxphene	Tyamine
Diflunisal	Nortriptyline	Uric Acid
4-Dimethyl-aminoantipyrine	Noscapine	Zomepirac sodium salt
Diphenhydramine	Octopamine	

Evaluation of Specific Gravity and pH on test results:

To evaluate the effect of pH value on the test results, urine controls at +/-25% and +/-50% of the cutoff value were used. Testing was conducted on 3 devices (dipcard-multi 9346T, cup 9346Z, cassette 9054). The pH levels tested were 4.5, 5.5, 6.5, 7.5, and 8.5. Each test sample was tested in triplicate.

To evaluate the effect of specific gravity, urine controls at +/-25% and +/-50% of the cut-off values had specific gravities of 1.002, 1.010, 1.015, 1.020, 1.025, and 1.030, 1.040. Testing was performed with 3 devices (dipcard- multi 9346T, cup 9346Z, and cassette 9054). Each test sample was tested in triplicate.

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:

The cut-off characterization study results can be found in the precision section of this summary. See section M.1.a.

2. Comparison studies:

a. Method comparison with predicate device:

Testing was performed at 3 point-of-care site. All four device formats (dipcard-multi 9346T, cup 9346Z, cassette 9054, dipcard-single 9058) were individually tested over a period of several days by 3 operators. Operators tested 106 (64 negative and 42 positive) unaltered clinical samples. The samples were blind labeled and randomized to each individual device prior to testing, such that operators tested both the samples and devices in a randomized fashion. The results were compared to GC/MS and are presented in the table below:

		Negative	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)
Dipcard-multi 9346T	Positive	0	0	4	22	20
	Negative	23	19	18	0	0
Cassette 9054	Positive	0	0	4	22	20
	Negative	23	19	18	0	0
Cup 9346Z	Positive	0	0	4	22	20
	Negative	23	19	18	0	0
Dipcard-single 9058	Positive	0	0	4	22	20
	Negative	23	19	18	0	0

Discordant results were the same for all 4 devices. The summary of discordant results are listed in the table below:

Assay	Cutoff Value (ng/mL)	Device Pos/Neg	Major metabolite present by GC/MS value (ng/mL)
Amphetamine	500	Positive	421.6 amphetamine
		Positive	440.2 amphetamine
		Positive	450.1 amphetamine
		Positive	454.6 amphetamine

b. Matrix comparison:

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

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.