whenever there is even a faint colored line.
INVALID: No line appears in the control region (C). If this occurs read the directions again and repeat the test with a new panel. If the result is still invalid stop using the test kit and contact your distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient sample volume, adequate membrane wicking and correct procedural technique.
It is recommended that external positive and negative controls be tested with each new opened kit, new lot or shipment of product, with each change in operator within the test kit, weekly as a check on continued storage conditions, and as otherwise required by your laboratory's internal quality system procedures. Control specimens should be performed the same as patient specimens (refer to Directions for Use and Interpretation of Results). If unexpected results are seen when running the external positive or negative controls, review the Directions for Use, Interpretation of Results and Limitations sections and repeat the test with another device. If the problem persists, discontinue use of the test kit immediately and contact the Manufacturer at (858) 535-2030.

LIMITATIONS

1. The One Step Multi-Drug, Multi-Line Screen Test Device provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. [3,4,7]
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine sample may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine samples may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine sample.
4. A Positive result does not indicate level of intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the One Step Multi-Drug, Multi-Line Screen Test Device and commercially available drug rapid tests. Testing was performed on approximately 1,000 samples previously collected from subjects presenting for Drug Screen Testing. Some samples in the +/- 25% cut-off levels were prepared by diluting from the more concentrated clinical samples with the neat urine. Presumptive positive results were confirmed by GC/MS. Negative urine samples were screened initially by Predicate test. Approximately 10% negative samples were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested in the following clinical studies:

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
COC	Benzoylecgonine
THC	11-nor-' ^{9}-tetrahydrocannabinol-9-carboxylic acid
mAMP	Methamphetamine
OPI	Morphine, Codeine
PCP	Phencyclidine

The following results were tabulated:

Method		GC/MS					
Multi-Drug Multi-Line		Neg. *	Neg. (< – 25% cutoff)	Near cutoff neg. (-25% cutoff to cutoff)	Near cutoff pos. (cutoff to +25% cutoff)	Pos. (> +25% cutoff)	% agreement with GC/MS
AMP	Positive	0	0	1	14	114	
	Negative	150	2	12	8	0	97%
COC	Positive	0	0	1	13	99	
	Negative	150	8	22	4	2	98%
THC	Positive	0	6	3	12	114	
	Negative	150	13	6	2	4	95%
Method		**GC/MS**					
Multi-Drug Multi-Line		**Neg. ***	**Neg. (< – 25% cutoff)**	**Near cutoff neg. (-25% cutoff to cutoff)**	**Near cutoff pos. (cutoff to +25% cutoff)**	**Pos. (> +25% cutoff)**	**% agreement with GC/MS**
mAMP	Positive	0	0	0	4	117	
	Negative	150	0	12	6	7	96%
OPI	Positive	0	0	2	18	111	
	Negative	150	0	14	2	1	98%
PCP	Positive	0	0	1	6	64	
	Negative	150	0	3	3	5	96%

***Negative urine samples were screened by predicate tests.**

Method			Predicate Test Results		% Agreement with Predicate Test
			Positive	Negative	
Multi-drug Multi-line Test Device	AMP	Positive	129	0	
		Negative	0	172	>99%
	COC	Positive	112	1	
		Negative	0	186	>99%
	THC	Positive	124	1	
		Negative	0	175	>99%
	mAMP	Positive	121	0	
		Negative	1	174	>99%
	OPI	Positive	131	0	99%
		Negative	2	164	
	PCP	Positive	71	0	
		Negative	1	160	>99%

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to various concentrations. >99% agreement with expected results was found at +/- 50% cut-off for each drug tested (with a 95% confidence interval.

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the One Step Multi-Drug, Multi-Line Screen Test Device at 5 minutes.

AMPHETAMINE	ng/mL
d-Amphetamine	1,000
d,l-Amphetamine sulfate	3,000
l-Amphetamine	50,000
(r)3,4-Methylenedioxyamphetamine	2,000
Phentermine	3,000
COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
MARIJUANA (THC)	
11-nor-' ^{9}-THC-9 COOH	50
Cannabinol	20,000
11-nor-' ^{8}-THC-9 COOH	30
' ^{8}-THC	15,000
' ^{9}-THC	15,000
METHAMPHETAMINE	
d-Methamphetamine	1,000
U-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
(r)-3,4-Methylenedioxymethamphetamine	2,000
Mephentermine	50,000
OPIATES	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levophanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3-E-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PCP	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

Precision

A study was conducted at three physician offices for Amphetamine, Cocaine, Marijuana, Methamphetamine, Opiate and Phencyclidine by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded samples, containing drugs at the concentration of +/-50% cut-off level was labeled as a blind and tested at each site. The correlation with expected results was >99% across all lots and sites (with a 95% confidence interval).

Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The One Step Multi-Drug, Multi-Line Screen Test Device was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the One Step Multi-Drug, Multi-Line Screen Test Device. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Cocaine, Amphetamine, Methamphetamine, Marijuana, Opiate or Phencyclidine positive urine. The following compounds show no cross-reactivity when tested with the One Step Multi-Drug, Multi-Line Screen Test Device at a concentration of 100 Pg/mL.

Non Cross-Reacting Compounds

Acetaminophen
N-Acetylprocainamide
Aminopyrine
Ampicillin
Apomorphine
Atropine
Benzoic acid
Bilirubin
Caffeine
Chloral hydrate
Chlorothiazide
Chlorpromazine
Cholesterol
Cortisone
Creatinine
Dextromethorphan
Diflunisal
Diphenhydramine
l -Ψ-Ephedrine
Estrone-3-sulfate
[1R,2S] (-) Ephedrine
Erythromycin
Furosemide
Hemoglobin
Hydrochlorothiazide
O-Hydroxyhippuric acid
p-Hydroxytyramine
Acetophenetidin
Acetylsalicylic acid
Amoxicillin
l-Ascorbic acid
Aspartame
Benzilic acid
Benzphetamine*
d,l-Brompheniramine
Cannabidol
Chloramphenicol
d,l-Chloropheniramine
Chloroquine
Clonidine
l-Cotinine
Deoxycorticosterone
Diclofenac
Digoxin
Ecgonine methyl ester
E-Estradiol
Ethyl-p-aminobenzoate
l(–)-Epinephrine
Fenoprofen
Gentisic acid
Hydralazine
Hydrocortisone
p-Hydroxyamphetamine
Ibuprofen

Iproniazid
Isoxsuprine
Ketoprofen
Loperamide
Meprobamate
Methylphenidate
Naloxone
Naproxen
Nifedipine
d-Norpropoxyphene
d,l-Octopamine
Oxolinic acid
Papaverine
Pentazocine
Phenelzine
l-Phenylephrine
Phenylpropanolamine
Prednisone
d-Propoxyphene
Quinacrine
Quindine
Salicylic acid
Sulfamethazine
Tetracycline
Tetrahydrocortisone 3 (E-D-glucuronide)
Thiamine
d,l-Tyrosine
Triamterene
Trimethoprim
d,l-Tryptophan
Uric acid
Zomepirac

d,l-Isoproterenol
Ketamine
Labetalol
Meperidine
Methoxyphenamine
Nalidixic acid
Naltrexone
Niacinamide
Norethindrone
Noscapine
Oxalic acid
Oxymetazoline
Penicillin-G
Perphenazine
Trans-2-phenylcyclo-propylamine
E-Phenylethylamine
Prednisolone
d,l-Propranolol
d-Pseudoephedrine
Quinine
Ranitidine
Serotonin
Sulindac
Tetrahydrocortisone 3-acetate
Tetrahydrozoline
Thioridazine
Tolbutamide
Trifluoperazine
Tryptamine
Tyramine
Verapamil

*Parent compound only; metabolizes into amphetamine and methamphetamine in the body.

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