ONE STEP DOA PANEL URINALYSIS CUP

General Package Insert for Multi-Drug Screen Test Cup (BL-CP08)

This Instruction Sheet is for testing of combination of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Phencyclidine and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine.

For healthcare professionals including professionals at point of care sites.

For in vitro diagnostic use only.

INTENDED USE

The One Step Drug Screen Test Cup is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methamphetamine (MET)	D-Methamphetamine	1,000 ng/mL
Methylenedioxymethamphetamine (MDMA)	D,L Methylenedioxymethamphetamine	500 ng/mL
Morphine (MOP 300 or OPI 300)	Morphine	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000 ng/mL

The configurations of the DOA Panel Test Cup come with any combination of the above listed drug analytes. This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUMMARY

The One Step Drug Screen Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of specific drugs in urine.

AMPHETAMINE (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use, and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The One Step Drug Screen Test Cup yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA)[3]

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short acting Barbiturates taken at 400 mg/day for 2-3 months produces a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days[1]

The One Step Drug Screen Test Cup yields a positive result when the Barbiturates in urine exceeds 300 ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal.

Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception.

Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days. The One Step Drug Screen Test Cup yields a positive result when the Benzodiazepines in urine exceeds 300 ng/mL.

COCAINE (COC)

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, and difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoylecgonine[1,2]. Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure[2].

The One Step Drug Screen Test Cup yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

MARIJUANA (THC)

THC (Δ^9--tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long term relatively heavy use may be associated with behavioral disorders. The peak effect of smoking marijuana occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid (Δ^9-THC-COOH).

The One Step Drug Screen Test Cup yields a positive result when the concentration of marijuana in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

METHADONE (MTD)

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of heroin (opiate dependence: Vicodin, Percocet, Morphine, etc.) addiction. Oral Methadone is very different than IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, Methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from Methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.[1]

The One Step Drug Screen Test Dipcard yields a positive result when the the concentration of Methadone in urine exceeds 300 ng/mL.

METHAMPHETAMINE (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The One Step Drug Screen Test Cup yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.[8] Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws. The One Step Drug Screen Test Dipcard yields a positive result when the the concentration of Methylenedioxymethamphetamine in urine exceeds 500 ng/mL.

MORPHINE (MOP 300 or OPI 300)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.

The One Step Drug Screen Test Cup yields a positive result when the concentration of opiate exceeds the 300 ng/mL cut-off level.

OPIATES (OPI2000)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor.

Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.[4]

The One Step Drug Screen Test Cup yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine.

PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days, depending on factors such as metabolic rate, user's age, weight, activity, and diet.[5]

Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).[6]

The One Step Drug Screen Test Cup yields a positive result when the phencyclidine metabolite in urine exceeds 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCA are taken orally or sometimes by injection. TCA are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The One Step Drug Screen Test Cup yields a positive result when the Tricyclic Antidepressants in urine exceeds 1,000 ng/mL.

PRINCIPLE

The One Step Drug Screen Test Cup is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates or Tricyclic antidepressants.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strips must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided

- Test cards
- Instruction for use

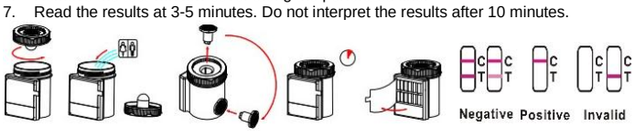
Materials Required But Not Provided

- Timer
- External controls

DIRECTIONS FOR USE

Allow the test card, urine specimen, and/or controls to equilibrate to room temperature (15-30ºC) prior to testing.

1. Bring test cup and specimens to the room temperature (15-28ºC) if they have been refrigerated.
2. Remove the urine test cup from the sealed foil pouch.
3. Remove the lid and collect the sample, ensuring that the sample is above the minimum fill line.
4. Secure the lid tightly and place the urine test cup on a flat surface.
5. Remove key from lid and insert in the side chamber, push to release the sample into the test zone, then shake the cup body Slightly to make urine flow into the specimen zone.
6. Remove the test window cover along the perforated line.
7. Read the results at 3-5 minutes. Do not interpret the results after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE*: Two lines appear. One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

***NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the drug concentration is above the detectable level.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The One Step Drug Screen Test Cup 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 specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level or 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 may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the One Step Single Drug Test Strip and commercially available drug rapid tests. Testing was performed on approximately 300 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results 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.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BZO	Oxazepam, Nordiazepam, a-OH-Alprazolam, Desalkylflurazepam
COC	Benzoylecgonine
THC	11-nor-Δ^9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
MET	Methamphetamine
MDMA	D,L Methyelnedioxymethamphetamine, Methylenedioxyamphetamine
MOP	Morphine, Codeine
PCP	Phencyclidine
TCA	Nortriptyline

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	90%	95%	98%	99%
Negative Agreement	100%	>99%	97%	>99%	100%	>99%
Total Results	98%	99%	94%	98%	99%	>99%

	MET	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	98%	100%	100%	>99%	98%	95%
Negative Agreement	100%	99%	100%	>99%	100%	>99%
Total Results	99%	99%	100%	>99%	99%	99%

%Agreement with GC/MS

	AMP	BAR	BZO	COC	THC	MTD
Positive Agreement	97%	>99%	96%	96%	97%	99%
Negative Agreement	95%	>99%	96%	>90%	88%	>94%
Total Results	96%	99%	96%	93%	91%	>96%

	MET	MDMA	MOP	OPI	PCP	TCA*
Positive Agreement	99%	96%	100%	>99%	100%	>99%
Negative Agreement	94%	98%	94%	>90%	97%	89%
Total Results	96%	97%	97%	>95%	98%	91%

Forty (40) clinical samples for each drug were run using each of The One Step Single Drug Test Strip by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained laboratory personnel.

*Note: TCA was based on HPLC data.

Precision

A study was conducted at three physician offices 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 specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled, blinded and tested at each site. The results are given below:

AMPHETAMINE (AMP)

Amphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	14	1
750	15	13	2	11	4	11	4
1,250	15	6	9	4	11	4	11
1,500	15	2	13	1	14	1	14

BARBITURATES (BAR)

Secobarbital conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	15	0	15	0
225	15	5	10	7	8	10	5
375	15	2	13	5	10	5	10
450	15	0	15	1	14	1	14

BENZODIAZEPINES (BZO)

Oxazepam conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	14	1	14	1	15	0
225	15	11	4	14	1	14	1
375	15	0	15	1	14	3	12
450	15	0	15	0	15	0	15

COCAINE (COC)

Benzoylecgonine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	14*	0	15	0	15	0
150	15	14	1	15	0	14	1
225	15	4	11	5	10	8	7
375	15	0	15	0	15	0	15
450	15	0	15	0	15	1	14

*Note: One invalid result was obtained.

MARIJUANA (THC)

11-nor-Δ^9-THC-9-COOH conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	14	1
37.5	15	9	6	14	1	9	6
62.5	15	2	13	0	15	0	15
75	15	0	15	0	15	0	15

METHADONE (MTD)

Methadone conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	12	3	15	0	15	0
225	15	8	7	14	1	15	0
375	15	0	15	0	15	1	14
450	15	1	14	0	15	0	15

METHAMPHETAMINE (MET)

Methamphetamine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	1	13	2
750	15	11	4	10	5	10	5
1,250	15	8	7	4	11	6	9
1,500	15	1	14	1	14	0	15

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methamphetamine Conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
375	15	15	0	15	0	15	0
625	15	6	9	4	11	7	8
750	15	0	15	0	15	0	15

MORPHINE (MOP 300 or OPI 300)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	13	2	13	2	15	0
225	15	3	12	7	8	10	5
375	15	0	15	1	14	0	15
450	15	0	15	0	15	0	15

OPIATES (OPI 2000)

Morphine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1,000	15	15	0	15	0	14	1
1,500	15	13	2	11	4	7	8
2,500	15	4	11	1	14	2	13
3,000	15	0	15	0	15	2	13

PHENCYCLIDINE (PCP)

Phencyclidine conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	14	1	14	1
18.75	15	11	4	13	2	10	5
31.25	15	8	7	5	10	1	14
37.5	15	4	11	0	15	0	15

TRICYCLIC ANTIDEPRESSANTS (TCA)

Nortiptyline conc. (ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	14	0	15	0
750	15	14	1	11	4	14	1
1,250	15	8	7	2	13	6	9
1,500	15	1	14	0	15	1	14

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		BAR		BZO		COC	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	27	3	26	4	30	0
Cut-off	30	18	12	22	8	12	18	4	26
+25% Cut-off	30	1	29	7	23	3	27	0	30
+50% Cut-off	30	0	30	2	28	0	30	0	30

Drug Concentration Cut-off Range	n	THC		MTD		MET		MDMA	
		-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	1	30	0	30	0
-50% Cut-off	30	30	0	29	1	30	0	30	0
-25% Cut-off	30	12	18	24	6	30	0	26	4
Cut-off	30	1	29	21	9	18	12	17	13
+25% Cut-off	30	1	29	2	28	1	29	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30

Drug Concentration Cut-off Range	n	MOP		OPI		PCP		TCA	
		-	+	-	+	-	+	-	+
0% Cut-off	**30**	30	0	30	0	30	0	30	0
-50% Cut-off	**30**	30	0	30	0	30	0	30	0
-25% Cut-off	**30**	30	0	30	0	19	11	22	8
Cut-off	**30**	11	19	13	17	16	14	12	18
+25% Cut-off	**30**	2	28	4	26	6	24	7	23
+50% Cut-off	**30**	0	30	0	30	0	30	0	30

Analytical Specificity

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

AMPHETAMINE (AMP)	**ng/mL**
D-Amphetamine	1,000
D,L-Amphetamine sulfate	3,000
L-Amphetamine	50,000
(±)3,4-Methylenedioxyamphetamine	2,000
Phentermine	3,000
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300
Alphenol	150
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	196
a-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlordiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
COCAINE (COC)	
Benzoylecgonine	300
Cocaine HCl	780
Cocaethylene	12,500
Ecgonine HCl	32,000
MARIJUANA (THC)	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
METHADONE(MTD)	
Methadone	300
Doxylamine	50,000
METHAMPHETAMINE (MET)	
D-Methamphetamine	1,000
ρ-Hydroxymethamphetamine	30,000
L-Methamphetamine	8,000
(±)-3,4-Methylenedioxymethamphetamine	2,000
Mephentermine	50,000
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxymethamphetamine HCl (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)	300
MORPHINE (MOP 300 or OPI 300)	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levophanol	1500
6-Monoacetylmorphine	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphone	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATES (OPI 2000)	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levophanol	75,000
6-Monoacetylmorphine	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphone	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Notriptyline	1,000
Nordoxepine	1,000
Trimipramine	3,000
Amitriptyline	1,500
Promazine	1,500
Desipramine	200
Imipramine	400
Clomipramine	12,500
Doxepin	2,000
Maprotiline	2,000
Promethazine	25,000

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 Drug Screen Test Cup 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 One Step Drug Screen Test Cup. 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 drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine, Methamphetamine, Marijuana, Methadone, Methylenedioxymethamphetamine , Morphine, Phencyclidine or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with One Step Drug Screen Test Cup at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Diclofenac	Maprotiline	D-Pseudoephedrine
Acetophenetidin	Diflunisal	MDE	Quinacrine
N-Acetylprocainamide	Digoxin	Meperidine	Quinidine
Acetylsalicylic acid	Diphenhydramine	Meprobamate	Quinine
Aminopyrine	Doxylamine	Methoxyphenamine	Ranitidine
Amitryptyline	Ecgonine methylester	Methyphenidate	Salicylic acid
Amoxicillin	(-) -Ψ-Ephedrine	Nalidixic acid	Serotonin
Ampicillin	β-Estradiol	Naloxone	Sulfamethazine
L-Ascorbic acid	Estrone-3-sulfate	Naltrexone	Sulindac
Apomorphine	Ethyl-p-aminobenzoate	Naproxen	Tetracycline
Aspartame	[1R,2S] (-) Ephedrine	Niacinamide	Tetrahydrocortisone
Atropine	(L) – Epinephrine	Nifedipine	3-acetate
Benzilic acid	Erythromycin	Norethindrone	Tetrahydrocortisone
Benzoic acid	Fenoprofen	D-Norpropoxyphene	3-(β-D-glucuronide)
Benzphetamine	Furosemide	Noscapine	Tetrahydrozoline
Bilirubin	Gentisic acid	DL-Octopamine	Thiamine
(±) – Brompheniramine	Hemoglobin	Oxalic acid	Thioridazine
Caffeine	Hydralazine	Oxolinic acid	Trans-2-phenylcyclo-
Cannabidiol	Hydrochlorothiazide	Oxymetazoline	propylamine
Chloralhydrate	Hydrocortisone	Papaverine	hydrochloride
Chloramphenicol	O-Hydroxyhippuric acid	Penicillin-G	DL-Tyrosine
Chlorothiazide	p-Hydroxyamphetamine	Pentazocine hydrochloride	Tolbutamide
(±) – Chlorpheniramine	3-Hydroxytyramine		Triamterene
Chlorpromazine	Ibuprofen	Perphenazine	Trifluoperazine
Chlorquine	Imipramine	Phenelzine	Trimethoprim
Cholesterol	Iproniazid	β-Phenylethylamine	Trimipramine
Clomipramine	(±) – Isoproterenol	Phenylpropanolamine	Tryptamine
Clonidine	Isoxsuprine	Prednisolone	DL-Tryptophan
Cortisone	Ketamine	Prednisone	Tyramine
(-) Cotinine	Ketoprofen	Promazine	Uric acid
Creatinine	Labetalol	Promethazine	Verapamil
Deoxycorticosterone	Loperamide	DL-Propranolol	Zomepirac
Dextromethorphan	L-Phenylephrine	D-Propoxyphene	

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