UA:06A by Labb (6-panel drug test cup)

Urine Drug Screen Data Document

This informational document is for the Labb UA:06A drug test kit designed to include some of the more popular drugs of abuse. This "Employment Use Only" EUO drug test cup is designed to screen for the following drugs: Methamphetamine, Cocaine, Marijuana, Morphine, Phencyclidine, & Amphetamine.

The UA:06A is a rapid, one step screening test for the simultaneous, qualitative detection of Methamphetamine, Amphetamine, Cocaine, Morphine, Phencyclidine, Marijuana and the metabolites in human urine.
For workplace use only.

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

Test	Calibrator	Cut-off
Methamphetamine (MET)	D-Methamphetamine	500
Cocaine (COC)	Benzoylecgonine	150
Marijuana (THC)	ll-nor-A9-TRC-9 COOR	50
Morphine (OPI)	Morphine	2000
Phencyclidine (PCP)	Phencyclidine	25
Amphetamine (AMP)	D-Amphetamine	500

This test will detect other related compounds, please refer to the Analytical Specificity table in this informational document. 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.

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 ofMethamphetamine 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 ofMethamphetamine 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 as amphetamine and oxidized and delaminated derivatives. However, 10-20% ofMethamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use.

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, 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

MARIJUANA (THC)

THC (8.9-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 l -nor-A9-tetrahydrocannabinol-9-carboxylic acid (A9-TRC-COOR). 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 ll -nor-A9-tetrahydrocannabinol-9-carboxylic acid (A9-TRC-COOR).

MORPHINE (MOP)

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 dependence 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

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 19501s. 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, user1s 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%).

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.

PRINCIPLE

(1) The One Step Multi-Drug Screen Test Cup (Urine) 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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.
(2) Alcohol Test: A pad coated with enzymes, turns to color shades of green and blue on contact with alcohol in urine. The alcohol pad employs a solid phase chemistry which uses the following highly specific enzymatic reaction:
CffiCHiOH + 02 Al ' 0h o l °"="™=' ---> CffiCHO + HiO,
Hi02+ DH, Peroxidase —- D+2Hi0

REAGENTS

Each test line in the test cup contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

PRECAUTIONS

- For workplace and insurance use only.
- Do not use after the expiration date.
- The Test Cup 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 Cup should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30° C). The Test Cup is stable through the expiration date printed on the sealed pouch. The Test Cup must remain in the sealed pouch until use. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE. Do not use beyond the expiration date.

WHEN TO COLLECT URINE FOR THE TEST?
The minimum detection time is 2-7 hours, so you may collect urine samples 2-7 hours after suspected drug use.

SPECIMEN COLLECTION AND PREPARATION

1. Urinate directly into the provided urine cup.
2. Open the Labeled Vial and carefully pour the urine specimens from the urine cup into the Labeled Vial. Fill the vial to about two thirds (2/3) full and tightly close the cap. This Labeled Vial urine sample is for shipping to the laboratory for confirmation testing. Make sure that the number on the Labeled Vial matches your personal Identification Number.
3. The residual urine sample in the urine cup is for your self-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

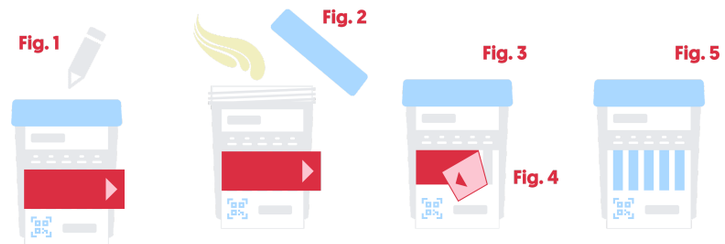
- Test Cup
- Disposable gloves
- Color Chart Card for Alcohol
- Package Insert
- Procedure card
- Desiccant

- Timer (Not provided)
- Labb Station app (Not provided)

DIRECTIONS FOR USE

Allow the test cup to come to room temperature [15-30° C (59-86° F)] prior to test.
1) Tear the foil bag open, remove the test cup and disposable gloves provided for the donor. Label the device with donor information. (Fig. 1)

2) Open the test cup lid. Urinate directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30ml to maximum 110ml. (Fig. 2)



3) Close the lid securely and place the cup on a flat surface. Start the timer. (Fig. 3)
4) Put on the glove provided. Peel off label to reveal test result.(Fig. 4)
5) Read the adulteration strip at 2 minutes. Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret or scan the drug test results. Either retest the urine or collect another specimen from the donor.
6) Read the drug strip results after 5 minutes. DO NOT INTERPRET RESULT OR SCAN AFTER 10 MINUTES. (Fig. 5)

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 (Drug/T). This negative result indicates that the drug concentration is below the detectable level
*NOTE: The shade of red in the test line region (Drug(f) 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 (Drugtr). 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 manufacturer.
Note: There is no meaning attributed to line color intensity or width.
A preliminary positive test result does not always mean a person took illegal drugs and a negative test result does not always mean a person did not take illegal drugs. There are a number of factors that influence the reliability of drug tests. Certain drugs of abuse tests are more accurate than others. IMPORTANT: The result you obtained is called preliminary for a reason. The sample must be tested by laboratory in order to determine if a drug of abuse is actually present. Send any sample which does not give a negative result to a laboratory for further testing.

What Is A False Positive Test?
The definition of a false positive test would be an instance where a substance is identified incorrectly by One Step Multi-Drug Screen Urine Test. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?
The definition of a false negative test is that the initial substance is present but isn't detected by One Step Multi-Drug Screen Urine Test. If the sample is diluted, or the sample is adulterated that may cause false negative results.

QUALITY CONTROL

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

LIMITATIONS

I. The One Step Multi-Drug Screen Test Cup (Urine) 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.
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 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 a drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result might be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

80 clinical urine specimens were analyzed by GC-MS and by the One Step Multi-Drug Screen Test Cup (Urine). Each test was performed by three operators. Samples were divided by concentration into five categories: drug-free, less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

ANALYTICAL SPECIFICITY

The following table lists compounds that are positively detected in urine by the One Step Multi-Drug Screen Test Cup (Urine) at 5 minutes.

Methamphetamine 500	
d-Methamphetamine	**500**
L-Methamphetamine	4,000
Mephentermine	25,000
d,l-Amphetamine	75,000
(1R,2S)(-)-Ephedrine	50,000
3,4-methylenedioxymethamphetamine(MDMA)	1,000
d-Amphetamine	50,000
Chloroquine	12,500
3,4-Methylenedioxymethamphetamine(MDEA)	20,000
Procaine (Novocaine	50,000
Trimethobenzamide	20,000

Cocaine 150	
Benzoylecgonine	**150**
Cocaethylene	2,500
Cocaine	500
Ecgonine	12,500
Ecgonine methylester	50,000

Morphine / Opiates 2000	
Morphine	**2,000**
Codeine	1,000
Ethylmorphine	250
Hydrocodone	5,000
Hydromorphone	2,500
Heroin	5,000
6-Acetylmorphine	2,500
Oxycodone	75,000

Marijuana 50	
11-nor-Δ9-THC-9-COOH	**50**
11-nor-Δ8-THC-9-COOH	**50**
Δ8- Tetrahydrocannabinol	15,000
Δ9- Tetrahydrocannabinol	50,000
Δ8- THC-COOH	50,000

Phencyclidine 25	
Phencyclidine	**25**
4-Hydroxy Phencyclidine	90

Amphetamine 500	
D-Amphetamine	**500**
L-Amphetamine	16,000
D,L-Amphetamine	750
Methylenedioxy-amphetamine (MDA)	800
d-Methamphetamine	>100,000
l-Methamphetamine	>100,000
Methylenedioxy-methamphetamine (MDMA)	>100,000
ephedrine	>100,000

PRECISION

This study is performed 2 runs/day and lasts 25 days for each format with three lots. Three operators who don't know the sample number system participate in the study. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs/day). A total of 50 determinations by each operator, at each concentration, were made. The results are given below:

Drug Conc. (Cut-off range)	AMP 500		COC 150		MET 500		MDMA		MOP 2000	
	-	+	-	+	-	+	-	+	-	+
0% Cut-Off	50	0	50	0	50	0	50	0	50	0
-75% Cut-Off	50	0	50	0	50	0	50	0	50	0
-50% Cut-Off	50	0	50	0	50	0	50	0	50	0
-25% Cut-Off	50	0	50	0	50	0	50	0	50	0
Cut-Off	32	18	31	19	25	25	30	20	20	30
125% Cut-Off	0	50	0	50	0	50	0	50	0	50
150% Cut-Off	0	50	0	50	0	50	0	50	0	50
175% Cut-Off	0	50	0	50	0	50	0	50	0	50
200% Cut-Off	0	50	0	50	0	50	0	50	0	50

Drug Conc. (Cut-off range)	PCP 25		THC 50	
	-	+	-	+
0% Cut-Off	50	0	50	0
-75% Cut-Off	50	0	50	0
-50% Cut-Off	50	0	50	0
-25% Cut-Off	50	0	50	0
Cut-Off	16	34	25	25
125% Cut-Off	0	50	0	50
150% Cut-Off	0	50	0	50
175% Cut-Off	0	50	0	50
200% Cut-Off	0	50	0	50

EFFECTS OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity from 1.000 to 1.035 were spiked with drugs at 25% below and 25% above cut-off levels respectively. The One Step Multi-drug Screen Test Cup (Urine) was tested in duplicate using ten drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

The pH of an aliquot of negative urine pool is adjusted in the range of 4.00 to 9.00 in 1 pH unit increment and spiked with the target drug at 25% below and 25% above Cutoff levels. The spiked, pH-adjusted urine was tested with The One Step Multi-Drug Screen Test Cup (Urine). The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Methamphetamine, Amphetamine, Cocaine, Morphine, Ecstasy, EDDP (Methadone Metabolites), Tricyclic Antidepressants, Oxycodone, Barbiturates, Buprenorphine, Phencyclidine, K2 (Synthetic Cannabinoid), Ketamine, Kratom, Methaqualone, Methadone, Fentanyl, Tramado, Ethyl Glucuronide, Cotinine, Hydrocodone, Hydromorphone, 6-Monoacetylrnorphine, Methylenedioxy-pyrovalerone, Lysergic acid diethylamide, Marijuana and Benzodiazepines positive urine. The following compounds show no cross-reactivity when tested with the One Step Multi-Drug Screen Test Cup (Urine) at a concentration of 100 µg/mL.

NON CROSS-REACTING COMPOUNDS

ACETOPHENETIDIN	CORTISONE	MEPROBAMATE
N-ACETYLPROCAINAMIDE	CREATININE	NAPROXEN
ACETYLSALICYLIC ACID	DEXAMETHASONE	NIACINAMIDE

AMILORIDE	DEXTROMETHORPHAN	NOSCAPINE
AMOXICILLIN	DIFLUNISAL	OCTOPAMINE
AMPICILLIN	DIGOXIN	PHENELZINE
L-ASCORBIC ACID	ETHOPROPAZINE	PREDNISONE
APOMORPHINE	FENOPROFEN	PRILOCAINE
ASPARTAME	GENTISIC ACID	QUINIDINE
BENZILIC ACID	HEMOGLOBIN	QUININE
P-AMINOBENZOIC ACID	HYDROCORTISONE	SALICYLIC ACID
BILIRUBIN	ISOXSUPRINE	SEROTONIN
CAFFEINE	PSEUDOEPHEDRINE	TETRAHYDROCORTISONE
CANNABIDIOL	KYNURENIC ACID	THIAMINE
CHOLESTEROL	LABETALOL	URIC ACID
CLONIDINE	LOPERAMIDE	ZOMEPIRAC

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This is not the official package insert for the UA:06A. This is an informational document that includes some information that is not included in the package insert. This document is exclusively for the UA:06A.

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