



## CupLab™ Urine Drug Test – 9

CUP0901

AMP/BAR/BZD/COC/MET/MTD/OPI/PCP/THC

### Name and Intended Use

The POC Panel Urine Drug Test – 9, qualitatively detects amphetamine (AMP), barbiturate (BAR), benzodiazepines (BZD), cocaine (COC), methamphetamine (MET), methadone (MTD), opiates (OPI), phencyclidine (PCP), tetrahydrocannabinols (THC) and/or their derivatives in human urine. The results obtained are of a preliminary nature; positive results should be confirmed by way of a non-immunological method, such as gas chromatography mass spectrometry (GC/MS).

### Summary of Test

**Amphetamine** is a potent central nervous system stimulant. Acute higher doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet.

**Barbiturates** act as central nervous system (CNS) depressants, by producing a wide spectrum of effects, from mild sedation to anesthesia. Some are also used as anticonvulsants. Barbiturates are believed to be GABA (gamma-amino butyric acid) agonists, acting on the GABA-A receptor. GABA is the principal inhibitory neurotransmitter in the mammalian CNS. Barbiturates were very popular in the first half of the twentieth century. In moderate amounts, these drugs produce a state of intoxication that is remarkably similar to alcohol intoxication. Symptoms include slurred speech, loss of motor coordination, and impaired judgment. Depending on the dose, frequency, and duration of use, one can rapidly develop tolerance, physical dependence, and psychological dependence on barbiturates. With the development of tolerance, the margin of safety between the effective dose and the lethal dose becomes very narrow. Majority therapeutic barbiturate use in the United States has been substituted with benzodiazepines.

**Benzodiazepines** are primarily used as depressants of the central system. Different benzodiazepine analogues can cause from muscle relaxing to intoxication and amnesia. Benzodiazepines are present in urine in the form of derivatives, as well as intact drugs. This is what denotes a benzodiazepines user.

**Cocaine**, a powerful stimulant of the central nervous system is metabolized in the human body and its metabolite benzoylecgonine (BE) is excreted into urine. After ingestion of cocaine, benzoylecgonine can be detected in the urine as soon as four hours. Generally, benzoylecgonine can be detected 24-60 hours after exposure to cocaine.

**Methamphetamine** is a central nervous system stimulant leading to increased alertness and energy, as well as euphoria. Methamphetamine is excreted as various derivatives in the urine,

including amphetamine. However, approximately 40% of consumed methamphetamine is excreted unaltered, discerning a methamphetamine user from an amphetamine user.

**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. 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.

**Opiates** test detects morphine and morphine analogues at a concentration equivalent to or higher than 300ng/ml of morphine. Morphine is an opiate compound, as well as a metabolite of heroin. These compounds function as analgesics by depressing the central nervous system. Most of heroin injected is metabolized to morphine and codeine; morphine can be detected in a user's urine several days after ingestion.

**Phencyclidine**, also known as PCP or Angel Dust, is a hallucinogen that was first market 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 powders, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administrated by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experience mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effect of Phencyclidine.

The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, the drug user's age, weight, activity and diet.

**Tetrahydrocannabinol**, psychoactive component of marijuana, is a central system stimulant relaxant. THC in marijuana is strongly absorbed by fatty tissues in various organs and a metabolite form of THC, delta-9-tetrahydrocannabinol, is present in urine 48-72 hours after a smoking-section. This is what denotes a marijuana user.

### Principle of Procedure

The CupLab urine drug test is an integrated test cup for conveniently collecting urine specimen and simultaneously testing the specimen for drugs of abuse. The cup device consists of a urine collection reservoir and a smaller test chamber containing immunochromatography test components based on the principle of competitive immunoassay. When a urine sample is collected in the cup container, a portion of urine flows into the test chamber and come to contact with the sample pad of the test strips. Each test strip in the device specifically detects one drug of abuse or its analogues. The nitrocellulose membrane on each interior test strip is immobilized with drug-carrier protein conjugate on the test zone (see Figure 1). Anti-drug antibodies, which have been conjugated with colloidal gold, are impregnated on a sample filter pad overlapping the bottom of the membrane. When the sample pad of a test contacts a urine sample, the urine will wick upwards through the pad. The antibody-gold conjugate will flow with the liquid front-end, in the absence of the substance to be tested, will bind to the immobilized drug conjugate causing a visible red band

to appear on the test zone. However, when a sufficient concentration of drug present in the urine sample, antibody-gold conjugate will bind with the free drug; thus, due to competitive binding, no visible band will appear on the test zone.

### Sample Collection

#### Fresh Urine Sample

The CupLab device is designed for simultaneously testing a fresh urine sample while the sample is collected in the cup container. The sample donor must be instructed to collect urine directly into the cup to or above the minimum level as indicated on the cup label. In order to maintain the integrity of the specimen, only urine is allowed in the test cup; no water, diluents, preservatives, or any other substances should be added into the cup or the urine sample. After the sample is collected, the cup device should be handed to the test administrator for reading the test result.

#### Pre-collected Urine Sample

If desired, pre-collected urine samples can be transferred into the device for testing. Pre-collected urine samples should be contained in either clean plastic or glass containers. Refrigerate samples after collection, until ready to test. Samples should be tested within 3 days of collection. Freeze the samples that must be stored long-term. Highly turbid urine should be centrifuged and save the clear fluid for testing.

### Warnings and Precautions

1. The test device is for in vitro diagnostics use only.
2. All specimens are considered health hazardous. Use proper protection when handling.
3. If the test cup with the urine sample is to be transported to a different site for re-testing, the lid must be tightly screwed to the cup opening. A leak-proof specimen bag in compliance with the applicable law must be used to contain the test cup and the specimen.

### Storage and Stability

Store the test below 30°C, do not freeze.

### Assay Procedure

1. Prior to use bring test sample and device components to room temperature.
2. Remove the device from the pouch and remove the screw lid.
3. Collect approximately 30-50 milliliters of urine directly in the cup device. The urine level must be equal or exceed the minimum fill level mark on the cup label. To test a pre-collected sample, transfer a same volume of the pre-collected sample into the cup device.
4. Keep the device in an upright position for the test result to develop.
5. Temperature validation: the temperature of a valid urine sample should be between 90-100°F or 30-38°C for up to five minutes.
6. The test is ready for result reading at about 3 minutes.

7. At the end of 3 minutes, the test administrator peels off the label, which will reveal the test result window. Negative test results may appear in less than 3 minutes. However, a positive test result should be read at least 5 minutes after the sample is collected. Do not interpret results after 30 minutes. (see Figure 1).

### Sensitivity Cut-off Levels

The test detects urine samples containing drugs or drug analogues at the following concentration cut-off levels.

Test	Cut-off (ng/ml)
AMP	1000
BAR	300
BZD	300
COC/BE	300
MET	1000
MTD	300
OPI	2000
PCP	25
THC	50

### PERFORMANCE CHARACTERISTICS

1. **Specificity.** Interference of substances that may be present in urine specimens, as well as sample effect of sample pH and specificity were studied.
  - a. Cross-reactivity of non-drug related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using the assay devices. No cross-reactivity was detected with the substances listed in Table 2.
  - b. Table 3 list the drug related substances and concentrations that produced results approximately equivalent to the cutoff level for amphetamine.
  - c. Varying sample pH within the range of 4 and 9 has no significant effect on the assay results.
  - d. Varying sample specific gravity within the range of 1.003 and 1.040 has no significant effect on the assay results.

Table 2: Compounds tested and found not to cross-react with the test at the concentrations of 10 µg/mL and 100 µg/mL in urine.

<i>Acetaminophen</i>	<i>Ibuprofen</i>
<i>Acetone</i>	<i>(+/-)-Isoproterenol</i>
<i>Albumin</i>	<i>Ketamine</i>
<i>Ampicillin</i>	<i>Levorphanol</i>
<i>Ascorbic Acid</i>	<i>Lidocaine</i>
<i>Aspartame</i>	<i>(+)-Naproxen</i>
<i>Aspirin</i>	<i>Niacinamide</i>
<i>Atropine</i>	<i>Nicotine</i>
<i>Benzocaine</i>	<i>(+/-)-Norephedrine</i>
<i>Bilirubin</i>	<i>Oxalic Acid</i>
<i>Caffeine</i>	<i>Penicillin-G</i>
<i>Chloroquine</i>	<i>Pheniramine</i>
<i>(+)-Chlorpheniramine</i>	<i>Phenothiazine</i>
<i>(+/-)-Chlorpheniramine</i>	<i>1-Phenylephrine</i>
<i>Creatine</i>	<input type="checkbox"/> <i>-Phenylethylamine</i>
<i>Dexbrompheniramine</i>	<i>Procaine</i>
<i>Dextromethrophan</i>	<i>Quinidine</i>
<i>Diphenhydramine</i>	<i>Ranitidine</i>

Dopamine  
 (+/-)-Epinephrine  
 Erythromycin  
 Ethanol  
 Furosemide  
 Glucose  
 Guaiacol Glyceryl Ether  
 Hemoglobin

Riboflavin  
 Sodium Chloride  
 Sulindac  
 Theophylline  
 Tyramine  
 4-Dimethylaminoantipyrine  
 (1R,  
 2S)-(-)-N-Methyl-Ephedrine

Ephedrine 100,000  
 Mephentermine 50,000

MTD

Methadone 300  
 Doxylamine 50,000

OPI

Morphine 300  
 Codeine 300  
 Ethylmorphine 150  
 Heroin 750  
 Hydrocodone 600  
 Hydromorphone 750  
 Morphine-3-glucuronide 400  
 Nalorphine 750

Table-3: Concentration of drug analyte-related compounds showing a positive response approximately equivalent to the cut-off set for the test.

AMP	Compound /	Concentration in ng/ml
	<i>d</i> -Amphetamine	1,000
	<i>dl</i> -Amphetamine	2,500
	(+/-) 3,4-MDA	1,250
	<i>d</i> -Methamphetamine	50,000
	(+/-)3,4-MDMA	50,000

BAR	Compound	Concentration
	Secobarbital	300
	Allobarbital	600
	Alphenal	200
	Amobarbital	1500
	Aprobarbital	300
	Barbital	1500
	Butobarbital	400
	Butalbital	300
	Pentobarbital	400
	Phenobarbital	450
	Lorazepam	>100,000

BZD	Compound	Concentration
	Oxazepam	300
	Alprazolam	196
	<i>a</i> -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
	Oxazepam	300
	Temazepam	98
	Triazolam	2,500

COC	Compound	Concentration
	Cocaine	800
	Benzoylcegonine	300
	Cocaethylene	600

MET	Compound	Concentration
	<i>d</i> -Methamphetamine	500
	<i>d</i> -Amphetamine	50,000
	<i>l</i> -Amphetamine	>100,000
	(+/-)3,4-MDEA	50,000
	(+/-)3,4-MDA	100,000
	(+/-)3,4-MDMA	2,000
	<i>l</i> -Methamphetamine	10,000

PCP

Phencyclidine 25  
 4-Hydroxyphencyclidine 12,500

THC

11-nor- $\Delta$ -9-THC-9-COOH 50  
 11-hydroxy- $\Delta$ -9-THC 1,000  
 $\Delta$ -8-tetrahydrocannabinol 5,000  
 $\Delta$ -9-tetrahydrocannabinol 5,000  
 Cannabinol 10,000  
 Cannabidiol >100,000

**Accuracy**

Table 4. Amphetamine Assay Accuracy Data

Acro AMP	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	Positive (> +50%)
Positive	2	2	13	45
Negative	78	8	1	0

%agreement of the positives: 58/59 = 98%

%agreement of the negatives: 78/80 = 98%

Table 5. Barbiturate Assay

Acro BAR	Positive	Negative
Positive	0	0
Negative	1	68

% Agreement among positives is 88/90 = 98%

% Agreement among negatives is 100%

Table 6. Benzodiazepine Assay

Acro BZD	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	Positive (> +50%)
Positive	0	6	13	25
Negative	70	10	6	0

% Agreement among positives is 93%

% Agreement among negatives is 86%

Table 7. Cocaine/Bezolecgonine Assay

Acro COC	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)
Positive	0	2	8	55
Negative	60	8	2	0

%agreement of the positives: 48/65 = 97%  
 %agreement of the negatives: 68/70 = 97%

Table 8. Methamphetamine Test

Acro MET	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)
Positive	0	3	9	40
Negative	70	7	1	0

%agreement of the positives: 49/50 = 98%  
 %agreement of the negatives: 77/80 = 96%

Table 9. Methadone Test

New Device	Negative By Predicate Devices	Near Cutoff Negative (-50% to Cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)
Positive	0	2	6	30
Negative	70	6	1	0

%agreement of the positives: 36/37 = 97%  
 %agreement of the negatives: 76/78 = 97%

Table 10. Opiate Test

New Device	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)
Positive	0	3	8	40
Negative	70	7	2	0

%agreement of the positives: 48/50 = 96%  
 %agreement of the negatives: 77/80 = 96%

Table 11. Phencyclidine (PCP)

Acro PCP	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)
Positive	0	4	6	37
Negative	70	8	5	0

%agreement of the positives: 43/48 = 90%  
 %agreement of the negatives: 78/83 = 94%

Table 12. Marijuana (THC) Test

Acro Rapid THC Test	Negative By Predicate Devices	Near Cutoff Negative (-50% to cutoff)	Near Cutoff Positive (cutoff to +50%)	Positive (> +50%)

Positive	0	3	7	59
Negative	70	7	3	1

% Agreement among the positives is 94% (66/70)  
 % Agreement among the negatives is 96% (77/80)

**Interpretation of Results**

- a. **POSITIVE:** A positive result is observed when there is a control line (C) and no test line (T) and indicates a **minimum** drug concentration of the test's detection cut-off level. At concentrations less than the cut-off level, there may be weak signal appearing at the test line area.
- b. **NEGATIVE:** If there is no drug or drug analogue present in urine, there will be a rose-color bands appearing on both the control and the test section.
- c. **INVALID:** If there is no rose-color band visible in the control window, then the test result is invalid. It is recommended that the urine be retested.

Fig. 1 Illustration of an example test result.



Interpretation: double line: negative; single line: positive; no line: invalid

\*\* A positive result indicated here should be confirmed by a non-immunological method, such as GC/MS.