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CardLab™ Dip Card Panel Urine Drug Test –3-9

For combo tests of 3-9

From AMP-BZD-COC-MET-MTD-OPI-OXY-PPX-THC

Name and Intended Use

The POC Panel Urine Drug Test – 5, qualitatively detects tetrahydrocannabinols (THC), methamphetmine (MET), benzodiazepines (BZD), opiates (OPI), and cocaine (COC) 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.

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 benzolecgonine (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.

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.) addition. 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.

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.

Opiates test detects morphine and morphine analogues at a concentration equivalent to or hight 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.

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 POC panel urine drug test is an immunochromatography device based on the principle of competitive immunoassay. 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-carrior 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 strip is dipped into the urine sample to perform the test, the urine will diffuse 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

Urine samples should be collected in either 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 sclear fluid for testing.

Warnings and Precautions

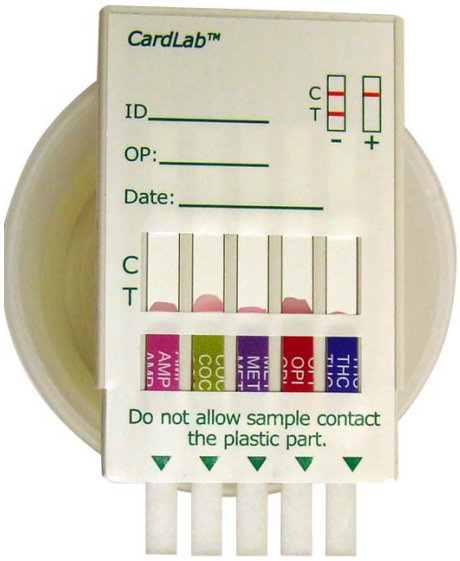
1. The test device is for in vitro diagnostics use only.
2. All specimens are considered health hazardous. Use proper protection when handling.

Storage and Stability

Store the test below 28°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 cap.
3. Dip the strip end of the device into the urine sample for at leat 10 seconds (Fig. 1).



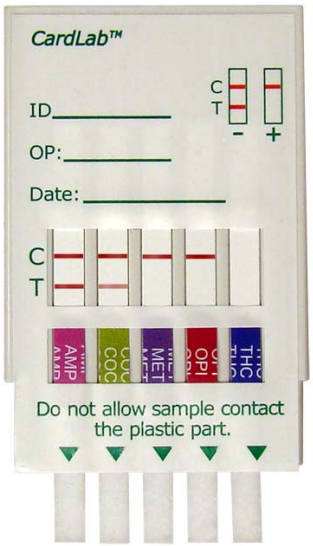
4. After flow appears in the result window of all the test channels, move the card away from the sample and. Lay the card on a flat surface to let the test develop (Fig. 2).
5. Wait for 5 minutes to read the test results.

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 or the drug concentration is below the cutoff level, 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.



Interpretation: beginning from the left test No. 1 and 2: negative, test No. 3 and 4: positive, test No. 5: invalid.

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
BZD	300
COC/BE	300
MET	500
MTD	300
OPI	2000
OXY	100
PPX	300
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 Amphetamine 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.

Acetaminophen	*Ibuprofen*
Acetone	*(+/-)-Isoproterenol*
Albumin	*Ketamine*
Ampicillin	*Levorphanol*
Ascorbic Acid	*Lidocaine*
Aspartame	*(+)-Naproxen*
Aspirin	*Niacinamide*
Atropine	*Nicotine*
Benzocaine	*(+/-)-Norephedrine*
Bilirubin	*Oxalic Acid*
Caffeine	*Penicillin-G*
Chloroquine	*Pheniramine*
(+)-Chlorpheniramine	*Phenothiazine*
(+/-)-Chlorpheniramine	*1-Phenylephrine*
Creatine	*β-Phenylethylamine*
Dexbrompheniramine	*Procaine*
Dextromethrophan	*Quinidine*
Diphenhydramine	*Ranitidine*
Dopamine	*Riboflavin*
(+/-)-Epinephrine	*Sodium Chloride*
Erythromycin	*Sulindac*
Ethanol	*Theophylline*
Furosemide	*Tyramine*
Glucose	*4-Dimethylaminoantipyine*
Guaiacol Glyceryl	*(1R,*
Ether Hemoglobin	*2S)-(-)-N-Methyl-Ephedrine*

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
d-Amphetamine	*1,000*
dl-Amphetamine	*2,500*
(+/-) 3,4-MDA	*1,250*
d-Methamphetamine	*50,000*
(+/-)3,4-MDMA	*50,000*

BZD

Oxazepam	*300*
Alprazolam	*196*
a-Hydroxyalprazolam	*1,262*
Bromazepam	*1,562*

Chlordiazepoxide	*1,562*
Chlorodiazepoxide HCI	*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

Cocaine	*800*
Benzoylecgonine	*300*
Cocaethylene	*600*

MET

d-Methamphetamine	*500*
d-Amphetamine	*50,000*
l-Amphetamine	*>100,000*
(+/-)3,4-MDEA	*50,000*
(+/-)3,4-MDA	*100,000*
(+/-)3,4-MDMA	*2,000*
l-Methamphetamine	*10,000*
Ephedrine	*100,000*
Mephentermine	*50,000*

MTD

Methadone	300
Doxylamine	50,000

OPI

Morphine	*2000*
Codeine	*300*
Ethylmorphine	*1000*
Heroin	*5000*
Hydrocodone	*4000*
Hydromorphine	*5000*
Morphine-3-glucuronide	*3000*
Nalorphine	*5000*

THC

11-nor-Δ-9-THC-9-COOH	*50*
11-hydroxy-Δ-9-THC	*1,000*
Δ-8-tetrahydrocannabinol	*5,000*
Δ-9-tetrahydrocannabinol	*5,000*
Cannabinol	*10,000*
Cannabidiol	*>100,000*

Accurasy

Table 4. Amphetamine Assay Accuracy Data

	GC/MS, Cutoff 1000ng/ml			
New Device	**Negative (<50% cutoff** by GC/MS or negative by predicate	Near Cutoff Negative (–50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	High Positive (> +50%)
Positive	0	2	13	45
Negative	70	8	1	0

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

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

Table 5. Benzodiazepine Assay

Acro BZD	**Less** than half the cutoff concentration by GC/MS analysis or negative by predicate device	**Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration)	**Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration)	**High Positive** (greater than 50% above the cutoff concentration)
Positive	0	6	13	25
Negative	70	10	6	0

% Agreement among positives is 93%

% Agreement among negatives is 86%

Table 6. Cocaine/Bezolecgonine Assay

Acro Acro COC	GC/MS, Cutoff 300ng/ml			
	Less than half the cutoff concentration confirmed by GC/MS	Near Cutoff Negative (–50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	Positive (> +50%)
Positive	0	2	7	40
Negative	60	8	3	0

%agreement of the positives: 47/50 = 94%

%agreement of the negatives: 68/70 = 97%

Table 7. Methamphetamine Test

Acro MET	**Negative (<50% cutoff** by GC/MS or negative by predicate	**Near Cutoff Negative** (50%- to cutoff)	**Near Cutoff Positive** (cutoff to 50%+ cutoff)	**High Positive** (>50%+ cutoff)
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 8. Methadone Test

	GC/MS, 300			
New Device	**Negative (<50% cutoff** by GC/MS or negative by predicate	Near Cutoff Negative (–50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	High 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 9. Opiate Test

	GC/MS, Cutoff 2000ng/ml			
New Device	**Negative (<50% cutoff** by GC/MS or negative by predicate	Near Cutoff Negative (–50% to cutoff)	Near Cutoff Positive (cutoff to +50% cutoff)	High 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 10. Marijuana (THC) Test

Acro Rapid THC Test	**Negative (<50% cutoff** by GC/MS or negative by predicate	**Near Cutoff Negative** (50%- to cutoff)	**Near Cutoff Positive** (cutoff to 50%+ cutoff)	**High Positive** (>50%+ cutoff)
Positive	0	3	7	37
Negative	70	7	3	3

% Agreement among the positives is 88% (44/50)
% Agreement among the negatives is 96% (77/80)

Effective: 11Sep2006