

## CardLab™ Urine Drug Test –5

CRD0504

THC-MET-BZD-OPI-COC

### Name and Intended Use

The CardLab Urine Drug Test – 5, qualitatively detects tetrahydrocannabinols (THC), methamphetamine (MET), benzodiazepines (BZD), opiates (OPI), and cocaine (COC) and/or their derivatives in human urine. The results obtained are of a preliminary nature; presumed positive results should be confirmed by way of a non-immunological method, such as gas chromatography mass spectrometry (GC/MS).

### Summary of Test

*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.

*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.

*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.

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

*Cocaine*, a powerful stimulant of the central nervous system is metabolized in the human body and its metabolite benzoylecgonine 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.

### Principle of Procedure

The CardLab urine drug test is an immunochromatography assay 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-carrier protein conjugate on the test zone. Anti-drug antibodies, which have been conjugated with colloidal gold, are impregnated on a sample filter pad overlapping the bottom of the membrane. When a urine sample is applied to the sample pad of a test strip 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 and Testing

CardLab Devices can be used for testing collected urine samples.

*Fresh Urine Sample:* Fresh urine samples can be tested with CardLab without any pre-treatment to the specimen. Simply remove the CardLab device and the pipette inside the pouch and pipette 2 drops of urine sample into each sample well of the CardLab device placed on a flat surface. The test results should be read at 5 minutes to 10 minutes (refer to Test Procedure of this instruction).

*Non-fresh Urine Sample:* Urine samples collected prior to testing can be tested using CardLab devices. 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 clear fluid for testing (refer to Test Procedure of this instruction).

### 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

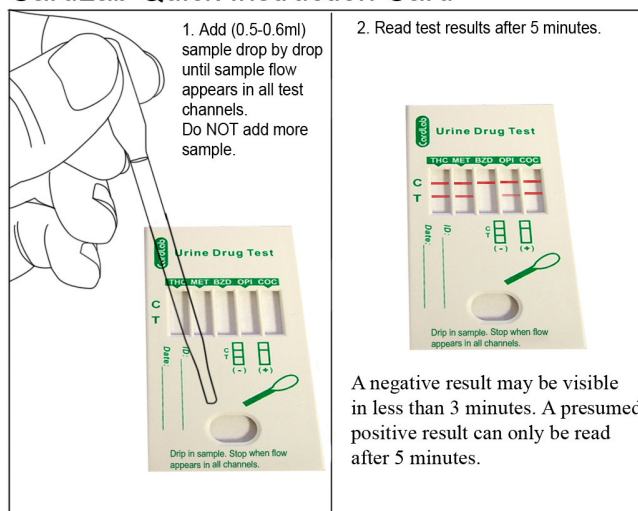
Store the test below 28°C, do not freeze.

### Assay Procedure

1. Prior to use bring test sample and device components to room temperature.
2. Remove the CardLab device and the pipette from the pouch.
3. Follow the CardLab Quick Instruction Card (Figure 1) to apply test sample. For the best performance of, use the pipette provided or use a laboratory liquid transferring device to transfer 500ul of sample to the sample wells. Over fill the sample wells will cause poor performance of CardLab and incorrect test results.

Fig. 1. CardLab Test Instruction

### CardLab Quick Instruction Card



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4. Read results at the end of 5 minutes; do not interpret results after 10 minutes. (See Figure 2).

### 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)
THC	50
MET	300
BZD	200
OPI	300
COC/BE	300

### Interpretation of Results

- a. **PRESUMED POSITIVE:** A presumed 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.

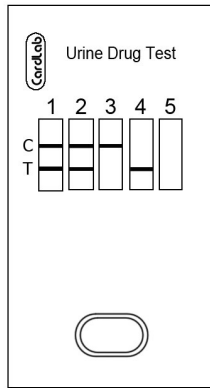


Fig. 2 Illustration of an example test result.

Interpretation: test No. 1 and 2: negative, test No. 3: presumed positive, test No. 4 and NO. 5: invalid.

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

#### 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
Dextromethorphan	Quinidine
Diphenhydramine	Ranitidine
Dopamine	Riboflavin
(+/-)-Epinephrine	Sodium Chloride
Erythromycin	Sulindac
Ethanol	Theophylline

Furosemide	Tyramine
Glucose	4-Dimethylaminoantipyrine
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.

#### BZD

Oxazepam	300
Alprazolam	196
a-Hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Chlorodiazepoxide HCl	781
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flumitrazepam	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
Benzoylcegonine	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

#### OPI

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

#### 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

#### Accuracy

Table 4. 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%

	negative by predicate		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)

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

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Table 5. 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%



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Table 6. 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 7. Opiate Test

New Device	GC/MS, Cutoff 2000ng/ml			
	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 8. Marijuana (THC) Test

Acro Rapid THC Test	Negative (<50% cutoff by GC/MS or	Near Cutoff Negative (50%- to cutoff)	Near Cutoff Positive (cutoff to	High Positive (>50%+ cutoff)