

## CDIA™ Drug Tests Cup (Urine)

CDIA™ Drug Tests Cup (Urine) is a lateral flow chromatographic immunoassay designed to qualitatively detect the presence of drugs and drug metabolites in human urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	D-Amphetamine	1,000
Amphetamine (AMP)	D-Amphetamine	500
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC )	Benzoyllecgonine	300
Cocaine (COC )	Benzoyllecgonine	150
Ecstasy (MDMA)	D,L-3,4-Methylenedioxymethamphetamine (MDMA)	500
Marijuana (THC )	11-nor- $\Delta^9$ -THC-9 COOH	50
Methadone (MTD)	Methadone	300
Methadone Metabolites (EDDP)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methamphetamine (MET, mAMP )	D-Methamphetamine	1,000
Methamphetamine (MET, mAMP )	D-Methamphetamine	500
Morphine (MOP )	Morphine	300
Morphine (MOP )	Morphine	2,000
Oxycodone (OXY )	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

## General Description

CDIA™ Drug Tests Cup (Urine) is an easy, fast, qualitative, visually read competitive binding immunoassay method for screening specific drugs and their metabolites without the need of instrumentation. The method employs a unique mixture of antibodies to selectively detect the elevated levels of specific drugs and their metabolites in urine.

**Amphetamine (AMP):** Amphetamines are central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and overall feeling of well-being. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Large doses and extended usage can result in higher tolerance levels and physiological dependency leading to substance abuse. The effect 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 CDIA™ Drug Tests Cup (Urine) 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 amphetamine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the amphetamine in urine exceeds 1000/500 ng/mL.

**Barbiturates (BAR):** Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of barbiturate could develop tolerance and physiological dependency and lead to its abuse. The CDIA™ Drug Tests Cup (Urine) 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 barbiturates in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the barbiturates in urine exceeds 300 ng/mL.

**Benzodiazepines (BZO):** Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of

benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of benzodiazepines are excreted unaltered in the urine, most of benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes oxazepam a useful marker of benzodiazepines abuse. The CDIA™ Drug Tests Cup (Urine) 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 benzodiazepines in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the benzodiazepines in urine exceeds 300 ng/mL.

**Buprenorphine (BUP):** Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain buprenorphine HCl alone or in combination with naloxone HCl. Therapeutically, buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free buprenorphine and norbuprenorphine in urine may be less than 1 ng/ml after therapeutic administration, but can range up to 20 ng/ml in abuse situations. The plasma half life of buprenorphine is 2-4 hours. While complete elimination of a single dose of the drug can take as long as 6 days, the window of detection for the parent drug in urine is thought to be approximately 3 days. The CDIA™ Drug Tests Cup (Urine) 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 buprenorphine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the buprenorphine in urine exceeds 10 ng/mL.

**Cocaine (COC):** Cocaine is an alkaloid present in Coca leaves (Erythroxine coca). Its pharmacological properties, such as stimulating and euphoric effects, have been known for centuries. Cocaine produces alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. In large dose, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. Cocaine is excreted in the urine primarily as benzoylecgonine, which can generally be detected for 24-48 hours after cocaine exposure. The CDIA™ Drug Tests Cup (Urine) 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 cocaine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the cocaine in urine exceeds 300/150 ng/mL.

**Ecstasy (MDMA):** MDMA belongs to a family of man-made drugs. Its relatives include MDA and MDEA. They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood altering chemicals, such as cartoning and L-dopa, and may generate feelings

of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2-3 hours. The CDIA™ Drug Tests Cup (Urine) 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 MDMA in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the MDMA in urine exceeds 500 ng/mL.

**Marijuana (THC):** THC ( $\Delta$ 9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). THC is central nervous stimulant that alters mood and sensory perceptions, produces loss of coordination, impairs short-term memory, produces symptoms of anxiety, paranoia, depression, confusion, hallucination, and increases heart rate. Large doses of marijuana could develop tolerances and physiological dependency and lead its abuse. The main metabolite excreted in the urine is 11-nor- $\Delta$ 9-tetrahydrocannabinol-9-carboxylic acid, which is found in the urine within hours of exposure and remains detectable for 3-10 days after smoking. The CDIA™ Drug Tests Cup (Urine) 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 marijuanain urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the marijuanain in urine exceeds 50 ng/mL.

**Methadone (MTD):** Detoxification using methadone can either be done relatively rapidly in less than a month or gradually over as long as six months. While a single dose has a rapid effect, maximum effect can take five days of use. The effects last about six hours after a single dose and a day and a half after long-term use in people with normal liver function. Methadone is usually taken by mouth and rarely by injection into a muscle or vein. Side effects are similar to those of other opioids. Commonly these include dizziness, sleepiness, vomiting, and sweating. Serious risks include opioid abuse and a decreased effort to breathe. Abnormal heart rhythms may also occur including prolonged QT. The CDIA™ Drug Tests Cup (Urine) 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 methadone in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the methadone in urine exceeds 300 ng/mL.

**Methadone Metabolites (EDDP):** Methadone, a Schedule II controlled substance, is often used in the treatment of opiate addiction and pain management; it also has a high potential for abuse. Methadone is metabolized primarily into two pharmacologically inactive metabolites, EDDP and EMDP. EDDP represents a better urine marker for monitoring methadone maintenance than testing for un-metabolized methadone alone. The CDIA™ Drug Tests Cup (Urine) 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 EDDP in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the EDDP in urine exceeds 300 ng/mL.

**Methamphetamine (MET, mAMP):** 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 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. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10 to 20% of methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates methamphetamine use. The CDIA™ Drug Tests Cup (Urine) 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 methamphetamine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the methamphetamine in urine exceeds 1000/500 ng/mL.

**Morphine (MOP):** Morphine is a naturally occurring substance extracted from the seedpod of the poppy plant, *Papaver somniferum*. Morphine is used medicinally for the relief of moderate to severe pain in both acute and chronic management. It can also be used to sedate a patient pre-operatively and to facilitate the induction of anesthesia. The drug is also used illicitly for recreational purposes among drug users. It is potentially highly addictive and can cause intense physical dependence that leads to abuse of the substance. The CDIA™ Drug Tests Cup (Urine) 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 morphine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the morphine in urine exceeds 2000/300 ng/mL.

**Oxycodone (OXY):** Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy. The CDIA™ Drug Tests Cup (Urine) 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 oxycodone in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the oxycodone in urine exceeds 100 ng/mL.

**Phencyclidine (PCP):** Phencyclidine, commonly known as PCP or “angel dust” is used primarily as recreational drug due to its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of phencyclidines are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heart rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of phencyclidine can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of phencyclidine could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%). The CDIA™ Drug Tests Cup (Urine) 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 phencyclidine in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the phencyclidine in urine exceeds 25 ng/mL.

**Propoxyphene (PPX):** Propoxyphene is a prescription drug for the relief of pain. Overdose of propoxyphene can have the symptoms including analgesia, stupor, respiratory depression and coma. The half-life of propoxyphene is 8 to 24 hours. Propoxyphene reaches its peak in 1 to 2 hours after oral administration. The CDIA™ Drug Tests Cup (Urine) 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 propoxyphene in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the propoxyphene in urine exceeds 300 ng/mL.

**Tricyclic Antidepressants (TCA):** Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs. The CDIA™ Drug Tests Cup (Urine) 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 TCAs in urine. The CDIA™ Drug Tests Cup (Urine) yields a positive result when the TCAs in urine exceeds 1000 ng/mL.

## Principle of the Test

CDIA™ Drug Tests Cup (Urine) is a competitive binding immunoassay in which drugs and drug metabolites in a urine sample compete with immobilized drug conjugate for limited labeled antibody binding sites. When a sufficient amount of urine specimen is applied to the sample pad of the test device, the urine specimen migrates

through the test device by capillary action. If the drug or drug metabolite concentration in the specimen is below the cut-off level, the anti-drug antibodies in colloidal gold particles will bind to the drug antigens coated in the test line of the nitrocellulose membrane to form a T line, which indicates a negative result. If the concentration of drug in the urine specimen is above the cut-off level, it will bind with antibodies conjugated with colloidal gold particles, so that no T line will be developed in the test region, which indicates a positive result.

## Materials Provides

1. CDIA™ Drug Tests Cup
2. One instruction

## Materials Required but Not Provided

1. External controls
2. Timer

## 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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

**Specimen Storage:** Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

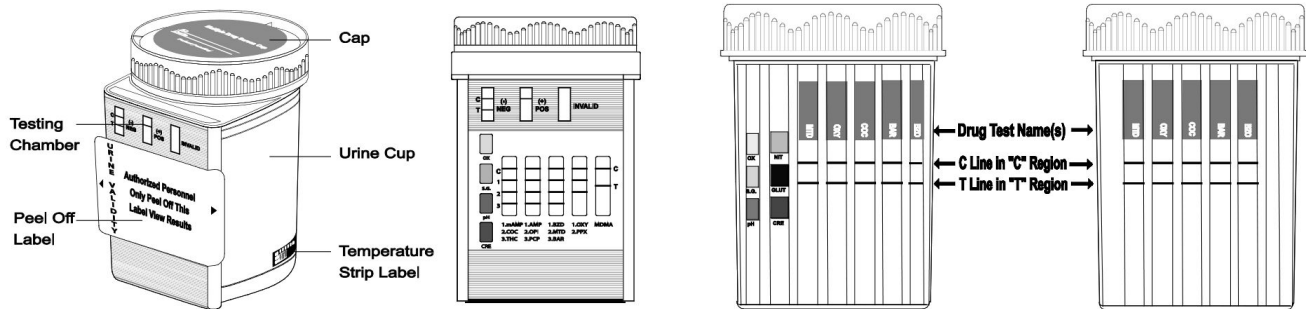
## Assay Operation

Allow the cup, urine specimen, and/or controls to reach room temperature (15-30°C) before testing.

1. Remove the cup from the sealed pouch and use it as soon as possible.
2. Collect specimen in the cup and secure the cap tightly.
3. If the temperature strip is included with Drug Test Cup, please read urine temperature between 2-4 minutes after voiding to verify the temperature ranges between 90-100°F (33-38°C).
4. Place the cup on a flat surface.
5. Date and initial the security seal, and place the security seal on the cap.
6. Peel off the label on the cup to view the results.

7. If adulteration test is included on the test cup, read the adulteration test results between 2 to 5 minutes. See the color chart for interpretation. If the specimen indicates adulteration, we recommend not to interpret the drug test results and either retest the urine or collect another specimen.

8. Read the test results in 5 minutes. It is important that the background is clear before the result is read. Do not read results after 10 minutes.

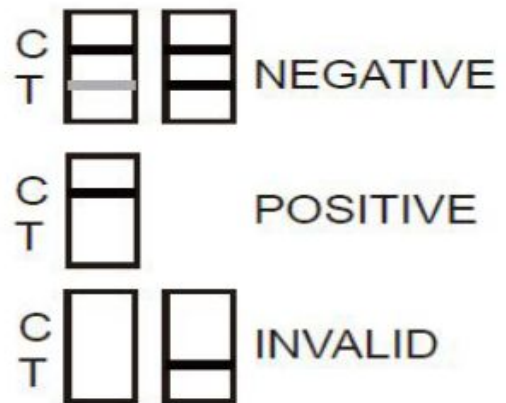


## Results

**Negative:** Two lines appear. One colored line should be in the control region (C) and another apparent colored line should be in the test line region (T).

**Positive:** One colored line appears in the control line region (C). No line appears in the test line region (T).

**Invalid:** Line C has no color, which indicates the strips are invalid. In this case, please read the instructions again, and redo the assay with new cassette device.



## 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 testing practice to confirm the test procedure and to verify proper test performance.



## Limitation

1. The CDIA™ Drug Tests 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. It is possible 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 indicates presence of the drug or its metabolites but 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 drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

## Storage

The CDIA™ Drug Tests Cup (Urine) can be stored at room temperature or refrigerated (2-30°C). It is stable through the expiration date printed on the sealed pouch. The test cassette must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## Notice for Operations

1. Please do the assay following the instruction, don not touch the membrane of the strip.
2. This Tests Cup is used for only once; please do not use it repeatedly.