

Clear CUP One Step Drug Test

Package Insert foe multi Drug Screen Test cup Test for Urine

This Instruction Sheet is for testing of any combination of Amphetamine, Barbiturates, Benzodiazepines, Cocaine, Marijuana, Methadone, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Oxycodone, Phencyclidine and Tricyclic Antidepressants.

Including Adulterant Test (Specimen Validity Tests) for:

Oxidants (OX), Specific Gravity (S.G) and PH.

A rapid, one step screening test for the simultaneous, qualitative detection of multiple drugs and drug Metabolites in human urine.

For Professional and In Vitro Diagnostic Use Only

INTENDED USE

The **Clear CUP One Step Drug Test** is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000ng/mL
Barbiturates (BAR)	Secobarbital	300ng/mL
Benzodiazepines (BZO)	Oxazepam	300ng/mL
Cocaine (COC)	Benzoyl ecgonine	300ng/mL
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	50ng/mL
Methadone (MTD)	Methadone	300ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000ng/mL
MDMA(Ecstasy)	D,L Methylenedioxy-methamphetamine	500ng/mL
Opiate 300 (OPI 300, MOP, MOR)	Morphine	300ng/mL
Opiate 2000 (OPI 2000)	Morphine	2,000ng/mL
Oxycodone (OXY)	Oxycodone	100ng/mL
Phencyclidine (PCP)	Phencyclidine	25ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000ng/mL
EDDP	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300ng/mL
Buprenorphine (BUP)	Buprenorphine	10ng/mL
Propoxyphene (PPX)	Propoxyphene	300ng/mL
K2 Synthetic Cannabinoid	JWH-073/JWH-018	50 ng/mL

Configurations of the **Clear CUP One Step Drug Test** can consist of any combination of the above listed drug analytes. This assay provides only a preliminary qualitative test result. Use a more specific alternate quantitative analytical method to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.¹ Apply clinical and professional judgment to any drug of abuse test result, particularly when preliminary positive results are obtained.

SUMMARY AND EXPLANATION OF THE TEST

The **Clear CUP One Step Drug Test** is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine without the use of an instrument.

AMPHETAMINE(AMP 1000)

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. The **Clear CUP One Step Drug Test** yields a positive result when Amphetamines in urine exceed 1,000ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA,USA).³

BARBITURATES(BAR)

Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death. Only a small amount (less than 5%) of most Barbiturates are excreted unaltered in the urine.

The approximate detection time limits for Barbiturates are:

Short acting (e.g. Secobarbital) 100 mg PO (oral) 4.5 days

Long acting (e.g. Phenobarbital) 400 mg PO (oral) 7 days⁴

The **Clear CUP One Step Drug Test** yields a positive result when the Barbiturates in urine exceed 300ng/mL.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days.

The **Clear CUP One Step Drug Test** yields a positive result when the Benzodiazepines in urine exceed 300ng/mL.

BUPRENORPHINE (BUP)

Buprenorphine is a semisynthetic opioid analgesic derived from thebain, a component of opium. It has a longer duration of action than morphine when indicated for the treatment of moderate to severe pain, peri-operative analgesia, and opioid dependence. Low doses buprenorphine produces sufficient agonist effect to enable opioid-addicted individuals to discontinue the misuse of opioids without experiencing withdrawal symptoms. Buprenorphine carries a lower risk of abuse, addiction, and side effects compared to full opioid agonists because of the “ceiling effect”, which means no longer continue to increase with further increases in dose when reaching a plateau at moderate doses. However, it has also been shown that Buprenorphine has abuse potential and may itself cause dependency. Subutex®, and a Buprenorphine/Naloxone combination product, Suboxone®, are the only two forms of Buprenorphine that have been approved by FDA in 2002 for use in opioid addiction treatment. Buprenorphine was rescheduled from Schedule V to Schedule III drug just before FDA approval of Suboxone and Subutex.

The **Clear CUP One Step Drug Test** yields a positive result when the Buprenorphine in urine exceeds 10ng/mL.

COCAINE (COC 300)

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

The **Clear CUP One Step Drug Test** yields a positive result when the cocaine metabolite in urine exceeds 300ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

MARIJUANA (THC 50)

THC (Δ⁹-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking 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 11-nor-Δ⁹-tetrahydrocannabinol-9-carboxylic acid (Δ⁹-THC-COOH).

The **Clear CUP One Step Drug Test** yields a positive result when the concentration of THC-COOH in urine exceeds 50ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).³

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, Morphine). The pharmacology of Oral

Methadone is very different from IV Methadone. Oral Methadone is partially stored in the liver for later use. IV Methadone acts more like heroin. In most states you must go to a pain clinic or a Methadone maintenance clinic to be prescribed Methadone. 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.⁴

The **Clear CUP One Step Drug Test** yields a positive result when the Methadone in urine exceeds 300ng/mL.

METHAMPHETAMINE (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 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 of Methamphetamine 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% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

The **Clear CUP One Step Drug Test** yields a positive result when the Methamphetamine in urine exceeds 1,000ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.⁸ Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

The **Clear CUP One Step Drug Test** yields a positive result when the Methylenedioxymethamphetamine in urine exceeds 500ng/mL.

OPIATE (OPI 300, MOR, 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 dependency 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

The **Clear CUP One Step Drug Test** yields a positive result when the concentration of opiate exceeds the 300ng/mL cut-off level.

OPIATE (OPI 2000)

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 dependency 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.³

The **Clear CUP One Step Drug Test** yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

OXYCODONE (OXY)

Oxycodone, [4,5-epoxy-14-hydroxy-3-methoxy-17-methyl-morphinan-6-one, dihydrohydroxycodeinone] is a semi-synthetic opioid agonist derived from thebaine, a constituent of opium. Oxycodone is a Schedule II narcotic analgesic and is widely used in clinical medicine. The pharmacology of oxycodone is similar to that of morphine, in all respects, including its abuse and dependence liabilities. Pharmacological effects include analgesia, euphoria, feelings of relaxation, respiratory depression, constipation, papillary constriction, and cough suppression. Oxycodone is prescribed for the relief of moderate to high pain under pharmaceutical

trade names as OxyContin® (controlled release), OxyIR®, OxyFast®(immediate release formulations), or Percodan® (aspirin) and Percocet® (acetaminophen) that are in combination with other nonnarcotic analgesics. Oxycodone's behavioral effects can last up to 5 hours. The controlled-release product, OxyContin®, has a longer duration of action (8-12 hours).

The **Clear CUP One Step Drug Test** yields a positive result when the Oxycodone in urine exceeds 100ng/mL.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed 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 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, user's age, weight, activity, and diet. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).⁶

The **Clear CUP One Step Drug Test** yields a positive result when the phencyclidine level in urine exceeds 25ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PROPOXYPHENE (PPX)

Propoxyphene (PPX) is a mild narcotic analgesic found in various pharmaceutical preparations, usually as the hydrochloride or napsylate salt. These preparations typically also contain large amounts of acetaminophen, aspirin, or caffeine. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels. In human, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity. The **Clear CUP One Step Drug Test** yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300ng/mL.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

The **Clear CUP One Step Drug Test** yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000ng/mL.

2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)

Clear CUP One Step Drug Test EDDP is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. EDDP, if present in the urine specimen below 300ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody-coated particles will then be captured by immobilized EDDP conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the EDDP level exceeds 300ng/mL because it will saturate all the binding sites of anti-EDDP antibodies. A drug-positive urine specimen will not generate a colored line in the test line region, 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.

The **Clear CUP One Step Drug Test** EDDP yields a positive result when the EDDP in urine exceed 300ng/mL.

SYNTHETIC CANNABINOID (K2)

Since 2004, herbal mixtures such as 'Spice' are sold in Switzerland, Austria, Germany and other European countries mainly via Internet shops. Although declared as incense, they are smoked as 'bio-drugs' by the consumers. In corresponding blogs, drug users reported cannabis-like effects after smoking. These products enjoy great popularity particularly among younger people, as up to now the mixtures are sold in head shops and via internet in many countries without age restriction.

JWH-018 was developed and evaluated in basic scientific research to study structure activity relationships related to the cannabinoid receptors. JWH-073 has been identified in numerous herbal products, such as "Spice", "K2", "K3" and others. These products may be smoked for their psychoactive effects.

The **Clear CUP One Step Drug Test** K2 yields a positive result when K2 synthetic cannabinoid in urine exceed 50ng/mL.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) SUMMARY

The Adulterant Test Strip contains chemically treated reagent pads. Observation of the color change on the strip compared to the color chart provides a semi-quantitative screen for oxidants, specific gravity and Ph in human urine which can help to assess the integrity of the urine specimen.

ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants in the urine specimen can cause false negative results by either interfering with the test and/or destroying the drugs present in the urine. Dilution may also be used to produce false negative drug test results. To determine certain urinary characteristics such as specific gravity and Ph, and to detect the presence of oxidants in urine are considered to be the best ways to test for adulteration or dilution.

- Oxidants (OX): Tests for the presence of oxidizing agents such as bleach and peroxide in the urine.
- Specific Gravity (S.G.): Tests for sample dilution. Normal levels for specific gravity will range from 1.003 to 1.030. Specific gravity levels of less than 1.003 or higher than 1.030 may be an indication of adulteration or specimen dilution.
- Ph: tests for the presence of acidic or alkaline adulterants in urine. Normal Ph levels should be in the range of 4.0 to 9.0. Values below Ph 4.0 or above Ph 9.0 may indicate the sample has been altered.

PRINCIPLE

The **Clear CUP One Step Drug Test** 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. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

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 will generate a line in the test line region because of the absence of drug competition.

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.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepines, Methadone, Barbiturates, Tricyclic Antidepressants or Oxycodone.

ADULTERANT TESTS(SPECIMEN VALIDITY TEST) REAGENTS

Adulteration Pad	Reactive Indicator	Buffers and Non-reactive Ingredients
Oxidants (OX)	0.39%	99.61%
Specific Gravity (S.G.)	0.30%	99.70%
Ph	0.08%	99.94%

PRECAUTIONS

For Professional Use Only.

For In vitro Diagnostic Use Only

Do not use after the expiration date.

The test panel should remain in the sealed pouch until use.

The test is for single use.

While urine is not classified by OSHA or the CDC as a biological hazard unless visibly contaminated with blood^{8,9}, the use of gloves is recommended to avoid unnecessary contact with the specimen. The used test device and urine specimen should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

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 precipitates should be allowed to settle to obtain a clear specimen for testing.

SPECIMEN STORAGE

Urine specimens may be stored at 2-8°C (36-46°F) 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

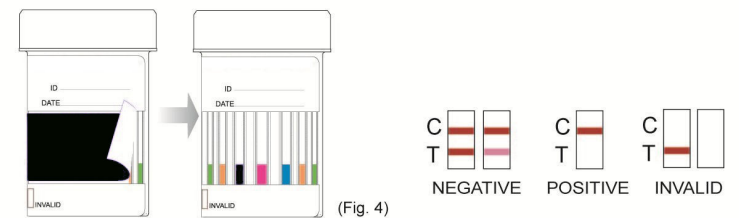
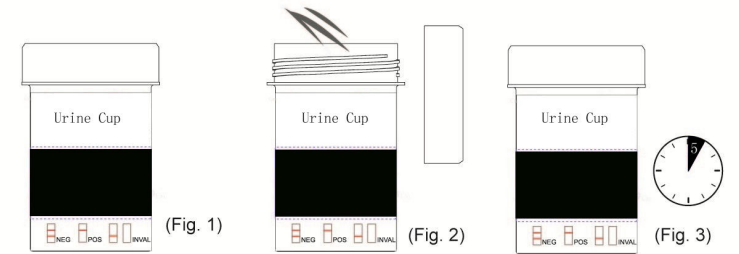
Materials Provided

- Test cup
 - Desiccants
 - Package insert
 - Procedure Card
 - Color Chart Card for Adulterant Interpretation (when applicable)
- Materials Required But Not Provided
- Timer
 - Disposable gloves

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 test cup and disposable gloves provided for donor. Label the device with donor information. (Fig. 1)
- 2) Wear disposable gloves to collect urine specimen. Open test cup lid. Urinary directly into the test cup. Be sure to fill up the test cup with the urine specimen between minimum 30ml to maximum 90ml (marked on the cup). (Fig. 2)
- 3) After urine specimen has been collected, close the lid securely and return cup to collection official. (Fig. 3)
- 4) Collection official use glove provided. Peel off label to reveal test result. Read test result at 5 minutes. DO NOT INTERPRET RESULT AFTER 10 MINUTES. (Fig. 4)



INTERPRETATION OF RESULTS

Please refer to the previous illustration)

NEGATIVE: Two lines appear. * One color line should be in the control region ©, and another apparent color line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of color in the test line region (T) will vary, but it should be considered negative whenever there is even a faint distinguishable color line.

POSITIVE: One color line appears in the control region ©. No line appears in the test region (T). 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 device. If the problem persists, discontinue using the lot immediately and contact your supplier.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color indicator on the color chart. No instrumentation is required.

ADULTERANT TESTS (SPECIMEN VALIDITY TESTS) LIMITATIONS

- The adulterant tests included with the product are meant to aid in the determination of abnormal specimens, but may not cover all the possible adulterants.
- Oxidants: Normal human urine should not contain oxidants. The presence of high level of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants pad.
- Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.

QUALITY CONTROL

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

LIMITATIONS

- The **Clear CUP One Step Drug Test** 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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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 and a new test device.
- A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
- 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.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

Testing on accuracy of the test strips was performed on clinical specimens collected for each of the following drug types. All clinical specimens were quantified by GC/MS analysis before testing. The quantity of the following compounds were analyzed by GC/MS and contributed to the total amount of drugs found in the positive specimens tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital
BZO	Oxazepam
COC	Benzoyllecgonine
THC	11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
MAMP	Methamphetamine
MDMA	D,L Methyleneoxyamphetamine, Methyleneoxyamphetamine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
TCA	Nortriptyline
EDDP	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine
BUP	Buprenorphine
PPX	Propoxyphene
K2	K2 synthetic cannabinoid

The following results are tabulated from these clinical studies.

	AMP	mAMP	OPI2000	OPI300	EDDP	THC	PCP
Positive Agreement	98%	95%	93%	93%	98%	95%	93%
Negative Agreement	98%	98%	95%	95%	95%	98%	95%
Overall Agreement	98%	96%	94%	94%	96%	96%	94%

	TCA	BAR	MDMA	PPX	BZO	BUP	MTD	OXY	K2
Positive Agreement	95%	98%	93%	95%	98%	93%	98%	95%	98%
Negative Agreement	98%	95%	95%	98%	93%	95%	95%	95%	95%
Overall Agreement	96%	96%	94%	96%	95%	94%	96%	95%	96%

Analyte	THC		BZO		PPX		OXY		MTD		EDDP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	3	17	1	19	2	18	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% cut-off]	18	2	19	1	18	2	18	2	19	1	19	1
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	95%	98%	98%	93%	95%	98%	95%	95%	98%	95%	98%	95%

Analyte	AMP		BAR		K2		METH		MDMA		OPI	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	1	19	2	18	2	18	1	19	2	18	2	18
Near Cut-off Positive Samples [between cutoff and 150% cut-off]	19	1	19	1	19	1	18	2	17	3	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0	20	0	20	0
Agreement with GC/MS	98%	98%	98%	95%	98%	95%	95%	98%	93%	95%	93%	95%

Analyte	PCP		MOP		TCA		BUP	
	Pos	Neg	Pos	Neg	Pos	Neg	Pos	Neg
Negative Samples	0	20	0	20	0	20	0	20
Near Cut-off Negative Samples [between 50% of cut-off and cut-off]	2	18	2	18	1	19	2	18
Near Cut-off Positive Samples [between cutoff and 150% cut-off]	17	3	17	3	18	2	17	3
Positive Samples [>150% of cut-off]	20	0	20	0	20	0	20	0
Agreement with GC/MS	93%	95%	93%	95%	95%	98%	93%	95%

Reproducibility

Reproducibility studies were carried out using commercially available stork solutions of the drug analytes listed. Dilutions were made from the stork solution of each drug to the concentrations specified in the following tables. A total of 40 determinations were made at each concentration. The results are listed in the following tables.

Amphetamine (AMP) conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Secobarbital conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	60	60 negative	>99%
150	60	60 negative	>99%
450	60	60 positive	>99%
600	60	60 positive	>99%

Oxazepam conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Benzoyllecgonine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

11-nor- Δ^9 -THC-9-COOH conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
25	40	40 negative	>99%
75	40	40 positive	>99%
100	40	40 positive	>99%

Methadone conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Methamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

Methyleneoxyamphetamine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
250	40	40 negative	>99%
750	40	40 positive	>99%
1000	40	40 positive	>99%

Opiate 300 (OPI 300, MOP, MOR)			
Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Opiate 2000 (OPI 2000)			
Morphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
1000	40	40 negative	>99%
3000	40	40 positive	>99%
4000	40	40 positive	>99%

Oxycodone (OXY)			
Oxycodone conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
50	40	40 negative	>99%
150	40	40 positive	>99%
200	40	40 positive	>99%

Phencyclidine (PCP)			
Phencyclidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
12.5	40	40 negative	>99%
37.5	40	40 positive	>99%
50	40	40 positive	>99%

Tricyc antidepressants (TCA)			
Nortriptyline conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
500	40	40 negative	>99%
1500	40	40 positive	>99%
2000	40	40 positive	>99%

EDDP			
EDDP 2-Ethylidene-1,5-dimethyl-3,3-diphepyrrolidine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Buprenorphine (BUP)			
Buprenorphine conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
5	40	40 negative	>99%
15	40	40 positive	>99%
20	40	40 positive	>99%

Propoxyphene (PPX)			
Propoxyphene conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
150	40	40 negative	>99%
450	40	40 positive	>99%
600	40	40 positive	>99%

Synthetic Cannabinoid (K2)			
JWH-073/JWH-018 conc.(ng/mL)	Total number of Determinations	Result	Precision
Drug-free Urine	40	40 negative	>99%
25	40	40 negative	>99%
75	40	40 positive	>99%
100	40	40 positive	>99%

Analytical Sensitivity
A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		BAR		BZO		COC		THC		BUP	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	27	3	27	3	27	3	30	0	20	10	28	2
Cut-off	30	17	13	15	15	15	15	9	21	13	17	16	14
+25% Cut-off	30	6	24	4	26	4	26	7	23	3	27	5	25
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	MTD		K2		mAMP		MDMA		MOP		PPX	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	24	6	27	3	24	6	28	2	28	2	26	4
Cut-off	30	16	14	16	14	14	16	19	11	20	10	16	14
+25% Cut-off	30	3	27	5	25	7	23	2	28	3	27	2	28
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OXY		PCP		TRA		TCA		EDDP		OPI2000	
		-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	23	7	27	3	26	4	20	10	27	3	27	3
Cut-off	30	10	20	19	11	16	14	14	16	16	14	14	16
+25% Cut-off	30	1	29	1	29	3	27	4	26	4	26	4	26
+50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30
2X Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical specificity
The following table lists the concentration of compounds (ng/mL) that were detected positive in urine by the **Clear CUP One Step Drug Test** at a read time of 5 minutes.

Drug	Concentration (ng/ml)
AMPHETAMINE (AMP1000)	
d-amphetamine	1,000
D,l-amphetamine	1,000
l-amphetamine	20,000
Phentermine	1,250
(+/-)-Methylenedioxyamphetamine (MDA)	1,500
(+/-)-4-Hydroxyamphetamine HCL	600
BARBITURATES (BAR)	
Secobarbital	300
Amobarbital	300

Alphenal	750
Aprobarbital	250
Butabarbital	6,000
Butalbital	2,500
Butethal	2,500
Cyclopentobarbital	500
Pentobarbital	2,500
Phenobarbital	25,000

BENZODIAZEPINES (BZO)	
Oxazepam	300
Alprazolam	2,500
Bromazepam	5,000
Chlordiazepoxide	1,565
Chlordiazepoxide HCl	780
Clobazam	100,000
Clonazepam	50,000
Clorazepate Dipotassium	1,000
Delorazepam	1,560
Desalkylflurazepam	390
Diazepam	125
Estazolam	75
Flunitrazepam	250
(±) Lorazepam	10,000
RS-Lorazepam glucuronide	160
Midazolam	5,000
Nitrazepam	750
Norchlordiazepoxide	250
Nordazepam	1,000
Temazepam	50,000
Triazolam	2,500
21-Hydroxy progesterone	100,000

COCAINE (COC)	
Benzoylcegonine	300
Cocacethylene	300
Cocaine	300
Metoclopramide	80,000
Procaine	75,000
Riboflavin	25,000
Norcocaine	50,000

MARIJUANA (THC)	
11-Nor- Δ^9 -Tetrahydrocannabinol	50
11-Hydroxy- Δ^9 -Tetrahydrocannabinol	5,000
11-Nor- Δ^8 -Tetrahydrocannabinol	50
11-Nor- Δ^9 -Tetrahydrocannabinol-9 Carboxylic Glucuronid	2,500
Δ^8 -Tetrahydrocannabinol	20,000
Δ^9 -Tetrahydrocannabinol	50,000

METHAMPHETAMINE (mAMP)	
+methamphetamine	1,000
(+/-) 3,4-Methylenedioxy-n-ethylamphetamine(MDEA)	20,000
Procaine (Novocaine)	60,000
Trimethobenzamide	20,000
+/-methamphetamine	1,000
Ranitidine (Zantac)	50,000
(+/-) 3,4-Methylenedioxyamphetamine (MDMA)	2,500
Chloroquine	50,000
Ephedrine	100,000
Fenfluramine	50,000
p-Hydroxymethamphetamine	10,000

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
D,L-3,4-Methylenedioxyamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine HCl (MDA)	3,000
3,4-Methylenedioxyethyla-amphetamine (MDEA)	300

Labetalol	50,000
OPIATES (OPI 300,MOP,MOR)	
Morphine	300
6-acetylmorphine	500
Codeine	100
Eserine (Physosotigmine)	15,000
Ethylmorphine	100
Heroin	500
Hydromorphone	2,000
Hydrocodone	1,250
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
OPIATES (OPI 2000)	
Morphine	2,000
6-acetylmorphine	2,500
Codeine	1,000
Ethyl Morphine	250
Heroin	5,000
Hydromorphone	2,500
Hydrocodone	5,000
Morphine-3-glucuronide	75
Oxycodone	75,000
Thebaine	13,000
Levorphanol	25,000
Eserine	50,000
OXYCODONE (OXY)	
Oxycodone	100
Codeine	50,000
Dihydrocodeine	12,500
Ethyl Morphine	75,000
Hydrocodone	1,580
Hydromorphone	100,000
Oxymorphone	750
Thebaine	50,000
PHENCYCLIDINE (PCP)	
Phencyclidine	25
4-Hydroxy PCP	90
PCP Morpholine Analog	625
TRICYCLIC ANTIDEPRESSANTS (TCA)	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	50,000
Desipramine	5,000
Doxepine	10,000
Imipramine	10,000
Maprotiline	100,000
Nordoxepin	10,000
Promazine	50,000
Promethazine	2,500
Trimipramine	50,000
Cyclobenzaprine Hydrochloride	5,000
Norclomipramine	50,000
Buprenorphine (BUP)	
Buprenorphine	10
Norbuprenorphine	20
Methadone (MTD)	
Methadone	300
Doxylamine	50,000

Propoxyphene (PPX)	
Norprooxyphene	300
Propoxyphene,d-	300
EDDP	
EDDP	300
Disopyramide	50,000
Tramadol	100,000
Venlafaxine hydrochloride	100,000

EFFECT OF URINARY SPECIFIC GRAVITY

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005, 1.015, 1.03) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The **Clear CUP One Step Drug Test** 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.

EFFECT OF THE URINARY PH

The pH of an aliquoted negative urine pool was adjusted to pH ranges of 4.0,4.5,5.0, 6.0 and 9.0, and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the **Clear CUP One Step Drug Test**. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

CROSS-REACTIVITY

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or drug positive urine containing Cocaine, Barbiturates, Benzodiazepines, Amphetamine , Methamphetamine, Marijuana, Methadone, MDMA(Ecstasy), Opiate , Oxycodone, Phencyclidine, K2 Synthetic Cannabinoid or Tricyclic Antidepressants. The following compounds show no cross-reactivity when tested with the **Clear CUP One Step Drug Test** at concentrations of 100 µg/mL.

NON CROSS-REACTIVITY COMPOUNDS

Acetophenetidin	l-Cotinine	Cortisone	d-Pseudoephedrine
N-Acetylprocainamide	Creatinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Deoxycorticosterone	Labetalol	Quinine
Aminopyrine	Dextromethorphan	Loperamide	Salicylic acid
Amoxicillin	Diclofenac	Meprobamate	Serotonin
Ampicillin	Diflunisal	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Digoxin	Methylphenidate	Sulindac
Apomorphine	Diphenhydramine	Nalidixic acid	Tetracycline
Aspartame	Ethyl-p-aminobenzoate	Naproxen	Tetrahydrocortisone,
Atropine	β-Estradiol	Niacinamide	3-Acetate
Benzilic acid	Estrone-3-sulfate	Nifedipine	Tetrahydrocortisone
Benzoic acid	Erythromycin	Norethindrone	Tetrahydrozoline
Bilirubin	Fenoprofen	Noscapine	Thiamine
d,l-Brompheniramine	Furosemide	d,l-Octopamine	Thioridazine
Caffeine	Gentisic acid	Oxalic acid	d,l-Tyrosine
Cannabidiol	Hemoglobin	Oxolinic acid	Tolbutamide
Chloralhydrate	Hydralazine	Oxymetazoline	Triamterene
Chloramphenicol	Hydrochlorothiazide	Papaverine	Trifluoperazine
Chlorothiazide	Hydrocortisone	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	o-Hydroxyhippuric acid	Perphenazine	d,l-Tryptophan
Chlorpromazine	3-Hydroxytyramine	Phenelzine	Uric acid
Cholesterol	d,l-Isoproterenol	Prednisone	Verapamil
Clonidine	Isosuprine	d,l-Propranolol	Zomepirac

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