Amazewell™

Multi-Drug Urine Test Cup

INSTRUCTIONS FOR USE

PLEASE READ ALL INFORMATION IN THE INSTRUCTIONS FOR USE BEFORE USING THE TEST!

REF See Box Label

This package insert applies to any combination of multi-drug tests and adulteration control tests. Therefore, some information on the performance characteristics of the product may not be relevant to your test. Please refer to the labels on the packaging and the prints on the test device to identify which drugs and adulteration controls are included in your test.

INTENDED USE

Multi-Drug Urine Test Cup is a rapid urine screening test. It's a lateral flow, one-step immunoassay for the qualitative detection of specific drugs and their principal metabolites in human urine at specified cut-off concentrations, with additional semi quantitative adulteration controls. The multi-drug test device can be combined with the adulteration controls such as Creatinine (CRE), Glutaraldehyde (GLU), Nitrite (NIT), pH, Specific Gravity (S.G.), and/or Oxidants/Pyridinium Chlorochromate (OXI/PCC), which is used for the determination of diluted or adulterated urine specimens. The adulteration control is an important pre-screening test for drug-testing.

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP 1000)	d-Amphetamine	1000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR 300)	Secobarbital	300
Benzodiazepines (BZO 300)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylecgonine	300
Cocaine (COC 150)	Benzoylecgonine	150
Cocaine (COC 100)	Benzoylecgonine	100
Cannabinoids (THC 50)	11-nor-Δ9-THC-9-COOH	50
Cannabinoids (THC 40)	11-nor-Δ9-THC-9-COOH	40
Cannabinoids (THC 25)	11-nor-Δ9-THC-9-COOH	25
Cotinine (COT)	Cotinine	200
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500
Fentanyl (FTY)	Fentanyl	20
Ketamine (KET 1000)	Ketamine	1000
Ketamine (KET 500)	Ketamine	500
Methamphetamine (MET 1000)	d-Methamphetamine	1000
Methamphetamine (MET 500)	d-Methamphetamine	500

Methamphetamine (MET 300)	d-Methamphetamine	300
Methadone (MTD 300)	Methadone	300
Methadone (MTD 200)	Methadone	200
Methadone Metabolite (EDDP 300)	2-ethylidene-1,5-dimethyl-3, 3-diphenylpyrrolidine (EDDP)	300
Methylenedioxymethamphetamine - ecstasy (MDMA 500)	3,4-Methylenedioxymethamp-hetamine HCl (MDMA)	500
Methylenedioxymethamphetamine - ecstasy (MDMA 300)	3,4-Methylenedioxymethamp-hetamine HCl (MDMA)	300
Morphine (MOP 300)	Morphine	300
Morphine (MOP 100)	Morphine	100
Opiate (OPI)	Morphine	2000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	d-Propoxyphene	300
Synthetic Cannabis (K2 50)	JWH-018 / JWH-073	50
Synthetic Cannabis (K2 25)	JWH-018 / JWH-073	25
Tricyclic Antidepressants (TCA)	Notriptyline	1000
Tramadol (TRA 1000)	Tramadol	1000
Tramadol (TRA 200)	Tramadol	200
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10

Configurations of the Multi-Drug Urine Test Cup can consist of any combination of the above listed drug analytes. ***It is intended for forensic use only.***
This assay provides a qualitative, preliminary test result. A more specific analytical method must be used in order to obtain a confirmed result. Gas Chromatography/Mass spectrometry (GC/MS) or Liquid Chromatography/Tandem Mass Spectrometry (LC/MS-MS) are the preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

SUMMARY

Amphetamine (AMP)
Amphetamine and the structurally related "designer" drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthymic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine. Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent

damage to certain essential nerve structural in the brain. 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. It can be detected in the urine for 1 to 2 days after use.

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.

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.

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. Substantial abuse of Buprenorphine has also been reported in many countries where various forms of the drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

Cocaine (COC)
Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoylecgonine in a short period of time.

Cannabinoids (THC)
Cannabinoids is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor-Δ9-tetrahydro cannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

Cotinine (COT)
Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays. In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

Ethyl Glucuronide (ETG)
Ethyl Glucuronide (ETG) is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of ETG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, ETG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The ETG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

Fentanyl (FTY)
Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain1. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc2,3, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

Ketamine (KET)
Ketamine was developed in the 1960s to replace phencyclidine (PCP) as an anesthetic agent and is most commonly used in veterinary medicine today. In addition to rohypnol (add hyperlink to page) and GHB, it is also considered a club drug, and may be used in drug-facilitated sexual assault situations. It is odorless, tasteless and usually swallowed in powder form or injected. Once taken, it is very short-acting and shows effects within minutes. Under federal law, ketamine is classified as a Schedule III drug, meaning it has approved medical use, but still possesses a high potential for abuse.

Methamphetamine (MET)
Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

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). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12~24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylprryolidine), and EMDP (2-ethyl-5-methy -3, 3-diphenylpyrrolidine).

Methadone Metabolite (EDDP)
EDDP(2-Ethylidine-1,5-dimethyl-3,3-diphenylpyrrolidine) is the primary metabolite of methadone. Methadone is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. The detection of EDDP is more beneficial than traditional methadone screening since EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

Methylenedioxymethamphetamine - ecstasy (MDMA)
MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphet amine). 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 cartooning 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.

Morphine (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.

Opiate (OPI)
Multi-Drug Urine Test Cup yields a positive result when the concentration of morphine in urine exceeds 2000ng/mL. See Morphine (MOP) for the summary.

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.

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 (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heat rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) 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%).

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.

Synthetic Cannabis (K2)
Synthetic cannabis is a psychoactive designer drug derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis, it is best known by the brand names K2 and Spice.
Synthetic cannabis act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabis most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug. Although synthetic cannabis does not produce positive results in drug tests for cannabis, it is

possible to detect its metabolites in human urine. The synthetic cannabinoids contained in synthetic cannabis products have been made illegal in many European countries. On November 24, 2010, the U.S. Drug Enforcement Administration announced it would use emergency powers to ban many synthetic cannabinoids within a month. As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47,497, JWH-200, and cannabicyclohexanol are now illegal in the US.

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.

Tramadol (TRA)
Tramadol is a quasi-narcotic analgesic used in the treatment of moderate to severe pain. It is a synthetic analog of codeine, but has a low binding affinity to the mu-opioid receptors. It has been for the treatment of diabetic neuropathy and restless leg syndrome. Large doses of Tramadol could develop tolerances and physiological dependency and lead to its abuse. Both Δ (d) and L forms of the isomers are controlled substances. Approximately 30% of the dose is excreted in the urine as unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucuronidation or sulfation in the liver.

6-Monoacetylmorphine (6-MAM)
6-Monoacetylmorphine (6-MAM) or 6-acetylmorphine (6-AM) is one of three active metabolites of heroin (diacetylmorphine), the others being morphine and the much less active 3-monoacetylmorphine (3-MAM). 6-MAM is rapidly created from heroin in the body, and then is either metabolized into morphine or excreted in the urine. 6-MAM remains in the urine for no more than 24 hours. So a urine specimen must be collected soon after the last heroin use, but the presence of 6-MAM guarantees that heroin was in fact used as recently as within the last day. 6-MAM is naturally found in the brain, but in such small quantities that detection of this compound in urine virtually guarantees that heroin has recently been consumed.

PRINCIPLE OF THE PROCEDURE

DRUGS-OF-ABUSE TESTS:
Multi-Drug Urine Test Cup is a competitive immunoassay that is used to screen for the presence of various drugs and drug metabolites in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.
When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C) of each strip, if the test has been performed properly.

ADULTERATION CONTROL:
In general, all adulteration control tests are based on the chemical reactions of the indicator reagents on the pads with components in the urine sample effecting color changes. Results are obtained by comparing the color on each of the test pads with the corresponding pad on the color chart.

Creatinine (CRE): Testing for sample dilution. In this assay, creatinine reacts with a creatinine indicator in an alkaline condition to form a purplish-brown color complex. The concentration of creatinine is directly proportional to the color intensity of the test pad.

Glutaraldehyde (GLU): Testing for the presence of exogenous aldehyde. In this assay, the aldehyde group on the glutaraldehyde reacts with an indicator to form a pink/purple color complex.

Nitrite (NIT): Testing for the presence of exogenous nitrite. Nitrite reacts with an aromatic amine to form a diazonium compound in an acid medium. The diazonium compound in turn couples with an indicator to produce a pink-red/purple color.

pH: Testing for the presence of acidic or alkaline adulterant. This test is based on the well-known double pH indicator method that gives distinguishable colors over wide pH range. The colors range from orange (low pH) to yellow and green to blue (high pH).

Specific Gravity (S.G.): Testing for sample dilution. This test is based on the apparent pKa change of certain pretreated polyelectrolytes in relation to the ionic concentration. In the presence of an indicator, the colors range from dark blue or blue-green in urine of low ionic concentration to green and yellow in urine of higher ionic concentration.

Oxidants/Pyridinium Chlorochromate (OXI/PCC): Tests for the presence of oxidizing reagents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is commonly used adulterant. Normal human urine should not contain Oxidants or PCC.

WARNINGS AND PRECAUTIONS

1. For external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use the test device beyond expiration date.
4. Do not use the test device if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. The used test cup should be discarded according to local regulations.

STORAGE AND STABILITY

1. Store at 35˚F - 86˚F (2ºC - 30ºC) in the sealed pouch up to the expiration date.

2. DO NOT FREEZE.
3. Keep away from direct sunlight, moisture and heat.
4. Preferably open the pouch only shortly before the test.

MATERIALS AND COMPONENTS

REAGENTS AND MATERIALS SUPPLIED
- 25x Multi-Drug Urine Test Cups
- 1x Adulteration Color Comparison Chart (If equipped)
- 1x Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer or stopwatch

SPECIMEN COLLECTION

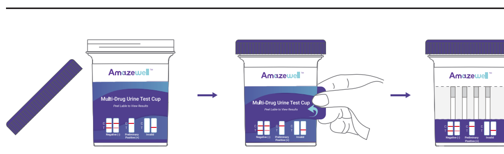
WHEN TO COLLECT URINE FOR THE TEST?
Collect urine specimen after minimum detection time following suspected drug use. Urine collection time is very important in detecting any drugs of abuse. Each drug is cleared by the body and is detected in the urine at different times and rates. Please refer to the minimum or maximum detection time of each drug in this instruction.

HOW TO COLLECT URINE?
1. Remove the test cup from the foil pouch by tearing at the notch. Use it as soon as possible. Instruct the donor to remove the test cup lid and void directly into the test cup until reach the Minimum Urine Level mark (approximately 25 mL). It is acceptable to collect extra volume of urine. If insufficient specimen has been collected, instruct the donor to provide urine specimen again with another new test cup. Wipe off any splashes or spills that may be on the outside of the cup. It is recommended to wear gloves when handling the test cup with urine specimen.

2. Observe the temperature strip affixed on the test cup between 2 to 4 minutes after urine is voided into the cup. The temperature between 90°F to 100°F (32°C-38°C) indicates the fresh uncontaminated specimen. If the temperature is out of this range, instruct the donor to provide urine specimen again with another new test cup.

TEST PROCEDURE

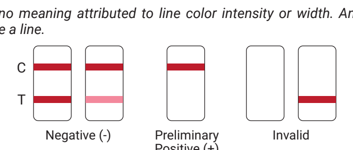
Test should be performed at room temperature (59°F- 86°F / 15°C - 30°C).
1. After the urine has been collected, tighten the lid until an audible click is heard, then place the cup on a flat surface.
2. Start the timer. Peel the label from right to left.
3. **For the adulteration strip(s) if equipped:** read results immediately, or at 30 seconds, or at 45 seconds and compare each adulterant pad to verify pad color is within acceptable range according to the Adulteration Color Comparison Chart. If the results indicate adulteration, do not read the drug test results. Instruct the donor to provide urine specimen again with another new test cup.
4. **For the drug tests:** read the drug test results at 5 minutes. **Do not read after 10 minutes.**



INTERPRETATION OF TEST RESULTS

ADULTERATION CONTROL:
Semi-quantitative results are obtained by visually comparing the color of each pad with the corresponding color blocks on the enclosed color chart.

DRUGS-OF-ABUSE TESTS:
Preliminary Positive (+)
A color band is visible in each control region (C). If no color band appears in the appropriate drug test region, a preliminary positive result is indicated for the corresponding drug of that specific test region.
Negative (-)
If a color band is visible in each control region (C) and the appropriate drug test region, it indicates that the concentration of the corresponding drug of that specific test region is absent or below the detection limit of the test.
Invalid
If a color band is not visible in the control region (C) or a color band is only visible in the drug test region, the test is invalid. Another test should be run to re-evaluate the specimen.
Note: *There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.*



QUALITY CONTROL

Users should follow the appropriate federal, state, and local guidelines concerning the frequency of assaying external quality control materials. Even though there is an internal procedural control line in the test device in the Control Region (C), the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative controls should give the expected results. When testing the positive and negative controls, the same assay procedure should be adopted. External Control (positive and negative) should be run with each new lot, each new shipment and each new operator to determine that tests are working properly.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. **DO NOT** use this device to test substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause incorrect results.
3. Contaminated urine samples may produce incorrect results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of contamination, repeat the test with another urine sample.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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.

PERFORMANCE CHARACTERISTICS

ADULTERATION CONTROL:
Expected Results
Creatinine: Daily creatinine excretion, related to muscle mass of the human body, is usually constant. The DOT guideline states that urine specimens with creatinine levels of less than 20 mg/dl are indications of adulteration. Although these ranges are affected by age, sex, diet, muscle mass and local population distribution2, sample with creatinine level of lower than 20 mg/dl should be considered adulterated.
Glutaraldehyde: Glutaraldehyde is not a natural component of human urine and it should not be present in normal urine. The presence of glutaraldehyde in the urine sample indicates the possibility of adulteration. However, false positive may result when ketone bodies are presence in urine. Ketone bodies may appear in urine when a person is in ketoacidosis, starvation or other metabolic abnormalities.
Nitrite: Although nitrite is not a normal component of urine, nitrite levels of up to 3.6 mg/dl may be found in some urine specimens due to urinary tract infections, bacterial contamination or improper storage. In this adulteration control, nitrite level above 7.5 mg/dl is considered abnormal.
pH: Normal urine pH ranges from 4.5 to 8.0. Values below pH 4.0 or above pH 9.0 are indicative of adulteration.
Specific Gravity: Random urine may vary in specific gravity from 1.003 - 1.030. Normal adults with normal diets and normal fluid intake will have an average urine specific gravity of 1.016 - 1.022. Elevated urine specific gravity value may be obtained in the presence of moderate quantities of protein. DOT guidelines state that a urine specimen with specific gravity level of less than 1.003 is an indication of adulteration. Specific gravity and creatinine values should be considered together to provide a better picture of whether the sample is adulterated.
Oxidants: The presence of Bleach and other oxidizing reagents in the urine is indicative of adulteration since oxidizing reagents are not normal constituents of urine. Other oxidizing reagents include Hydrogen Peroxide, Ferricyanide, Persulfate, Pyridinium Chlorochromate...etc.
Pyridinium Chlorochromate: The presence of any chromate in urine is indicative of adulteration as chromate is not a normal constituent of urine.

DRUGS-OF-ABUSE TESTS:

A. Precision and Sensitivity
To investigate the precision and sensitivity, each drug samples were analyzed at the following concentrations: +100% cutoff, +75% cutoff, +50% cutoff, +25% cutoff, cutoff, -25% cutoff, -50% cutoff, -75% cutoff and -100% cutoff. All concentrations were confirmed with GC-MS. The study was performed 2 runs /day and lasted 25 days using three different lots of the corresponding drug of abuse test. Totally 3 operators participated in the study of the corresponding drug of abuse test. Each of the 3 operators tests 2 aliquots at each concentration for each lot per day (2 runs /day), for a total of 50 determinations per concentration per lot of the corresponding drug of abuse test.

Drug test	Approximate concentration of sample (ng/mL)	Number of determinations per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
AMP 1000	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	13/37	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
AMP 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
AMP 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50

AMP 300	Cutoff	50	15/35	15/35	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
BAR 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	14/36	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
BZO 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	12/38	11/39
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
BZO 200	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	13/37	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
BZO 100	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50

BZO 100	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
BUP 10	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	15/35	15/35	16/34
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
COC 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	12/38	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
COC 150	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	14/36	15/35
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0

COC 100	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	15/35	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
THC 50	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	14/36	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
THC 40	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	13/37	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
THC 25	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	11/39	11/39
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0

THC 25	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
COT 200	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
ETG 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	15/35	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
FTY 20	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	13/37	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
KET 1000	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	13/37	12/38

KET 1000	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
KET 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	11/39
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MET 1000	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	10/40	11/39	11/39
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MET 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	13/37	13/37	12/38
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MET 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50

MET 300	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MTD 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	15/35	14/36	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MTD 200	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	14/36	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
EDDP 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	12/38	13/37
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0

MDMA 500	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	10/40	11/39	10/40
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MDMA 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	12/38	11/39	11/39
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MOP 300	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	15/35	14/36	14/36
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0
MOP 100	+100% Cutoff	50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50
	Cutoff	50	14/36	14/36	15/35
	-25% Cutoff	50	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0