

This package insert applies to all single-drug tests listed. Therefore, some information may not be relevant to your test. You can identify which drug and associated cutoff are included in your test from the labels on the packaging and the prints on the test device.

INTENDED USE

Single Drug Urine Test Dipcard is a rapid urine screening test. It's a lateral flow, one-step immunoassay for the qualitative detection of single drugs in human urine at the following cut-off concentrations.

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 (BZD 300)	Oxazepam	300
Benzodiazepines (BZD 200)	Oxazepam	200
Benzodiazepines (BZD 100)	Oxazepam	100
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylgonine	300
Cocaine (COC 150)	Benzoylgonine	150
Cocaine (COC 100)	Benzoylgonine	100
Cannabidiols (THC 50)	11-nor-Δ ⁹ -THC-9-COOH	50
Cannabidiols (THC 40)	11-nor-Δ ⁹ -THC-9-COOH	40
Cannabidiols (THC 25)	11-nor-Δ ⁹ -THC-9-COOH	25
Cotinine (COT 200)	Cotinine	200
Cotinine (COT 100)	Cotinine	100
Ethyl Glucuronide (ETG 500)	Ethyl Glucuronide	500
Ethyl Glucuronide (ETG 300)	Ethyl Glucuronide	300
Fentanyl (FTY 50)	Fentanyl	50
Fentanyl (FTY 20)	Fentanyl	20
Fentanyl (FTY 10)	Fentanyl	10
Gabapentin (GAB)	Gabapentin	1000
Ketamine (KET 1000)	Ketamine	1000
Ketamine (KET 500)	Ketamine	500
Kratom (KRA 300)	Mitragynine	300

Single Drug Urine Test Dipcard

INSTRUCTIONS FOR USE

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

[REF] See Box Label

Kratom (KRA 250)	Mitragynine	250
Kratom (KRA 100)	Mitragynine	100
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
Methylenedioxyamphetamine (MDMA 300)	3,4-Methylenedioxyamphet-amine	300
Methylenedioxyamphetamine (MDMA 500)	3,4-Methylenedioxyamphet-amine	500
Morphine (MOP 300)	Morphine	300
Morphine (MOP 100)	Morphine	100
Opiate (OP)	Morphine	2000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	d-Propoxyphene	300
Synthetic Cannabinoids (K2 50)	JWH-018 / JWH-073	50
Synthetic Cannabinoids (K2 25)	JWH-018 / JWH-073	25
Synthetic Cannabinoids (K3)	AB-PINACA	10
Tricyclic Antidepressants (TCA)	Nortriptyline	1000
Tramadol (TRA 1000)	Tramadol	1000
Tramadol (TRA 200)	Tramadol	200
Tramadol (TRA 100)	Tramadol	100
Xylazine (XYL)	Xylazine	300
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine	10

One dipcard is used to detect only one drug of abuse, and only one cutoff concentration under same drug condition will be included per dipcard. **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 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, hyperthyroid, 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 hydrolyzed 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 (BZD)
Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by anxiolysis, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenergic receptors, 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 primary metabolites of buprenorphine are Buprenorphine-3-O and Buprenorphine-6-O, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment with buprenorphine is a form of medical care offered to individuals with heroin addictions 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 its metabolites in urine are less than 1 ng/mL after oral 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 abuse 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.

Cannabidiols (THC)
Cannabidiols is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabidiols, THF-C and Cannabidiol can be metabolized and excreted as 11-nor-Δ⁹-tetrahydrocannabinol-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 Cannabidiols/cannabis. Higher doses of cannabis by alternate routes such as edibles, 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 psychomotor 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 parental 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 after alcohol is eliminated from the body. Therefore, ETG is a more accurate indicator of recent intake of alcohol than measuring 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 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 pain. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, 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.

Gabapentin (GAB)
Gabapentin is a medicine used to treat partial seizures, nerve pain from shingles and restless leg syndrome, and is in a class of medications called anticonvulsants. It works on the chemical messengers in the brain and nerves. Gabapentin may cause serious side effects such as drowsiness, dizziness, weakness, problems with balance or muscle movement, or increased seizures. Gabapentin can cause life-threatening breathing problems, especially if the users take gabapentin with drugs that cause sleepiness or decreased awareness. Some examples include narcotic opioids, anti-anxiety medicines, antidepressants, and antihistamines.

Ketamine (KET)
Ketamine was developed in the 1960s to replace phenylethylamine (PCP) as an anesthetic agent and is most commonly used in veterinary medicine today. In addition to rolypud (add hyperlink link) 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 a 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.

Kratom (KRA)
Kratom is an herbal extract that comes from the leaves of an evergreen tree (Mitragyna speciosa) grown in Southeast Asia and Africa. Kratom extract is often marketed as a treatment for muscle pain, or to suppress appetite and stop cramps and diarrhea. Kratom is also sold as a treatment for panic attacks. At low doses, kratom acts as a stimulant, making users feel more energetic. At higher doses, it reduces pain and may bring on euphoria. At very high doses, it acts as a sedative, making users quiet and unresponsive. In fact, kratom's potential for severe side effects outweigh its potential benefits, and in extreme cases, kratom has even caused death.

Methamphetamine (MET)
Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Cocaine 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 when using methamphetamine will appear at a half-life of about 15 hours if excreted as 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 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-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3,3-diphenylpyrrolidine).

Methadone Metabolite (EDDP)
EDDP(2-Ethylidene-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.

Methylenedioxyamphetamine (MDMA)
MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxymethamphetamine). They all share the amphetamine-like effects: MDMA is 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, anorexia, 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.

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 equivalent 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 abused. 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.

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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 heart 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, stuor, 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 Cannabinoids (K2/K3)
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 cannabis brands for 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 drug 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 and Δ (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.

Xylazine (XYL)
Xylazine is not a controlled substance, it is marketed as a veterinary drug and used as a sedative, analgesic and muscle relaxant. In humans, it could cause central nervous system depression, respiratory depression, bradycardia, hypotension, and even death. Most of the non-fatal cases involved medical intervention. Over recent years, xylazine has emerged as an adulterant in recreational drugs, such as heroin or speedball (a cocaine and heroin mixture). Its chronic use is reported to be associated with physical detour and skin ulceration. Literature shows some pharmacologic effects between xylazine and heroin in humans. These similar pharmacologic effects may create synergistic toxic effects in humans. Therefore, fatalities among drug users may increase due to the use of xylazine as an adulterant. Xylazine alone has proven harmful to humans and even more when it is combined with drugs of abuse.

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.

To serve as a procedure control, a colored line will appear at the Control Region (C), if the test has been performed properly.

WARNINGS AND PRECAUTIONS

- For external use only. Do not swallow.
- Discard after first use. The test cannot be used more than once.
- Do not use the test device beyond expiry date.
- Do not use the test device if the pouch is punctured or not well sealed.
- Keep out of the reach of children.
- The used test dipcard should be discarded according to local regulations.

STORAGE AND STABILITY

- Store at 35°F - 86°F (2°C - 30°C) in the sealed pouch up to the expiration date.
- DO NOT FREEZE.
- Keep away from direct sunlight, moisture and heat.
- Preferably open the pouch only shortly before the test.

MATERIALS AND COMPONENTS

- REAGENTS AND MATERIALS SUPPLIED**
- Single Drug Urine Test Dipcard
 - Instructions for use
- MATERIALS REQUIRED BUT NOT PROVIDED**
- Dropper
 - Urine collection cup
 - Timer or stopwatch

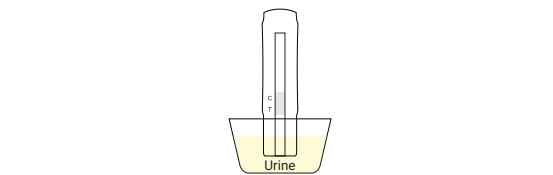
SPECIMEN COLLECTION AND STORAGE

- Collect urine specimen with a urine collection cup. Urine collected at any time of the day may be used.
- For best results, test the urine specimen immediately following collection.
- Urine specimens may be refrigerated at 35°F - 46°F / 2°C - 8°C and stored up to forty-eight hours. For longer storage, freeze the samples at 4°F / -20°C or below. Bring frozen or refrigerated specimens to room temperature before testing.
- DO NOT REFREEZE.

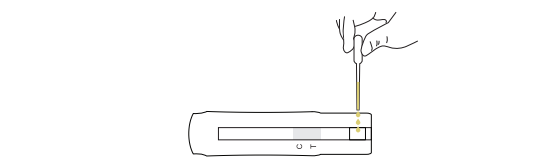
TEST PROCEDURE

- Test should be performed at room temperature (59°F- 86°F / 15°C - 30°C).
- 2 WAYS TO TEST:**
- **Test as a dipcard:**
- Remove the Single Drug Urine Test Dipcard from the pouch and use it within the first hour after opening.
 - Hold the one side of the device with one hand. Use the other hand to pull out the cap

- and expose the absorbent end.
- Dip the absorbent end into the urine specimen for about 10 seconds. Make sure that the urine level does not touch the plastic device.
- Re-cap and lay the device flat on a clean, dry, non-absorbent surface.
- Read the result at 5 minutes. Do not read after 60 minutes.



- **Test as a cassette:**
- Remove the Single Drug Urine Test Dipcard from the pouch and use it within the first hour after opening.
 - Place the device on a clean and level surface. Hold the dropper (not included in the box) vertically and transfer 3 drops of urine (approx. 80 µL) to the specimen well of the device.
 - Read the result at 5 minutes. Do not read after 60 minutes.



INTERPRETATION OF TEST RESULTS

Preliminary Positive (+)
A color band is visible in the control region (C). No color band appears in the test region (T). A preliminary positive result is indicated that the drug concentration is equal to or higher than the detection limit.

Negative (-)
A color band is visible in both the control region (C) and the test region (T). This negative result indicates that the drug concentration is absent or below the detection limit.

Invalid
If a color band is not visible in the control region (C), 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 positive and negative controls, the detection of the presence of the result should be adopted. External controls (positive and negative) should be run with each new lot, one new shipment and each new operator to determine that tests are working properly.

TEST LIMITATIONS

- 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.
- There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause incorrect results.
- 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.
- This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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

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.

COT 200	-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
	+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	13/37
	-25% Cutoff	50	50/0	50/0	50/0

