

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 (BZO 300)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO 100)	Oxazepam	100
Buprenorphine (BUP 10)	Buprenorphine	10
Cocaine (COC 300)	Benzoylgonine	300
Cocaine (COC 150)	Benzoylgonine	150
Cocaine (COC 100)	Benzoylgonine	100
Cannabis (THC 50)	11-nor-Δ ⁹ -THC-9-COOH	50
Cannabis (THC 40)	11-nor-Δ ⁹ -THC-9-COOH	40
Cannabis (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

1	2	3	4	5	6	7
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It is a synthetic analog of cocaine, 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 (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 required 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 deterioration and skin ulceration. Literature shows some similar 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.

PRINCIPLE OF THE PROCEDURE

Single Drug Urine Test Dipcard 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 in 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 the test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When the drug in 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 the drug in the urine sample is 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.

8	9	10	11	12	13	14
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COT 200	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
COT 100	Cutoff	50	13/37	14/36	13/37	
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
ETG 500	Cutoff	50	13/37	13/37	14/36	
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
ETG 300	Cutoff	50	14/36	15/35	14/36	
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
FTY 50	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50

FTY 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	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
FTY 20	Cutoff	50	12/38	12/38	13/37	
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
FTY 10	Cutoff	50	12/38	13/37	13/37	
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
FTY 1	Cutoff	50	11/39	12/38	12/38	
	-25% Cutoff	50	50/0	50/0	50/0	50/0
	-50% Cutoff	50	50/0	50/0	50/0	50/0
	-75% Cutoff	50	50/0	50/0	50/0	50/0
	-100% Cutoff	50	50/0	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50	0/50
	+75% Cutoff	50	0/50	0/50	0/50	0/50
	+50% Cutoff	50	0/50	0/50	0/50	0/50
	+25% Cutoff	50	0/50	0/50	0/50	0/50
GAB 1000	+100% Cutoff	50	0/50	0/50	0/50	0/50

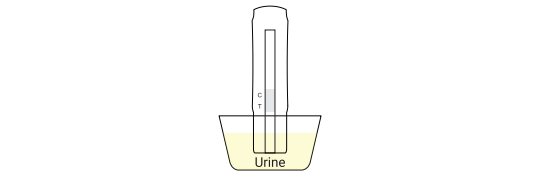
Kratom (KRA 300)	Mitragynine	300
Kratom (KRA 250)	Mitragynine	250
Kratom (KRA 100)	Mitragynine	100
Methamphetamine (MET 1000)	d-Methamphetamine	1000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methadone (MTD 300)	Methadone	300
Methadone (MTD 200)	Methadone	200
Methadone Metabolite (EDDP 300)	2-ethyliden-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Methylenedioxymethamphetamine (MDMA 500)	3,4-Methylenedioxymethamphetamine	500
Methylenedioxymethamphetamine (MDMA 300)	3,4-Methylenedioxymethamphetamine	300
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 Cannabis (K2 50)	JWH-018 / JWH-073	50
Synthetic Cannabis (K2 25)	JWH-018 / JWH-073	25
Synthetic Cannabis (K3)	AB-Pinica	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 the 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 the preferred confirmatory methods. Professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

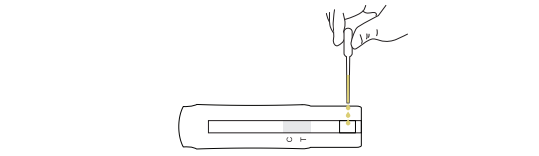
1	2	3	4	5	6	7
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and expose the absorbent end.
3. Dip the absorbent end into the urine specimen for about 10 seconds. Make sure that the urine level does not touch the plastic device.
4. Re-cap and lay the device flat on a clean, dry, non-absorbent surface.
5. 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.

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 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 (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 adrenergic response and an increase 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 Benzodiazepine abuse.

Buprenorphine (BUP)
Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. It is a synthetic Buprenorphine "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 people with opioid dependency (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 dependency. Concentrations of free Buprenorphine and Norbuprenorphine in urine are 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.

Cannabis (THC)
Cannabis is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabisoids, 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 Cannabisoids/cannabis. Higher doses may be achieved by altering the 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 cardiovascular 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 that 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 detecting 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 as it metabolite is eliminated from the body. Therefore, ETG is a more accurate indicator of the recent intake of alcohol than measuring the presence of alcohol itself. The ETG test can aid in the diagnosis of drug driving and alcoholism, which has important significance in the forensic identification and medical examination.

Drug test	Approximate concentration of sample (ng/mL)	Number of determination ns per lot	Results Negative/ Positive		
			Lot 1	Lot 2	Lot 3
	+25% Cutoff	50	0/50	0/50	0/50
	-25% Cutoff	50	50/0	50/0	50/0
	+100% Cutoff	50	0/50	0/50	0/50
	-100% Cutoff	50	50/0	50/0	50/0
	+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
	-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

