DOA Rapid Urine Test Device Cup(Colloidal Gold)

Cup

Instruction for Use

A lateral flow chromatographic immunoassay for the qualitative detection of Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, Nicotine, Fentanyl, Ketamine, Marijuana, Methadone, EDDP, Methamphetamine, Methaqualone, Ecstasy, Morphine,Oxycodone, Phencyclidine, Propoxyphene, Tramadol, Tricyclic Antidepressants, K2, MDPV, MCAT, LSD,ETG and SOMA in urine.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

1T/box,10T/box,20T/box,25T/box,40T/box,50T/box

INTENDED USE

DOA Rapid Urine Test Device Cup a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and/or drug metabolites in urine at the following cut-off concentrations:

Item	Calibrator	Cut-off
Amphetamine (AMP)	S(+)-Amphetamine	1,000ng/mL
Barbiturates (BAR)	Secobarbital	300ng/mL
Buprenorphine (BUP)	Buprenorphine	10ng/mL
Benzodiazepines (BZO)	Oxazepam	300ng/mL
Cocaine (COC)	Benzoyleogomine	300ng/mL
Nicotine (COT)	(-)-Cotinine	200ng/mL
Fentanyl (FYL)	Fentanyl	200ng/mL
Ketamine (KET)	Ketamine	1,000ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50ng/mL
Methadone (MTD 300)	Methadone	300ng/mL
EDDP	EDDP perchlorate	100ng/mL
Methamphetamine (MET)	S(+)-Methamphetamine	1000ng/mL
Methaqualone (MQL)	Methaqualone	300ng/mL
Ecstasy (MDMA)	(±) - Methylenedioxymethamphetamine	500ng/mL
Morphine (MOP)	Morphine	300ng/mL
Opiates (OPI)	Morphine	2,000ng/mL
Oxycodone (OXY)	Oxycodone	100ng/mL
Phencyclidine (PCP)	Phencyclidine	25ng/mL
Propoxyphene (PPX)	Propoxyphene	300ng/mL
Tramadol (TML)	Tramadol	300ng/mL
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000ng/mL
Synthetic Cannabinoid (K2)	JWH-073/JWH-018	50ng/mL
LSD	Lysergic acid diethylamide	20ng/mL
ETG	Ethul-beta-D-glucuronide	500ng/mL
SOMA	Carisoprodol(SOMA)	1000ng/mL

SUMMARY

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by presecription (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 does lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, GKPD044-2.1 Instructions for use_DOA Rapid Urine Test Device Cup(Colloidal Gold)(1).docxreduced 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.

It yields a positive result when the concentration of amphetamine in urine exceeds 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).

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 produces 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 days

It yields a positive result when the concentration of Barbiturates in urine exceeds 300ng/mL.

Buprenorphine (BUP)

Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names Subutex™, Buprenex™, Temgesic™ and Suboxone™, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. Concentrations of free Buprenorphine and Norbuprenorphine in urine may be less than 1ng/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.

It yields a positive result when the concentration of Buprenorphine in urine

exceeds 10ng/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.

It yields a positive result when the concentration of Benzodiazepines in urine exceeds 300ng/mL.

Cocaine (COC)

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, and 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. 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.

It 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).

Nicotine (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 hydroxyl cotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, it's 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.

It yields a positive result when the concentration of Barbiturates in urine exceeds 200ng/mL.

Fentanyl (FYL)

Fentanyl is a synthetic opioid related to the phenylpiperidines. Fentanyl is approximately 100 times more potent than morphine. This agent is highly lipid soluble and rapidly cross the blood-brain barrier. This is reflected in the half-life for equilibration between the plasma and cerebrospinal fluid of approximately 5 minutes for fentanyl. The levels in plasma and cerebrospinal fluid decline rapidly owing to redistribution of fentanyl from highly perfused tissue groups to other tissues, such as muscle and fat. As saturation of less well-perfused tissue occurs, the duration of effect of fentanyl and sufentanil approaches the length of their elimination half-lives of between 3 and 4 hours. Fentanyl undergoes hepatic metabolism and renal excretion. Therefore, with the use of higher doses or prolonged infusions, fentanyl becomes longer acting.

It yields a positive result when the concentration of Fentanyl in urine exceeds 200ng/mL.

Ketamine (KET)

Ketamine is a narcotic drugs and hallucinogens, usually approach to the use of the abuse of cigarettes, inhalants, intravenous or powder into drinks and wine to drink. Usually with heroin, cannabis and other drugs combined, ketamine users easily generate physical dependence, leading to abuse. Generally taking 2-4 hours can be detected.

It yields a positive result when the concentration of ketamine in urine exceeds 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).

Marijuana (THC)

THC (Δ^9-tetrahydrocannabinol) is the primary active ingredient in cannabinoids (marijuana). When smoked or orally administered, it 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 smoking marijuana 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).

It yields a positive result when the concentration of marijuana 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).

Methadone (MTD 300)

Methadone is a narcotic pain reliever for medium to severe pain. It is also used in the treatment of heroin (opiate dependence: Vicodin, Percocet, morphine, etc.) addiction. Oral methadone is very different than 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.

It yields a positive result when the concentration of methadone in urine exceeds 300ng/mL.

EDDP perchlorate **(EDDP 100)**

EDDP (2-Ethyliden-1, 5-Dimethyl-3, 3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMDP (2-Ethyl-5-Methyl-3, 3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value,dose, and the patient's metabolism. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

It yields a positive result when the concentration of EDDP in urine exceeds 100ng/mL.

Methamphetamine (MET)

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 primarily as amphetamine and oxidized and deaminated 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.

It yields a positive result when the concentration of methamphetamine in urine exceeds 1000ng/mL.

Methaqualone (MQL)

Methaqualone (Quaalude, Sopor) is a quinazoline derivative that was first synthesized in 1951 and found clinically effective as a sedative and hypnotic in 1956. It soon gained popularity as a drug of abuse and in 1984 was removed from the US market due to extensive misuse. It is occasionally encountered in illicit form, and is also available in Europeon countries in combination with diphenhydramine (Mandrax). Methaqualone is extensively metabolized in vivo principally by hydroxylation at every possible position on the molecule. At least 12 metabolites have been identified in the urine.

It yields a positive result when Methaqualone in urine exceed 300 ng/mL.

Ecstasy (MDMA)

Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.3 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.

It yields a positive result when the concentration of methylenedioxymethamphetamine in urine exceeds 500ng/mL.

Morphine (MOP 300)

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 substance which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance level and 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.

It yields a positive result when the concentration of morphine in urine exceeds 300ng/mL.

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It yields a positive result when the concentration of morphine in urine exceeds 2,000ng/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 is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox, Percodan and Percocet contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone. In a 24-hour urine, 33-61% of a single, 5mg oral dose is excreted with the primary constituents being unchanged drug (13-19%), conjugated drug (7-29%) and conjugated oxymorphone (13-14%). The window of detection for oxycodone in urine is expected to be similar to that of other opioids such as morphine.

It yields a positive result when the oxycodone level in urine exceeds 100ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for oxycodone positive specimens.

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. PCP is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

It yields a positive result when the concentration of phencyclidine 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 narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, Propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of Propoxyphene napsylate and 325-650 mg of acetaminophen. 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 humans, 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.
It yields a positive result when Propoxyphene in urine exceeds 300 ng/mL.

Tramadol (TML)

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 prescribed off-label for the treatment of diabetic neuropathy and restless leg syndrome.2 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, glucoronidation or sulfation in the liver.
It yields a positive result when the Tramadol 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.
It yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000ng/mL.

Synthetic Cannabinoid (K2)

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.
It yields a positive result when the concentration of K2 in urine exceed 50ng/mL.

LSD

Lysergic acid diethylamide, abbreviated LSD or LSD-25, also known as lysergide and colloquially as acid, is a semisynthetic psychedelic drug of the ergoline family, well known for its psychological effects which can include altered thinking processes, closed and open eye visuals, synaesthesia, an altered sense of time and spiritual experiences, as well as for its key role in 1960s counterculture. It is used mainly as an entheogen, recreational drug, and as an agent in psychedelic therapy. LSD is non-addictive, is not known to cause brain damage, and has extremely low toxicity relative to dose, although in rare cases adverse psychiatric reactions such as anxiety or delusions are possible.
It yields a positive result when the concentration of LSD in urine exceed 20ng/mL.

ETG

Ethul-beta-D-glucuronide（ETG）is compounds produced by the metabolism of alcohol in the human body.It is a biochemical marker extensively utilized for the detection of alcohol abuse. It can be detected in urine, blood, or hair samples. ETG is generated through the reaction of glucuronide, a compound produced in the liver, with alcohol. This reaction occurs secondary to the metabolic process of alcohol and typically takes place when acetaldehyde is oxidized to acetic acid. The presence of EtG serves as a robust indicator of alcohol abuse, as it can persist in the body for an extended period following alcohol consumption, remaining until metabolism is completely terminated.
It yields a positive result when the concentration of ETG in urine exceed 500ng/mL.

Carisoprodol(SOMA)

Carisoprodol, a muscle relaxant, is employed in the treatment of chronic back pain. Calyptol, a prescription drug available under trade names such as Soma and Sanoma, has been demonstrated to be efficacious in treating back pain. However, there has been significant criticism regarding its potential for abuse and the toxic side effects associated with excessive dosage.On 16 November 2007, the European Medicines Agency (EMEA) disseminated information advising its member states to suspend the marketing authorization of all medications containing carisoprodol.
It yields a positive result when the concentration of SOMA in urine exceed 1000ng/mL.

TEST PRINCIPLE

The product 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 to saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible line will show up in the test region. The presence of drug above the cut-off concentration able to saturate all the binding sites of the antibody. Therefore, the line will not form in the test line region.
To serve as a procedural control, a line will always appear at the control region, indicating that proper volume of specimen has been added and proper procedural has been conducted.

Materials Provided

Each box contains test strip/cassette/panels and package insert.

Materials Required but Not Provided

1. Specimen collection container
2. Timer
3. External controls

PRECAUTIONS

1. For in vitro diagnostic use only.
2. For healthcare professionals and professionals at point of care sites.
3. Do not use after the expiration date.
4. Please read all the information in this leaflet before performing the test.
5. The test panel should remain in the sealed pouch until use.
6. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
7. The used test panel should be discarded according to federal, state and local regulations.

STORAGE AND STABILITY

1. Store as packaged in the sealed pouch at room temperature (2-30℃).
2. The kit is stable within the expiration date printed on the labeling.
3. DO NOT FREEZE.
4. Once open the pouch, the test should be used within one hour.
5. Prolonged exposure to hot and humid environment will cause product deterioration.

ASSAY PROCEDURES

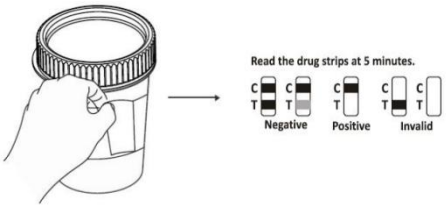
Instructions must be read entirely before taking the test. Allow the test device to equilibrate to room temperature (10°C-30°C) to testing. Do not open the inner package until ready, it must be used within one hour if opened (Humidity≤60%, Temp: 10°C-30°C). Please use immediately when the humidity exceeded to 60%.

Cup:

Allow the test cup, urine specimen, and/or controls to equilibrate to room temperature (10-30℃) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it within one hour.
2. Donor provides specimen.

3. Technician dates and initials the security seal and attaches the security seal over the cup cap.
4. Technician peels off label to reveal adulteration strip(s), if applicable.
5. Technician peels off the label on the multi-drug test cup to view results.
6. Read the adulteration strips between 3-5 minutes (when applicable) compare the colors on the adulteration pads to the enclosed color chart.If the specimen indicates adulteration, refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not to interpret the drug test results and either retest the urine or collect another specimen.
7. The drug strip result should be read at 5 minutes.



INTERPRETATION OF ASSAY RESULT

Negative Result

Two lines appear. One line should be in the control region (C), and another apparent red or pink should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

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

Positive Result

Only one line appears in the control region (C). This positive result indicates that the drug concentration is above the detectable level.

Invalid Result

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 panel. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

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

Control standards are not supplied with this kit. However, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The product provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level or intoxication, administration route or concentration in urine.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

PERFORMANCE

1. Accuracy

A side-by-side comparison was conducted using the product and commercially available drug rapid test products. Testing was performed on approximately 380 specimens per drug type previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following compounds were quantified by GC/MS and contributed to the total amount of drugs found in presumptive positive urine samples tested.

Test	Compounds Contributed to the Totals of GC/MS
AMP	Amphetamine
BAR	Secobarbital
BUP	Buprenorphine
BZO	Oxazepam, Diazepam
COC	Benzoylecgonine
COT	Cotinine
FYL	Fentanyl
KET	Ketamine
THC	11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid
MTD	Methadone
EDDP	EDDP perchlorate
MET	Methamphetamine
MQL	Methaqualone
MDMA	D,L-Methyelnedioxymethamphetamine, Methylenedioxyamphetamine
MOP	Morphine, Codeine
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TML	Tramadol
TCA	Nortriptyline
K2	JWH-073/JWH-018
LSD	9,10-Didehydro-N,N-diethyl-6-methylergoline-8beta-carboxamide
ETG	Ethul-beta-D-glucuronide
SOMA	Carisoprodol(SOMA)

The following results are tabulated from these clinical studies:

%Agreement with Commercial Kit

	AMP	BAR	BUP	BZO	COC	COT
Positive Agreement	98%	100%	100%	100%	96%	100%
Negative Agreement	100%	100%	99%	97%	100%	99%
Total esults	99%	100%	>99%	98%	98%	>99%

	FYL	KET	THC	MTD	EDDP	MET
Positive Agreement	98%	100%	100%	100%	96%	100%
Negative Agreement	100%	100%	99%	97%	100%	99%
Total esults	99%	100%	>99%	98%	98%	>99%

%Agreement with GC/MS

	MQL	MDMA	MOP	OPI	OXY	PCP
Positive Agreement	96%	98%	97%	97%	>99%	98%
Negative Agreement	92%	96%	96%	97%	>99%	97%
Total Results	94%	97%	97%	97%	>99%	98%

	PPX	TML	TCA	K2	LSD	ETG	SOMA
Positive Agreement	100%	96%	98%	97%	97%	97%	97%
Negative Agreement	98%	92%	96%	96%	97%	96%	97%
Total Results	99%	94%	97%	97%	97%	97%	97%

Note: TCA was based on HPLC data.

2. Precision

A study was conducted at three physician offices by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing drugs at the concentration of ± 50% cut-off level, was labeled as a blind and tested at each site. The results are given below:

Amphetamine (AMP)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1,500	15	0	15	0	15	0	15

Secobarbital（BAR）

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Buprenorphine（BUP）

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
5	15	15	0	15	0	15	0
15	15	0	15	0	15	0	15

Benzodiazepines (BZO)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Cocaine (COC)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Nicotine (COT)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
100	15	15	0	15	0	15	0
300	15	0	15	0	15	0	15

Fentanyl (FYL)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
100	15	15	0	15	0	15	0
300	15	0	15	0	15	0	15

Ketamine (KET)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1500	15	0	15	0	15	0	15

Marijuana (THC)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	15	0
75	15	0	15	0	15	0	15

Methadone (MTD)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

EDDP

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
150	15	0	15	0	15	0	15

Methamphetamine (MET)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1500	15	0	15	0	15	0	15

Methaqualone (MQL)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Ecstasy (MDMA)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
750	15	0	15	0	15	0	15

Morphine (MOP 300)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Opiates (OPI 2000)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
1000	15	15	0	15	0	15	0
3000	15	0	15	0	15	0	15

Oxycodone (OXY)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
50	15	15	0	15	0	15	0
150	15	0	15	0	15	0	15

Phencyclidine (PCP)

conc.(ng/mL)	n per	Site A	Site B	Site C

	site	-	+	-	+	-	+
0	15	15	0	15	0	15	0
12.5	15	15	0	15	0	15	0
37.5	15	0	15	0	15	0	15

Propoxyphene (PPX)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Tramadol (TML)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
150	15	15	0	15	0	15	0
450	15	0	15	0	15	0	15

Tricyclic Antidepressants (TCA)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1500	15	0	15	0	15	0	15

Synthetic Cannabinoid (K2)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
25	15	15	0	15	0	15	0
75	15	0	15	0	15	0	15

LSD

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
10	15	15	0	15	0	15	0
30	15	0	15	0	15	0	15

ETG

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
250	15	15	0	15	0	15	0
750	15	0	15	0	15	0	15

Carisoprodol(SOMA)

conc.(ng/mL)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	15	15	0	15	0	15	0
500	15	15	0	15	0	15	0
1500	15	0	15	0	15	0	15

3. Effect of Urinaru Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.000-1.037) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The product was tested in duplicate using fifteen drug-free urine and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

4. Effect of the Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with drugs at 50% below and 50% above cut-off levels. The spiked, pH-adjusted urine was tested with the product. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

5. 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. The following compounds show no cross-reactivity when tested with the product at a concentration of 100μg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Phenelzine	L(–)-Epinephrine
N-Acetylprocainamide	L-Phenylephrine	Fenoprofen
Aminopyrine	Phenylpropanolamine	Gentisic acid
Ampicillin	Prednisone	Hydralazine
Atropine	Quinacrine	Hydrocortisone
Benzoic acid	Quindine	Ibuprofen
Bilirubin	Salicylic acid	D/L-Isoproterenol
Caffeine	Sulfamethazine	Labetalol
Chloralhydrate	Tetracycline	Methoxyphenamine
Chlorothiazide	Tetrahydrozoline	Nalidixic acid
Chlorpromazine	Thiamine	Niacinamide
Cholesterol	D/L-Tyrosine	Norethindrone
Cortisone	Triamterene	Noscapine
Creatinine	Trimethoprim	Oxalic acid
Dextromethorphan	D/L-Tryptophan	Oxymetazoline
Diflunisal	Uric acid	Penicillin-G
Estrone-3-sulfate	Zomepirac	Perphenazine
Erythromycin	Acetophenetidin	Trans-2-phenylcyclo-propyl amine hydrochloride
Furosemide	Acetylsalicylic acid	β-Phenylethylamine
Hemoglobin	Amoxicillin	Prednisolone
Hydrochlorothiazide	L-Ascorbic acid	D/L-Propranolol
O-Hydorxyhippuric acid	Aspartame	Quinine
p-Hydroxytyramine	Benzilic acid	Ranitidine
Iproniazid	Benzphetamine*	Serotonin
Isoxsuprine	D/L-Brompheniramine	Sulindac
Ketoprofen	Chloramphenicol	Tetrahydrocortisone 3-acetate
Loperamide	D/L-Chloropheniramine	Tetrahydrocortisone 3 (β-D-glucuronide)
Meprobamate	Chloroquine	Thioridazine
Methylphenidate	Clonidine	Tolbutamide
Naproxen	Deoxycorticosterone	Trifluoperazine
Nifedipine	Diclofenac	Tryptamine
D/L-Octopamine	Digoxin	
Oxolinic acid	β-Estradiol	Verapamil
Pentazocine hydrochloride	Ethyl-p-aminobenzoate	

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Index of CE Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests per kit
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:

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