Multi-Drug Test Cup

- CLIA Waived

Package Insert

Instruction Sheet for testing of any combination of the following drugs: AMP/BAR/BZO/COC/THC/MOP/MET/MTD/PCP/TCA/EDDP/OXY/MDMA/BUP/TRA/PPX/FYL/6-MAM.

A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in human urine. For healthcare professionals including professionals at point of care sites. Immunoassay for in vitro diagnostic use only.

【INTENDED USE】

The Multi-Drug Test Cup tests are competitive binding, lateral flow immunochromatographic assays for qualitative and simultaneous detection of Amphetamine, Buprenorphine, Secobarbital, Benzodiazepines, Cocaine, 2- ethylidene-1,5-dimethyl-3,3- diphenylpyrrolidine, Methamphetamine, Methylenedioxymethamphetamine, Morphine, Methadone, Oxycodone, Phencyclidine, Nortriptyline, Marijuana, Tramadol, Propoxyphene Fentanyl and 6-monoacetylmorphine in human urine at the cutoff concentrations of:

Drug (Identifier)	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	500 or 1000
Buprenorphine (BUP)	Buprenorphine	10
Secobarbital (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Cocaine (COC)	Benzoylecgonine	150 or 300
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Methamphetamine (MET)	d-Methamphetamine	500 or 1000
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP/OPI)	Morphine	300 or 2000
Methadone (MTD)	Methadone	300
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Nortriptyline (TCA)	Nortriptyline	1000
Marijuana (THC)	11-nor-Δ9-THC-9 COOH	50
Tramadol (TRA)	Tramadol	100
Propoxyphene (PPX)	Propoxyphene	300
Fentanyl (FYL)	Fentanyl	1
6-monoacetylmorphine (6-MAM)	6-monoacetylmorphine	10

The Multi-Drug Test Cup can be a single drug test cup or used for any combination of the above listed analytes. It is for in vitro diagnostic use only.

The tests may yield positive results for the prescription drugs when taken at or above prescribed doses. It is not intended to distinguish between prescription use or abuse of these drugs. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The tests provide only preliminary results. To obtain a confirmed analytical result, a more specific alternate chemical method must be used. GC/MS or LC/MS is the recommended confirmatory method.

【SUMMARY】

The Multi-Drug Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

The Multi-Drug Test Cup yields a positive result when the concentration of amphetamines in urine exceeds detective level.

Secobarbital (BAR)

Secobarbital is one of CNS depressants (barbiturates). They are used therapeutically as sedatives, hypnotics, and anticonvulsants barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of barbiturates leads to tolerance and physical dependence.

Short-acting barbiturates taken at 400 mg/day for 2-3 months can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Only a small amount (less than 5%) of most secobarbital are excreted unaltered in the urine.

The approximate detection time limits for secobarbital are:

Short acting (e.g. Secobarbital)	100 mg PO (oral)	4.5 days
Long acting (e.g. Phenobarbital)	400 mg PO (oral)	7 days

The Multi-Drug Test Cup yields a positive result when the concentration of secobarbital in urine exceeds detective level.

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 secobarbital 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 benzodiazepines in urine is 3-7 days.

The Multi-Drug Test Cup yields a positive result when the concentration of benzodiazepines in urine exceeds detective level.

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.

The Multi-Drug Test Cup yields a positive result when the Buprenorphine in urine exceeds detective level.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness.

Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine. 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.

The Multi-Drug Test Cup yields a positive result when the concentration of Cocaine in urine exceeds detective level.

Marijuana (THC)

THC (Δ9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor-Δ9-tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

The Multi-Drug Test Cup yields a positive result when the concentration of THC-COOH in urine exceeds detective level.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (heroin, Vicodin, Percocet, morphine). The pharmacology of oral methadone is very different from IV methadone. Oral methadone is partially stored in the liver for later use. IV methadone acts more like heroin. In most states you must go to a pain clinic or a methadone maintenance clinic to be prescribed methadone.

Methadone is a long acting pain reliever producing effects that last from twelve to forty-eight hours. Ideally, methadone frees the client from the pressures of obtaining illegal heroin, from the dangers of injection, and from the emotional roller coaster that most opiates produce. Methadone, if taken for long periods and at large doses, can lead to a very long withdrawal period. The withdrawals from methadone are more prolonged and troublesome than those provoked by heroin cessation, yet the substitution and phased removal of methadone is an acceptable method of detoxification for patients and therapists.

The Multi-Drug Test Cup yields a positive result when the concentration of methadone in urine exceeds detective level.

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 have 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.

The Multi-Drug Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Methamphetamine in urine. The Multi-Drug Test Cup yields a positive result when the Methamphetamine in urine exceeds detective level.

Methylenedioxymethamphetamine (MDMA)

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

The Multi-Drug Test Cup yields a positive result when the concentration of Methylenedioxymethamphetamine in urine exceeds detective level.

Morphine (MOP/OPI 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 substances which control pain by depressing the CNS. 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.

The Multi-Drug Test Cup yields a positive result when the concentration of morphine in urine exceeds detective level.

Morphine (MOP/OPI 2000)

The Multi-Drug Test Cup yields a positive result when the concentration of morphine in urine exceeds 2,000 ng/m. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA). See morphine (MOP 300) for summary.

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.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP 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 PCP.

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

The Multi-Drug Test Cup yields a positive result when the concentration of phencyclidine in urine exceeds detective level. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Nortriptyline (TCA)
Nortriptyline is one of the Tricyclic Antidepressants, TCA are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver. Both TCAs and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.
The Multi-Drug Test Cup yields a positive result when the concentration of tricyclic antidepressants in urine exceeds detective level. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cut-off for tricyclic antidepressant positive specimens.
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, 5 mg 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.
The Multi-Drug Test Cup is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Oxycodone in urine. The Multi-Drug Test Cup yields a positive result when Oxycodone in urine exceeds detective level.
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)
Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound. Exacerbating this problem, there is a subsection of the population classified as “extensive metabolizers” of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better urine marker for methadone maintenance than unmetabolized methadone.
The Multi-Drug Test Cup yields a positive result when the concentration of EDDP in urine exceeds detective level.
Tramadol (TRA)
Tramadol (TRA) 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. Large doses of tramadol can develop tolerance and physiological dependency and lead to its abuse. Tramadol is extensively metabolized after oral administration. 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.
The Multi-Drug Test Cup yields a positive result when the concentration of TRA in urine exceeds detective level.
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.
The Multi-Drug Test Cup yields a positive result when the concentration of PPX in urine exceeds detective level.
Fentanyl (FYL)
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 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.
The Multi-Drug Test Cup yields a positive result when the concentration of FYL in urine exceeds detective level.

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.
The Multi-Drug Test Cup yields a positive result when the concentration of 6-MAM in urine exceeds detective level.

【PRINCIPLE】
During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test region of the specific drug dipstick. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test region.
A drug-positive urine specimen will not generate a colored line in the specific test region of the dipstick because of drug competition, while a drug-negative urine specimen will generate a line in the test region because of the absence of drug competition.
To serve as a procedural control, a colored line will always appear at the control region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

【REAGENTS】
Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti-rabbit IgG polyclonal antibodies and rabbit IgG.

【PRECAUTIONS】
- For healthcare professionals including professionals at point of care sites.
- Immunoassay for *in vitro* diagnostic use only. The test cup should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test cup should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】
Store as packaged in the sealed pouch at 35.6-86°F (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test Cup must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay
The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage
Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -4°F (-20°C). Frozen specimens should be thawed and mixed well before testing.

【MATERIALS】

Materials Provided
- Test Cups
- Package Insert
- Adulteration Color Chart (when applicable)

Materials Required But Not Provided
- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】
Allow the test, urine specimen, and/or controls to reach room temperature 59-86°F (15-30ºC) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch.
2. Donor provides specimen.
3. Technician replaces and secures cap while the cup is on a flat surface.
4. Check the temperature label (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 90-100°F (32-38°C).
5. Technician dates and initials the security seal and attaches the security seal over the cup cap.
6. Technician peels off label to reveal adulteration strip(s), if applicable.
7. Technician peels off the label on the multi-drug test cup to view results.
8. The adulteration strip(s), if applicable, should be read between **3-5 minutes**. Compare the colors on the adulteration strip to the color chart. If the results indicate adulteration, do not read the drug test results. Refer to your Drug Free Policy for guidelines on adulterated specimens. We recommend not interpret the drug test results and either retest the urine or collect another specimen in case of any positive result for any adulteration test.
9. If results do not indicate adulteration, read the drug test result at **5 minutes.** Do not interpret the result after 10 minutes.
10. If preliminary positive results are observed, please send the cup to the laboratory for confirmation.

TEST PROCEDURE Cup

- Open the cap and add specimen.
- Specimen volume must exceed the minimum line.

- Peel off the label to view results

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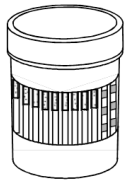
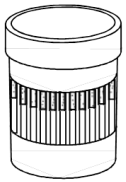


Cup with adulteration

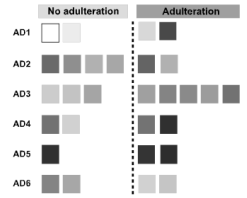


Cup without adulteration

Read Drug Result at 5 minutes.

Negative Positive Invalid

Interpret adulteration strips between 3-5 minutes. See enclosed color chart for interpretation.



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【INTERPRETATION OF RESULTS】
(Please refer to the illustration above)
***NEGATIVE: A colored line appears in the Control region (C) and a colored line appears in the Test region (T)**. This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.
***NOTE:** The shade of the colored line(s) in the Test region (T) may vary. The result should be considered negative whenever there is even a faint line.
POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.
INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test cup. If the result is still invalid, contact your manufacturer.

【INTERPRETATION OF RESULTS (S.V.T ADULTERATION)】
(Please refer to the color chart)
Semi Quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart.
No instrumentation is required.

【QUALITY CONTROL】

A procedural control is included in the test. A 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 Multi-Drug Test Cup provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry or Liquid Chromatography/mass spectrometry is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as 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. This 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. Alcohol in the atmosphere, such as spray from perfumes, deodorizers, glass cleaners etc. can affect the Alcohol Rapid Tests. Therefore, adequate measures should be taken to avoid undue interference from such atmospheric agents in the testing area.

【EXPECTED VALUES】

The negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

【PERFORMANCE CHARACTERSTICS】

Accuracy

About 80 clinical urine specimens with known GC/MS or LC/MS values and tested by Multi-Drug Test Cup. Each test was performed by three operators. Results were as follows:

Amphetamine(AMP500)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1	6	58
NEG	45	7	0	0
Total Result	100.0%	87.5%	100.0%	100.0%

Amphetamine(AMP1000)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	2	40	78
NEG	72	46	2	0
Total Result	100.00%	95.8%	95.2%	100.00%

Secobarbital(BAR300)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	9	40
NEG	45	9	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Benzodiazepines(BZO300)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	49
NEG	45	5	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Cocaine(COC150)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	41
NEG	45	4	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Cocaine(COC300)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	2	29	90
NEG	66	52	1	0
Total Result	100.00%	96.3%	96.7%	100.00%

Marijuana(THC50)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	9	43
NEG	45	9	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Morphine (MOP/OPI 2000)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	42
NEG	45	5	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Morphine(MOP/OPI 300)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	57
NEG	45	6	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Methamphetamine(MET500)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	1	3	72
NEG	45	3	0	0
Total Result	100.0%	75.0%	100.0%	100.0%

Methamphetamine(MET1000)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	3	30	87
NEG	69	48	3	0
Total Result	100.00%	94.1%	90.9%	100.00%

Methadone(MTD300)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	3	14	38
NEG	46	11	0	0
Total Result	100.0%	78.6%	100.0%	100.0%

Phencyclidine(PCP25)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	12	42
NEG	45	8	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Nortriptyline(TCA1000)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	8	33
NEG	45	9	0	0
Total Result	100.0%	100.0%	100.0%	100%

Methadone Metabolites(EDDP300)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	2	9	44
NEG	45	8	1	0
Total Result	100.0%	80.0%	90.0%	100.0%

Oxycodone(OXY100)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	37
NEG	45	4	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Ecstasy(MDMA500)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	4	36
NEG	45	4	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Buprenorphine(BUP10)

Candidate Device Result	Concentration by GC/MS (ng/mL)			
	≤ cutoff – 50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	0	8	36
NEG	45	10	0	0
Total Result	100.0%	100.0%	100.0%	100.0%

Tramadol(TRA100)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	2	31	87
NEG	78	40	2	0
Total Result	100.0%	95.2%	93.9%	100.0%

Propoxyphene (PPX300)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	2	29	90
NEG	75	43	1	0
Total Result	100.0%	95.6%	96.7%	100.0%

Fentanyl(FYL 1)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	7	66	48
NEG	75	38	6	0
Total Result	100.0%	84.4%	91.7%	100.0%

6-monoacetylmorphine (6-MAM10)

Candidate Device Result	Concentration by LC-MS/MS (ng/mL)			
	≤ cutoff –50%	cutoff –50% to the cutoff	cutoff to cutoff +50%	≥ cutoff +50%
POS	0	4	40	78

NEG	69	47	2	0
Total Result	100.0%	92.2%	95.2%	100.0%

Analytical Specificity

The following table lists compounds that are positively detected in urine by Multi-Drug Test Cup.

Drug	Concentration (ng/ml)	Cross-Reactivity (%)
Amphetamine(AMP500)		
d-Amphetamine	500	100%
Methylenedioxyethylamphetamine (MDEA)	100000	0.5%
d,l-Methamphetamine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
d-Methamphetamine	>100000	<0.5%
l-Methamphetamine	>100000	<0.5%
d,l - Methylenedioxy methamphetamine	100000	0.5%
l-Amphetamine	500	100%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
d, l-Amphetamine	500	100%
d,l-3,4-Methylenedioxyamphetamine (MDA)	25	2000%
Phentermine	500	100%
Amphetamine(AMP1000)		
d-Amphetamine	1000	100%
Methylenedioxyethylamphetamine (MDEA)	>100000	<1%
d,l-Methamphetamine	>100000	<1%
Phenylephrine	>100000	<1%
d-Methamphetamine	>100000	<1%
l-Methamphetamine	>100000	<1%
d,l - Methylenedioxy methamphetamine	>100000	<1%
l-Amphetamine	1000	100%
Ephedrine	>100000	<1%
Pseudoephedrine	>100000	<1%
d, l-Amphetamine	1000	100%
d,l-3,4-Methylenedioxyamphetamine (MDA)	50	2000%
Phentermine	1000	100%
Secobarbital(BAR300)		
Secobarbital	300	100%
Pentobarbital	200	150%
Alphenal	300	100%
Amobarbital	300	100%
Aprobarbital	300	100%
Barbital	300	100%
Butabarbital	500	60%
Butalbital	2000	15%
Cyclopentabarbital	500	60%
Phenobarbital	200	150%
Benzodiazepines(BZO300)		
Oxazepam	300	100%
Alprazolam	200	150%
Alpha-Hydroxyalprazolam	10000	3%
Bromazepam	1000	30%
Chlordiazepoxide	300	100%
Clobazam	200	150%
Clonazepam	200	150%
Clorazepate	300	100%
Desalkylflurazepam	>100000	<0.3%
Diazepam	300	100%
Estazolam	100	300%
Flunitrazepam	300	100%
Flurazepam	300	100%
Lorazepam	1000	30%
Lormetazepam	100	300%
Midazolam	1000	30%
Nitrazepam	200	150%
Nordiazepam	200	150%
Temazepam	100	300%
Triazolam	300	100%
Buprenorphine(BUP10)		
Buprenorphine	10	100%
Buprenorphine 3- D-Glucuronide	20	50%
Codeine	>100000	<0.01%
Morphine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Norbuprenorphine	20	50%
Norbuprenorphine 3-D-lucuronide	20	50%
Cocaine(COC150)		
Benzoylecgonine	150	100%
Cocaine	125	120%
Cocaethylene	250	60%
Ecgonine	>100000	<0.15%
Norcocaine	>100000	<0.15%
Cocaine(COC300)		
Benzoylecgonine	300	100%
Cocaine	250	120%
Cocaethylene	500	60%
Ecgonine	>100000	<0.3%
Norcocaine	>100000	<0.3%
Methadone Metabolites(EDDP300)		
EDDP	300	100%
Doxylamine	>100000	<0.3%
Methadone	>100000	<0.3%
Methadol	>100000	<0.3%
Methamphetamine(MET500)		
d-Methamphetamine	500	100%
l -Methamphetamine	10000	5%
d,l-Amphetamine	250	200%
Phentermine	>100000	<0.5%
d,l – Methamphetamine	250	200%
d-Amphetamine	100000	0.5%
l-Amphetamine	100000	0.5%
Ephedrine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
3,4- Methylenedioxy methamphetamine (MDMA)	1000	50%
d,l- Methylenedioxy ethylamphetamine (MDEA)	6000	8.3%
d,l-3,4-Methylenedioxyamphetamine (MDA)	>100000	<0.5%
Methamphetamine(MET1000)		
d-Methamphetamine	1000	100%
l -Methamphetamine	25000	4%
d,l-Amphetamine	500	200%
Phentermine	>100000	<1%
d,l-Methamphetamine	500	200%
d-Amphetamine	>100000	<1%
l-Amphetamine	>100000	<1%
Ephedrine	>100000	<1%
Phenylephrine	>100000	<1%
Pseudoephedrine	>100000	<1%
3,4- Methylenedioxy methamphetamine (MDMA)	2500	40%
d,l- Methylenedioxy ethylamphetamine (MDEA)	12500	8.0%
d,l-3,4-Methylenedioxyamphetamine (MDA)	>100000	<1%
Morphine(MOP/OPI 300)		
Morphine	300	100%
Codeine	250	120%
6-Acetylmorphine	250	120%
Diacetylmorphine (Heroin)	500	60%
Hydrocodone	1000	30%
Hydromorphone	10000	3%
Oxycodone	>100000	<0.3%
Oxymorphone	>100000	<0.3%
Procaine	>100000	<0.3%
Phencyclidine(PCP25)		
Phencyclidine	25	100%
Pheniramine	50000	0.05%
Methadone(MTD300)		
Methadone	300	100%
Doxylamine	>100000	<0.3%
Pheniramine	100000	0.3%
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	>100000	<0.3%
Oxycodone(OXY100)		
Oxycodone	100	100%
Codeine	100000	0.1%
Hydrocodone	50000	0.2%
Oxymorphone	100	100%
Hydromorphone	25000	0.4%
Morphine (MOP/OPI 2000)		
Morphine	2000	100%
Codeine	5000	40%
Diacetylmorphine (Heroin)	>100000	<2%
Hydrocodone	10000	20%
Hydromorphone	5000	40%
Oxycodone	>100000	<2%
6-Acetylmorphine	>100000	<2%
Oxymorphone	>100000	<2%
Normorphine	>100000	<2%
Ethylmorphine	500	400%
Norcodeine	50000	4%
Marijuana (THC50)		
11-nor-Δ9-THC-9-COOH	50	100%
11-nor-Δ8-THC-9-COOH	20000	0.25%
Δ9 -Tetrahydrocannabinol	100000	0.05%
Cannabidiol	>100000	<0.05%
Cannabinol	>100000	<0.05%
Estasy(MDMA500)		
d,l - Methylenedioxy methamphetamine (MDMA)	500	100%
l-Methamphetamine	>100000	<0.5%
Ephedrine	>100000	<0.5%
Pseudoephedrine	>100000	<0.5%
d,l- Amphetamine	>100000	<0.5%
l-Amphetamine	>100000	<0.5%
Phentermine	>100000	<0.5%
d,l- Methamphetamine	>100000	<0.5%
Phenylephrine	>100000	<0.5%
Methylenedioxy ethylamphetamine (MDEA)	250	200%
d,l-3,4-Methylenedioxyamphetamine (MDA)	1000	50%
d-Methamphetamine	>100000	<0.5%
d-Amphetamine	>100000	<0.5%
Nortriptyline (TCA1000)		
Nortriptyline	1000	100%
Amitriptyline	2500	40%
Clomipramine	100000	1%
Doxepine	>100000	<1%
Desipramine	800	125%
Imipramine	500	200%
Promethazine	>100000	<1%
Trimipramine	50000	2%
Tramadol (TRA100)		
Tramadol	100	100%
N-Desmethyl-cis-tramadol	200	50%

O-Desmethyl-cis-tramadol	1000	10%
Venlafaxine	100000	0.1%
(±)-O-Desmethylvenlafaxine	100000	0.1%
Propoxyphene (PPX300)		
(+)-Propoxyphene	300	100%
(+)-Norpropoxyphene	500	60%
Fentanyl(FYL1)		
Fentanyl	1	100%
Acetyl fentanyl	1	100%
Acrylfentanyl	1	100%
ω-1-Hydroxyfentanyl	20000	0.005%
Isobutyryl fentanyl	1	100%
Ocfentanil	2.5	40%
Butyryl fentanyl	2.5	40%
Furanyl fentanyl	5	20%
Valeryl fentanyl	10	10%
(±) β-hydroxythiofentanyl	2	50%
4-Fluoro-isobutyrylfentanyl	50	2%
Para-fluorobutyryl fentanyl	4	25%
Para-fluoro fentanyl	3	33.3%
(±)-3-cis-methyl fentanyl	50	2%
Carfentanil	2	50%
Sufentanil	10	10%
Alfentanil	5000	0.02%
Despropionyl fentanyl (4-ANPP)	2500	0.04%
Remifentanil	>100000	<0.001%
Norfentanyl	>100000	<0.001%
Acetyl norfentanyl	>100000	<0.001%
Norcarfentanil	>100000	<0.001%
6-Acetyl morphine	>100000	<0.001%
Amphetamine	>100000	<0.001%
Buprenorphine	>100000	<0.001%
Buprenorphineglucuronide	>100000	<0.001%
Codeine	>100000	<0.001%
Dextromethorphan	>100000	<0.001%
Dihydrocodeine	>100000	<0.001%
EDDP	>100000	<0.001%
EMDP	>100000	<0.001%
Fluoxetine	>100000	<0.001%
Heroin	>100000	<0.001%
Hydrocodone	>100000	<0.001%
Hydromorphone	>100000	<0.001%
Ketamine	>100000	<0.001%
Levorphanol	>100000	<0.001%
Meperidine	>100000	<0.001%
Methadone	>100000	<0.001%
Morphine	>100000	<0.001%
Morphine-3-glucuronide	>100000	<0.001%
Naloxone	>100000	<0.001%
Naltrexone	>100000	<0.001%
Norbuprenorphine	>100000	<0.001%
Norcodeine	>100000	<0.001%
Norketamine	>100000	<0.001%
Normeperidine	>100000	<0.001%
Normorphine	>100000	<0.001%
Noroxycodone	>100000	<0.001%
Oxycodone	>100000	<0.001%
Oxymorphone	>100000	<0.001%
Pentazocine (Talwin)	>100000	<0.001%
Pipamperone	>100000	<0.001%
Risperidone	>100000	<0.001%
Tapentadol	>100000	<0.001%
Thioridazine	>100000	<0.001%
Tilidine	>100000	<0.001%
Tramadol	>100000	<0.001%
Tramadol-O-Desmethyl	>100000	<0.001%
Tramadol-N-Desmethyl	>100000	<0.001%
Isotonitaze	>100000	<0.001%
Cyclopropylfentanyl	3	33.3%
AH-7921 HCL	>100000	<0.001%
6-monoacetylmorphine (6-MAM 10)		
6-Monoacetylmorphine	10	100%
Hydrocodone	>100000	<0.01%
Hydromorphone	>100000	<0.01%
Morphine	>100000	<0.01%
Oxymorphone	>100000	<0.01%
Procaine	>100000	<0.01%
Thebaine	>100000	<0.01%
Diacetylmorphine (heroin)	300	3.3%
Acetylcodeine	>100000	<0.01%
Buprenorphine	>100000	<0.01%
Dihydrocodeine	>100000	<0.01%
Nalorphine	>100000	<0.01%
Mitragynine (kratom)	>100000	<0.01%
Norbuprenorphine	>100000	<0.01%
s-Monoacetylmorphine	10	100%
Codeine	>100000	<0.01%
Ethylmorphine	>100000	<0.01%
Levorphanol tartrate	>100000	<0.01%
Morphine-3-β-D-glucuronide	>100000	<0.01%
Norcodeine	>100000	<0.01%
Normorphine	>100000	<0.01%
Oxycodone	>100000	<0.01%
Dextromethorphan	>100000	<0.01%
Imipramine hydrochloride	>100000	<0.01%
Levacetylmethadol (LAAM)	>100000	<0.01%
Meperidine	>100000	<0.01%
(±)-Methadone	>100000	<0.01%
Naloxone hydrochloride	>100000	<0.01%
Naltrexone hydrochloride	>100000	<0.01%
Naproxen	>100000	<0.01%
Noroxycodone HCL	>100000	<0.01%
Noroxymorphone HCL	>100000	<0.01%
(+)-Norpropoxyphene maleate	>100000	<0.01%
Oxymorphone-3β-D-glucuronide	>100000	<0.01%
Tapentadol HCl	>100000	<0.01%
Tramadol hydrochloride	>100000	<0.01%
Chlordiazepoxide	>100000	<0.01%
Clobazam	>100000	<0.01%
D-Amphetamine	>100000	<0.01%
(±)-Amphetamine	>100000	<0.01%

Precision

This study is performed by three personnel who don't know the sample number system participate in the study. Three lots were run in different days at each concentration. The results as follows:

Drugs	Concentration	n	Lot 1		Lot 2		Lot 3	
			+	-	+	-	+	-
MOP/ OPI 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	25	0	25	0	25	0	25
	150ng/ml	25	0	25	0	25	0	25
	225ng/ml	25	0	25	0	25	0	25
	300ng/ml	25	21	4	23	2	21	4
	375ng/ml	25	25	0	25	0	25	0
	450ng/ml	25	25	0	25	0	25	0
	600ng/ml	25	25	0	25	0	25	0
MOP/ OPI 2000	0ng/ml	25	0	25	0	25	0	25
	500ng/ml	25	0	25	0	25	0	25
	1000ng/ml	25	0	25	0	25	0	25
	1500ng/ml	25	0	25	0	25	0	25
	2000ng/ml	25	21	4	24	1	23	2
	2500ng/ml	25	25	0	25	0	25	0
	3000ng/ml	25	25	0	25	0	25	0
	4000ng/ml	25	25	0	25	0	25	0
MDMA 500	0ng/ml	25	0	25	0	25	0	25
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	25	0	25	0	25	0	25
	375ng/ml	25	0	25	0	25	0	25
	500ng/ml	50	41	9	43	7	40	10
	625ng/ml	25	25	0	25	0	25	0
	750ng/ml	25	25	0	25	0	25	0
	1000ng/ml	50	50	0	50	0	50	0
OXY 100	0ng/ml	25	0	25	0	25	0	25
	25ng/ml	50	0	50	0	50	0	50
	50ng/ml	25	0	25	0	25	0	25
	75ng/ml	25	0	25	0	25	0	25
	100ng/ml	50	41	9	37	13	38	12
	125ng/ml	25	25	0	25	0	25	0
	150ng/ml	25	25	0	25	0	25	0
	200ng/ml	50	50	0	50	0	50	0
EDDP 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	25	0	25	0	25	0	25
	225ng/ml	25	0	25	0	25	0	25
	300ng/ml	50	40	10	38	12	40	10
	375ng/ml	25	25	0	25	0	25	0
	450ng/ml	25	25	0	25	0	25	0
	600ng/ml	50	50	0	50	0	50	0
PCP 25	0ng/ml	25	0	25	0	25	0	25
	6.25ng/ml	50	0	50	0	50	0	50
	12.5ng/ml	50	0	50	0	50	0	50
	18.75ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	45	5	40	10	42	8
	31.25ng/ml	50	50	0	50	0	50	0
	37.5ng/ml	50	50	0	50	0	50	0
	50ng/ml	50	50	0	50	0	50	0
COC 150	0ng/ml	25	0	25	0	25	0	25
	37.5ng/ml	50	0	50	0	50	0	50
	75ng/ml	25	0	25	0	25	0	25
	112.5ng/ml	25	0	25	0	25	0	25
	150ng/ml	50	43	7	41	9	38	12
	187.5ng/ml	25	25	0	25	0	25	0
	225ng/ml	25	25	0	25	0	25	0
	300ng/ml	50	50	0	50	0	50	0
COC 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	25	0	25	0	25	0	25
	150ng/ml	25	0	25	0	25	0	25
	225ng/ml	25	0	25	0	25	0	25
	300ng/ml	25	20	5	19	6	21	4
	375ng/ml	25	25	0	25	0	25	0
	450ng/ml	25	25	0	25	0	25	0
	525ng/ml	25	25	0	25	0	25	0
	600ng/ml	25	25	0	25	0	25	0
MTD 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	42	8	45	5	41	9

	375ng/ml	50	50	0	50	0	50	0
	450ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
BAR 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	41	9	44	6	42	8
	375ng/ml	50	50	0	50	0	50	0
	450ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
BZO 300	0ng/ml	25	0	25	0	25	0	25
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	0	50	0	50	0	50
	300ng/ml	50	46	4	41	9	43	7
	375ng/ml	50	50	0	50	0	50	0
	450ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
AMP 500	0ng/ml	25	0	25	0	25	0	25
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	25	0	25	0	25	0	25
	375ng/ml	25	0	25	0	25	0	25
	500ng/ml	50	45	5	43	7	40	10
	625ng/ml	50	50	0	50	0	50	0
	750ng/ml	25	25	0	25	0	25	0
	1000ng/ml	50	50	0	50	0	50	0
AMP 1000	0ng/ml	25	0	25	0	25	0	25
	250ng/ml	25	0	25	0	25	0	25
	500ng/ml	25	0	25	0	25	0	25
	750ng/ml	25	0	25	0	25	0	25
	1000ng/ml	25	19	6	19	6	20	5
	1250ng/ml	25	25	0	25	0	25	0
	1500ng/ml	25	25	0	25	0	25	0
	1750ng/ml	25	25	0	25	0	25	0
	2000ng/ml	25	25	0	25	0	25	0
MET 500	0ng/ml	25	0	25	0	25	0	25
	125ng/ml	50	0	50	0	50	0	50
	250ng/ml	25	0	25	0	25	0	25
	375ng/ml	25	0	25	0	25	0	25
	500ng/ml	50	46	4	41	9	42	8
	625ng/ml	50	45	5	50	0	50	0
	750ng/ml	25	25	0	25	0	25	0
	1000ng/ml	50	50	0	50	0	50	0
MET 1000	0ng/ml	25	0	25	0	25	0	25
	250ng/ml	25	0	25	0	25	0	25
	500ng/ml	25	0	25	0	25	0	25
	750ng/ml	25	0	25	0	25	0	25
	1000ng/ml	25	19	6	19	6	20	5
	1250ng/ml	25	25	0	25	0	25	0
	1500ng/ml	25	25	0	25	0	25	0
	1750ng/ml	25	25	0	25	0	25	0
	2000ng/ml	25	25	0	25	0	25	0
TCA 1000	0ng/ml	25	0	25	0	25	0	25
	250ng/ml	50	0	50	0	50	0	50
	500ng/ml	50	0	50	0	50	0	50
	750ng/ml	50	0	50	0	50	0	50
	1000ng/ml	50	41	9	38	12	37	13
	1250ng/ml	50	50	0	50	0	50	0
	1500ng/ml	50	50	0	50	0	50	0
	2000ng/ml	50	50	0	50	0	50	0
THC 50	0ng/ml	25	0	25	0	25	0	25
	12.5ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	0	50	0	50	0	50
	37.5ng/ml	50	0	50	0	50	0	50
	50ng/ml	50	43	7	38	12	40	10

	62.5ng/ml	50	50	0	50	0	50	0
	75ng/ml	50	50	0	50	0	50	0
	100ng/ml	50	50	0	50	0	50	0
BUP 10	0ng/ml	25	0	25	0	25	0	25
	2.5ng/ml	50	0	50	0	50	0	50
	5ng/ml	25	0	25	0	25	0	25
	7.5ng/ml	25	0	25	0	25	0	25
	10ng/ml	50	49	1	40	10	42	8
	12.5ng/ml	25	25	0	25	0	25	0
	15ng/ml	25	25	0	25	0	25	0
	20ng/ml	50	50	0	50	0	50	0
TRA 100	0ng/ml	50	0	50	0	50	0	50
	25ng/ml	50	0	50	0	50	0	50
	50ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	1	49
	100ng/ml	50	28	22	25	25	26	24
	125ng/ml	50	50	0	50	0	50	0
	150ng/ml	50	50	0	50	0	50	0
	175ng/ml	50	50	0	50	0	50	0
	200ng/ml	50	50	0	50	0	50	0
PPX 300	0ng/ml	50	0	50	0	50	0	50
	75ng/ml	50	0	50	0	50	0	50
	150ng/ml	50	0	50	0	50	0	50
	225ng/ml	50	1	49	0	50	0	50
	300ng/ml	50	28	22	27	23	30	20
	375ng/ml	50	50	0	50	0	49	1
	450ng/ml	50	50	0	50	0	50	0
	525ng/ml	50	50	0	50	0	50	0
	600ng/ml	50	50	0	50	0	50	0
FYL 1	0ng/ml	50	0	50	0	50	0	50
	0.25ng/ml	50	0	50	0	50	0	50
	0.50ng/ml	50	0	50	0	50	0	50
	0.75ng/ml	50	0	50	2	48	1	49
	1ng/ml	50	25	25	27	23	26	24
	1.25ng/ml	50	50	0	50	0	50	0
	1.50ng/ml	50	50	0	50	0	50	0
	1.75ng/ml	50	50	0	50	0	50	0
	2ng/ml	50	50	0	50	0	50	0
6-MAM 10	0ng/ml	50	0	50	0	50	0	50
	2.5ng/ml	50	0	50	0	50	0	50
	5ng/ml	50	0	50	0	50	0	50
	7.5ng/ml	50	2	48	0	50	1	49
	10ng/ml	50	26	24	25	25	27	23
	12.5ng/ml	50	50	0	49	1	50	0
	15ng/ml	50	50	0	50	0	50	0
	17.5ng/ml	50	50	0	50	0	50	0
	20ng/ml	50	50	0	50	0	50	0

Effect of Urinary Specific Gravity

Total 12 urine samples of specific gravities (SG) ranging from 1.000-1.035 were collected. Values of SG levels were determined by a refractometer. Target drugs were spiked to these urine samples at +50% cut-off and -50% cut-off concentrations. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquot of negative urine pool is adjusted in the range of 4.0, 5.0, 6.0, 7.0, 8.0 and 9.0 and spiked with the target drug at 50% below and 50% above Cutoff levels. The spiked pH-adjusted urine was tested with the Multi-Drug Test Cup. The results demonstrate the varying ranges of urinary pH do not affect the test results.

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or target drugs urine with concentrations at 50% below and 50% above Cut-Off levels. The following compounds show no cross-reactivity when tested with the Multi-Drug Test Cup at a concentration of 100µg/ml or specified concentrations.

Non Interference Compounds

Acetaminophen	D-Pseudoephedrine	Norfentanyl
Acetone (1000mg/dL)	Duloxetine	Noscapine
Acetophenetidin	4-Dimethyl-aminoantipyrine	(+)-Naproxen
Acetylsalicylic Acid	5, 5-Diphenylhydantoin	19-Norethindrone
Acyclovir	Ecgonine methyl ester	Octopamine
Albumin (100mg/dL)	EMDP	O-Hydroxyhippuric acid
Albuterol sulfate (Proair HFA)	Ephedrine	Olanzapine
Alpha Methadol	Erythromycin	Omeprazole
Aminophylline	Esomeprazole Magnesium (except MTD test)	Oxalic acid (100 mg/dL)
Aminopyrine	Estradiol	Oxolinic acid
Amoxicillin	Estrone	Oxymetazoline
Ampicillin	Ethanol (1%)	Paliperidone
Aripiprazole	Fenofibrate	Papaverine
Aspartame	Fenoprofen	Penicillin-G
Aspirin	Fentanyl(except FYL test)	PenicillinV Potassium
Atomoxetine	Fluoxetine Hydrochloride	Perphenazine
Atorvastatin Calcium	Fluphenazine	Phenacetin
Atropine	Fotemustine	Phenelzine
Azithromycin	Furosemide	Phenethylamine
Baclofen	Gabapentin	Phenylethylamine
Benzilic acid	Galactose(10mg/dL)	Phenylpropanolamine
Benzocaine	Gamma Globulin(500mg/dL)	Prednisone
Benzoic Acid	Gatifloxacin	Pregablin
Benzphetamine	Gemfibrozil	Procaine
Bilirubin	Gentisic acid	Promazine
Boric Acid (1%)	Glucose(3000mg/dL)	Promethazine
Bupropion	Guaiacol glyceryl ether	Propoxyphene (except PPX test)
Caffeine	Hemoglobin	Propranolol
Cannabidiol	Hydralazine	Pseudoephedrine
Captopril	Hydrochlorothiazide	Pyridoxine
Carbamazepine	Hydrocortisone	Pyrilamine
Carfentanil (except FYL test)	3-Hydroxytyramine	Pyrogallol
Carisoprodol	Ibuprofen	Quetiapine
Cefradine	Isoxsuprine	Quinine
Cephalexin	(+/-)-Isoproterenol	Quinolinic Acid
Chloralhydrate	Ketamine	R-(-)-Apomorphine
Chloramphenicol	Ketoprofen	Ranitidine
Chlordiazepoxide (except BZO test)	LAAM HCl	Riboflavin (10mg/dL)
Chloroquine (except MET test)	Labetalol	Rifampicin
Chlorothiazide	L-Ascorbic Acid	Risperidone
Chlorpromazine	L-Ephedrine	Salicylic Acid
Cholesterol	L-Epinephrine	Serotonin(5-Hydroxytyramine)
Ciprofloxacin Hydrochloride	Levofloxacin Hydrochloride	Sertraline
Citalopram	Levonorgestrel	Sildenafil Citrate
Clarithromycin	Levothyroxine Sodium	Simvastatin
Clonidine	Lidocaine Hydrochloride	Sulfamethazine
Clozapine	Lisinopril	Sulindac
Conjugated Estrogens	Loperamide	Telmisartan
Cortisone	Loratadine	Tetracycline
Creatine Hydrate	L-phenylephrine	Tetrahydrocortisone 3-(β-Dglucuronide)
Creatinine	Magnesium	Tetrahydrocortisone, 3-acetate
Cyclobenzaprine	Maprotiline	Tetrahydrozoline
Cyclodextrin	Meperidine	Theophylline
(-)-Cotinine	Meprobamate	Thiamine
(+)-Chlorpheniramine	Methapyrilene	Thioridazine
D,L-Epinephrine	Methaqualone	Tramadol (except TRA test)
D,L-Octopamine	Methoxyphenamine (except AMP/MET test)	Triamterene
d,l-Propranolol	Methylphenidate	Trifluoperazine
D,L-Tryptophan	Metoprolol Tartrate	Trimethobenzamide

D,L-Tyrosine	Metronidazole (300ug/ml)	Trimethoprim
Delorazepam (except BZO test)	Mifepristone	Tryptamine
Deoxycorticosterone	N-Acetylprocainamide	Tyramine
Desloratadine	NaCl(4000mg/dL)	Urea (2000mg/dL)
Dextromethorphan	Nalidixic Acid	Uric Acid
Diclofenac	Naloxone hydrochloride (except OXY test)	Valproic acid (250ug/mL)
Diflunisal	Naltrexone	Venlafaxine HCl (except TRA test)
Digoxin	Niacinamide	Verapamil
Diphenhydramine HCl	Nicotine	Vitamin B2
Disopyramide (except MTD test)	Nicotinic Acid	Vitamin C
Dopamine HCl	Nifedipine	Zaleplon
Doxepin	Nitroglycerin	Zomepirac sodium salt
Doxylamine	Nordoxepin	

【BIBLIOGRAPHY】

1. Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
2. Tietz NW. Textbook of Clinical Chemistry. W.B. Saunders Company. 1986; 1735.
3. Winger, Gail, A Handbook of Drug and Alcohol Abuse, Third Edition, Oxford Press, 1992, page 146.
4. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991; 216
5. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
6. Brunton L. Goodman and Gilman's: The Pharmacological Basis for Therapeutics. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

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