

Multi-Drug Multi-Line Test Cassette



This package insert is for testing of any combination of AMP, BZO, BAR, BUP, COC, COT, EDDP, FYL, KET, K2, mAMP/MET, MDMA, MOP, MTD, MQL, OPI, OXY, PCP, PPX, TCA, THC and TRA.

For professional and in vitro diagnostic use only.

[INTENDED USE]

Multi-Drug Multi-Line Test Cassette is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP1000)	D-Amphetamine	1,000
Amphetamine (AMP500)	D-Amphetamine	500
Amphetamine (AMP300)	D-Amphetamine	300
Benzodiazepines (BZO300)	Oxazepam	300
Benzodiazepines (BZO200)	Oxazepam	200
Barbiturates (BAR)	Secobarbital	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylcegonine	300
Cotinine (COT)	Cotinine	200
Methadone metabolite (EDDP)	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100
Fentanyl (FYL)	Fentanyl	200
Ketamine (KET)	Ketamine	1,000
Synthetic Cannabinoid (K2 50)	JWH-073/JWH-018	50
Synthetic Cannabinoid (K2 200)	JWH-073/JWH-018	200
Methamphetamine (mAMP1000/ MET1000)	D-Methamphetamine	1,000
Methamphetamine (mAMP500/ MET500)	D-Methamphetamine	500
Methamphetamine (mAMP300/ MET300)	D-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA)	D,L-Methylenedioxymethamphetamine	500
Morphine (MOP300/ OPI300)	Morphine	300
Methadone (MTD)	Methadone	300
Methaqualone (MQL)	Methaqualone	300
Opiates (OPI 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50
Tramadol (TRA)	Tramadol	200

Configurations of the Multi-Drug Multi-Line Test Cassette can consist of any combination of the above listed drug analytes.

[SUMMARY]

Amphetamine (AMP1000)

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 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 Multi-Line Test Cassette 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).

Amphetamine (AMP500)

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of amphetamine in urine exceeds 500ng/mL. See Amphetamine (AMP1000) for the summary.

Amphetamine (AMP300)

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of amphetamine in urine exceeds 300ng/mL. See Amphetamine (AMP1000) for the summary.

Benzodiazepines (BZO300)

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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Benzodiazepines in urine exceeds 300ng/mL.

Benzodiazepines (BZO200)

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Benzodiazepines in urine exceeds 200ng/mL. See Benzodiazepines (BZO300) for the summary.

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

The Multi-Drug Multi-Line Test Cassette 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 20ng/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 Multi-Line Test Cassette yields a positive result when the concentration of Buprenorphine in urine exceeds 10ng/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 Benzoylcegonine. Benzoylcegonine, 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 Multi-Line Test Cassette 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).

Cotinine (COT)

Cotinine is the first-stage metabolite of nicotine, a toxic alkaloid that produces stimulation of the autonomic ganglia and central nervous system when in humans. Nicotine is a drug to which virtually every member of a tobacco-smoking society is exposed whether through direct contact or second-hand inhalation. In addition to tobacco, nicotine is also commercially available as the active ingredient in smoking replacement therapies such as nicotine gum, transdermal patches and nasal sprays.

In a 24-hour urine, approximately 5% of a nicotine dose is excreted as unchanged drug with 10% as cotinine and 35% as hydroxycotinine; the concentrations of other metabolites are believed to account for less than 5%. While cotinine is thought to be an inactive metabolite, its elimination profile is more stable than that of nicotine which is largely urine pH dependent. As a result, cotinine is considered a good biological marker for determining nicotine use. The plasma half-life of nicotine is approximately 60 minutes following inhalation or parenteral administration. Nicotine and cotinine are rapidly eliminated by the kidney; the window of detection for cotinine in urine at a cut-off level of 200ng/mL is expected to be up to 2-3 days after nicotine use.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the Cotinine in urine exceeds

200ng/mL.

2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)

2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, is the primary metabolite of methadone. Methadone is a controlled substance and is used for detoxification and maintenance of opiate dependant patients. Patients on methadone maintenance may exhibit methadone (parent) levels that account for 5-50% of the dosage and 3-25% of EDDP in urinary excretion during the first 24 hours. The detection of EDDP is more beneficial than traditional methadone screening, in that EDDP exists only in urine from individuals that ingested methadone. The tampering of specimens by spiking the urine with methadone can be prevented. Secondly, renal clearance of EDDP is not affected by urinary pH, therefore the EDDP test provides a more accurate result of methadone ingestion than the methadone parent screen.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Methadone Metabolites in urine exceeds 100ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

Fentanyl (FYL)

Fentanyl is a synthetic opioid. It has the brand names of Sublimaze, Actiq, Durogestic, Fentora and others. The Fentanyl drug is approximately 100 times more potent than morphine, with 100 micrograms of fentanyl approximately equivalent to 10 mg. of morphine or 75 mg. of meperidine in analgesic activity. The Fentanyl drug is a potent narcotic analgesic with rapid onset and short duration of action. Historically, the fentanyl drug has been used to treat chronic breakthrough pain and is commonly used pre-procedures. Illicit use of pharmaceutical fentanyl drugs first appeared in the mid-1970s. Because the effects of the fentanyl drug last for only a very short time, it is even more addictive than heroin. Regular users may become addicted very quickly. The Fentanyl drug is much more potent than heroin, and tends to produce significantly worse respiratory depression, making it somewhat more dangerous than heroin to users. Overdose of the fentanyl drug has caused death. In the United States, the fentanyl drug is classified as a Schedule II controlled substance.

The Multi-Drug Multi-Line Test Cassette 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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of ketamine in urine exceeds 1,000ng/mL.

Synthetic Cannabinoid (K2 50)

Since 2004, herbal mixtures such as 'Spice' are sold in Switzerland, Austria, Germany and other European countries mainly via Internet shops. Although declared as incense, they are smoked as 'bio-drugs' by the consumers. In corresponding blogs, drug users reported cannabis-like effects after smoking. These products enjoy great popularity particularly among younger people, as up to now the mixtures are sold in head shops and via internet in many countries without age restriction.

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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when synthetic cannabinoid in urine exceed 50ng/mL.

Synthetic Cannabinoid (K2 200)

The Multi-Drug Multi-Line Test Cassette yields a positive result when K2 synthetic cannabinoid in urine exceed 200ng/mL. See Synthetic Cannabinoid (K2 50) for the summary.

Methamphetamine (mAMP1000/ MET1000)

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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of methamphetamine in urine exceeds 1,000ng/mL.

Methamphetamine (mAMP500/ MET500)

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Methamphetamine in urine exceeds 500ng/mL. See Methamphetamine (mAMP1000/MET 1000) for the summary.

Methamphetamine (mAMP300/ MET300)

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Methamphetamine in urine exceeds 300ng/mL. See Methamphetamine (mAMP1000/MET 1000) for the summary.

Methylenedioxyamphetamine (MDMA)

Methylenedioxyamphetamine (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 Oberlander, 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 Multi-Line Test Cassette yields a positive result when the concentration of methylenedioxyamphetamine in urine exceeds 500ng/mL.

Morphine (MOP300 or OPI300)

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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of morphine in urine exceeds 300ng/mL.

Methadone (MTD)

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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of methadone in urine exceeds 300ng/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 European 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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Methaqualone in urine exceeds 300ng/mL.

Opiates (OPI 2000)

The Multi-Drug Multi-Line Test Cassette 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). See Morphine (MOP300 or OPI300) for the summary.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying the baine, 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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the oxycodone level in urine exceeds 100ng/mL.

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%).

The Multi-Drug Multi-Line Test Cassette 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 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 Multi-Line Test Cassette yields a positive result when the concentration of Propoxyphene 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.

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Tricyclic Antidepressants in urine exceeds 1,000ng/mL.

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- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH).

The Multi-Drug Multi-Line Test Cassette 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).

Tramadol (TRA)

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

The Multi-Drug Multi-Line Test Cassette yields a positive result when the concentration of Tramadol in urine exceeds 200ng/mL.

[PRINCIPLE]

The Multi-Drug Multi-Line Test Cassette 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 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 line region of the specific drug strip. 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 line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

[WARNINGS AND PRECAUTIONS]

- For in vitro diagnostic use only.
- For healthcare professionals and professionals at point of care sites.
- Do not use after the expiration date.
- Please read all the information in this leaflet before performing the test.
- The test Cassette 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 Cassette should be discarded according to federal, state and local regulations.

[COMPOSITION]

Each test contains specific drug anti-coupled particles and corresponding drug protein conjugates. A goat antibody is employed in each control line. The quantity of tests was printed on the labeling.

Materials Provided

- Test Cassette
- Specimen collection container
- Package insert
- Materials Required But Not Provided
- Timer

[STORAGE AND STABILITY]

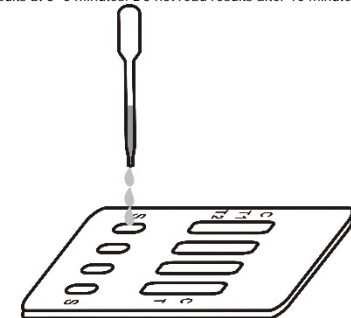
- Store as packaged in the sealed pouch at room temperature (4-30°C or 40-86°F). The kit is stable within the expiration date printed on the labeling.
- Once open the pouch, the test should be used within one hour. Prolonged exposure to hot and humid environment will cause product deterioration.
- The LOT and the expiration date were printed on the labeling.

[SPECIMEN]

- The urine specimen must 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 supernatant for testing.
- Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

[TEST PROCEDURE]

- Allow the test and urine samples to equilibrate to room temperature (15-30°C or 59-86°F) prior to testing.
1. Remove the test cassette from the sealed pouch. Place the cassette on a clean and level surface.
 2. Hold the dropper vertically and transfer 3 full drops (approx. 100µl) of urine to the specimen well of the test cassette, and then begin timing. See the illustration below.
 3. Start the timer and wait for the colored line(s) to appear.
 4. Interpret the test results at 3-5 minutes. Do not read results after 10 minutes.



(The picture is for reference only, please refer to the material object.)

[INTERPRETATION OF RESULTS]

Two lines strip



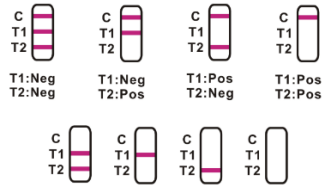
Negative: **Two lines appear.** One colored line should be in the control region (C), and another apparent colored line adjacent should be in the test region (T). This negative result indicates that the drug concentration is below the detectable level.

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

Positive: **One colored line appears in the control region (C). No line appears in the test region (T).** This positive result indicates that the drug concentration is above the detectable level.

Invalid: **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 dip card. If the problem persists, discontinue using the lot immediately and contact your local distributor.

Three lines strip



Invalid

Negative: *Three lines appear. One colored line should be in the control region (C), and another two apparent colored lines adjacent should be in the test region (T₁ and T₂). This negative result indicates that the drug concentration is below the detectable level.

*NOTE: The shade of the colored lines in the test line region (T₁ and T₂) may vary, but it should be considered negative whenever there is even a faint line.

Positive: One colored line appears in the control region (C). No line appears in the test region (T₁ or T₂). This positive result indicates that the drug concentration is above the detectable level.

Invalid: 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. A colored 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]

- The Multi-Drug Multi-Line Test Cassette 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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A Positive result does not indicate level or intoxication, administration route or concentration in urine.
- A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.

[PERFORMANCE CHARACTERISTICS]

Accuracy

A side-by-side comparison was conducted using the Drug Rapid Tests and commercially available drug rapid tests. Testing was performed on approximately 300 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	D-Amphetamine
BZO	Oxazepam, Nordiazepam, a-OH-Alprazolam, Desalkylflurazepam
BAR	Secobarbital, Butalbital, Phenobarbital, Pentobarbital
BUP	Buprenorphine
COC	Benzoylcocaine
COT	Cotinine
EDDP	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine
FYL	Fentanyl
KET	Ketamine
K2	JWH-073/JWH-018
mAMP	D-Methamphetamine
MDMA	D,L-Methylenedioxymethamphetamine, Methylenedioxyamphetamine
MOP	Morphine, Codeine

MTD	Metadone
MQL	Methaqualone
OPI	Morphine, Codeine
OXY	Oxycodone
PCP	Phencyclidine
PPX	Propoxyphene
TCA	Nortriptyline
THC	11-nor-Δ ⁹ -tetrahydrocannabinol-9-carboxylic acid
TRA	Tramadol

The following results are tabulated from these clinical studies:

Drugs	%Agreement with Commercial Kit			%Agreement with GC/MS		
	Positive Agreement	Negative Agreement	Total Results	Positive Agreement	Negative Agreement	Total Results
AMP1000	98%	100%	99%	97%	96%	96%
AMP500	98%	100%	99%	96%	96%	96%
AMP300	97%	100%	98%	97%	95%	96%
BZO300	100%	97%	98%	96%	98%	97%
BZO200	99%	97%	98%	96%	97%	96%
BAR	100%	100%	100%	98%	98%	98%
BUP	100%	99%	>99%	98%	98%	98%
COC	96%	100%	98%	98%	95%	96%
COT	100%	99%	>99%	98%	97%	98%
EDDP	>99%	>99%	>99%	>99%	>99%	>99%
FYL	94%	100%	97%	97%	100%	98%
KET	100%	99%	>99%	100%	95%	97%
K2 50	100%	99%	>99%	100%	96%	98%
K2 200	100%	99%	>99%	100%	95%	97%
mAMP1000	98%	100%	99%	97%	96%	96%
mAMP500	98%	99%	98%	96%	96%	96%
mAMP300	97%	99%	98%	97%	95%	96%
MDMA	100%	99%	>99%	97%	97%	97%
MOP300	100%	99%	>99%	100%	97%	98%
MTD	100%	100%	100%	98%	96%	97%
MQL	>99%	>99%	>99%	>99%	>99%	>99%
OPI 2000	100%	99%	>99%	100%	97%	98%
OXY	99%	100%	99%	98%	97%	98%
PCP	98%	100%	99%	100%	98%	99%
PPX	>99%	>99%	>99%	94%	99%	97%
TCA	97%	100%	99%	98%	97%	97%
THC	100%	100%	100%	96%	92%	94%
TRA	>99%	>99%	>99%	>99%	>99%	>99%

Forty (40) clinical samples for each drug were run using each strip contained within the Drug Rapid Tests by an untrained operator at a Professional Point of Care site. Based on GC/MS data, the operator obtained statistically similar Positive Agreement, Negative Agreement and Overall Agreement rates as trained Laboratory personnel.

*Note: TCA was based on HPLC data.

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 Cassette of coded specimens, containing drugs at the concentration of ± 50% and ± 25% cut-off level, was labeled as a blind and tested at each site. The results across all lots and sites meet the expected results.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at concentrations listed. The results are summarized below.

Drug concentration Cut-off Range	n	AMP1000		AMP 500		AMP 300		BZO 300		BZO200		BAR		BUP	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	27	3	28	2	26	4	27	3	26	4
Cut-off	30	18	12	19	11	18	12	10	20	15	15	13	17	19	11

25% Cut-off	30	1	29	3	27	2	28	2	28	3	27	4	26	9	21
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	COC		COT		EDDP		FYL		KET		K2 50		K2 200	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	30	0	27	3	30	0	29	1	29	1	29	1
Cut-off	30	3	27	13	17	16	14	13	17	16	14	16	14	18	12
25% Cut-off	30	0	30	4	26	4	26	0	30	1	29	1	29	1	29
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	mAMP1000		mAMP500		mAMP300		MDMA		MOP		MTD		MQL	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	28	2	26	4	28	2	30	0	27	3	19	11
Cut-off	30	17	13	16	14	17	13	13	17	11	19	19	11	15	15
25% Cut-off	30	1	29	2	28	2	28	2	28	2	28	2	28	10	20
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Drug concentration Cut-off Range	n	OPI		OXY		PCP		PPX		TCA		THC		TRA	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-50% Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0	30	0
-25% Cut-off	30	30	0	25	5	19	11	26	4	27	3	16	14	26	4
Cut-off	30	11	19	7	23	13	17	19	11	9	21	2	28	16	14
25% Cut-off	30	2	28	0	30	4	26	8	22	2	28	1	29	3	27
50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the Multi-Drug Multi-Line Test Cassette at 3-5 minutes.

Drugs	Con.(ng/mL)	Drugs	Con.(ng/mL)
Amphetamine (AMP1000)			
D-Amphetamine	1,000	L-Amphetamine	50,000
D,L-Amphetamine sulfate	3,000	Phentermine	3,000
(±)-3,4-Methylenedioxyamphetamine	2,000		
Amphetamine (AMP500)			
D-Amphetamine	500	L-Amphetamine	25,000
D,L-Amphetamine sulfate	1,500	Phentermine	1,500
(±)-3,4-Methylenedioxyamphetamine	1,000		
Amphetamine (AMP300)			
D-Amphetamine	300	L-Amphetamine	15,000
D,L-Amphetamine sulfate	1,000	Phentermine	1,000
(±)-3,4-Methylenedioxyamphetamine	600		
Benzodiazepines (BZO300)			
Oxazepam	300	Diazepam	195
Alprazolam	196	Estazolam	2,500
a-Hydroxylalprazolam	1,262	Flunitrazepam	390
Bromazepam	1,562	(±)-Lorazepam	1,562
Chlordiazepoxide	1,562	RS-Lorazepamglucuronide	156
ChlordiazepoxideHCl	781	Midazolam	12,500
Clobazam	98	Nitrazepam	98
Clonazepam	781	Norchlordiazepoxide	195
Clorazepatedipotassium	195	Nordiazepam	390
Delorazepam	1,562	Temazepam	98
Desalkylflurazepam	390	Triazolam	2,500
Benzodiazepines (BZO200)			
Oxazepam	200	Diazepam	130
Alprazolam	131	Estazolam	1,667
a-Hydroxylalprazolam	841	Flunitrazepam	260
Bromazepam	1,041	(±)-Lorazepam	1,041
Chlordiazepoxide	1,041	RS-Lorazepamglucuronide	104
Chlordiazepoxide HCl	521	Midazolam	8,333
Clobazam	65	Nitrazepam	65

Clonazepam	521	Norchlordiazepoxide	130
Clorazepatedipotassium	130	Nordiazepam	260
Delorazepam	1,041	Temazepam	65
Desalkylflurazepam	260	Triazolam	1,667
Barbiturates (BAR)			
Secobarbital	300	Butalbital	2,500
Amobarbital	300	Butethal	100
Alphenol	150	Cyclopentobarbital	600
Aprobarbital	200	Pentobarbital	300
Butabarbital	75	Phenobarbital	100
Buprenorphine (BUP)			
Buprenorphine 3-D-glucuronide	15	Buprenorphine	10
Norbuprenorphine 3-D-glucuronide	200	Norbuprenorphine	20
Cocaine (COC)			
Benzoylcegonine	300	Cocaethylene	12,500
Cocaine HCl	780	Ecgonine HCl	32,000
Cotinine (COT)			
Cotinine	200	Nicotine	6,250
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)			
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	100	Venlafaxine hydrochloride	30,000
		Methadone	100
Disopyramide	20,000	Doxylamine	20,000
Tramadol	30,000		
Fentanyl (FYL)			
Fentanyl	200	Norfentanyl	375
Ketamine (KET)			
Ketamine	1,000	D-Methamphetamine	12,500
Methoxy-amphetamine	12,500	Promethazine	25,000
4-hydroxyphenylcyclohexylpiperidine			50,000
Synthetic Cannabinoid (K2 50)			
JWH-073	50	JWH-018	50
Synthetic Cannabinoid (K2 200)			
JWH-073	200	JWH-018	200
Methamphetamine (mAMP1000)			
D-Methamphetamine	1,000	L-Methamphetamine	8,000
p-Hydroxymethamphetamine	30,000	Mephentermine	50,000
(±)-3,4-Methylenedioxyamphetamine			2,000
Methamphetamine (mAMP500)			
D-Methamphetamine	500	L-Methamphetamine	4,000
p-Hydroxymethamphetamine	15,000	Mephentermine	25,000
(±)-3,4-Methylenedioxyamphetamine			1,000
Methamphetamine (mAMP300)			
D-Methamphetamine	300	L-Methamphetamine	2,400
p-Hydroxymethamphetamine	10,000	Mephentermine	15,000
(±)-3,4-Methylenedioxyamphetamine			600
Methylenedioxyamphetamine (MDMA)			
D,L-3,4-Methylenedioxyamphetamine HCl (MDMA)			500
3,4-Methylenedioxyamphetamine HCl (MDA)			3,000
3,4-Methylenedioxyethyl-amphetamine (MDE)			300
Morphine (MOP300)			
Morphine	300	6-Monoacetylmorphine	400
Codeine	300	Norcodeine	6,250
Ethylmorphine	6,250	Normorphine	100,000
Hydrocodone	50,000	Oxycodone	30,000
Hydromorphone	3,125	Oxymorphone	100,000
Levorphanol	1500	Procaine	15,000
Morphine 3-β-D-glucuronide	1,000	Thebaine	6,250
Methadone (MTD)			
Methadone	300	Doxylamine	50,000
Methaqualone (MQL)			
Methaqualone	300		
Opiates (OPI 2000)			
Morphine	2,000	6-Monoacetylmorphine	5,000
Codeine	2,000	Norcodeine	12,500
Ethylmorphine	5,000	Normorphine	50,000
Hydrocodone	12,500	Oxycodone	25,000
Hydromorphone	5,000	Oxymorphone	25,000

Levophanol	75,000	Procaine	150,000
Morphine 3-β-D-glucuronide	2,000	Thebaine	100,000
Oxycodone (OXY)			
Oxycodone	100	Hydrocodone	1,562
Codeine	50,000	Hydromorphone	12,500
Dihydrocodeine	12,500	Oxymorphone	1,562
Ethylmorphine	25,000	Thebaine	50,000
Phencyclidine (PCP)			
Phencyclidine	25	4-Hydroxyphencyclidine	12,500
Propoxyphene (PPX)			
D-Propoxyphene	300	D-Norpropoxyphene	300
Tricyclic Antidepressants (TCA)			
Notriptyline	1,000	Imipramine	400
Nordoxepin	1,000	Clomipramine	12,500
Trimipramine	3,000	Doxepin	2,000
Amitriptyline	1,500	Maprotiline	2,000
Promazine	1,500	Promethazine	25,000
Desipramine	200		
Marijuana (THC)			
11-nor-Δ ⁹ -THC-9-COOH	50	Δ ⁹ -THC	15,000
Cannabinol	20,000	Δ ⁹ -THC	15,000
11-nor-Δ ⁹ -THC-9-COOH	30		
Tramadol (TRA)			
Tramadol	200	O-desmethyl-tramadol	20,000
N-desmethyl-tramadol	500		

Effect of Urinary 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 Multi-Drug Multi-Line Test Cassette 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.

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 Multi-Drug Multi-Line Test Cassette. The results demonstrate that varying ranges of pH does not interfere with the performance of the test.

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 containing Amphetamine, Benzodiazepines, Barbiturates, Buprenorphine, Cocaine, Cotinine, 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine, Fentanyl, Ketamine, Synthetic Cannabinoid, Methamphetamine, Methylenedioxyamphetamine, Morphine, Methadone, Methaqualone, Opiates, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, Marijuana or Tramadol. The following compounds show no cross-reactivity when tested with the Multi-Drug Multi-Line Test Cassette at a concentration of 100µg/mL.

Non Cross-Reacting Compounds

Acetaminophen	Deoxycorticosterone	Labelalol	Prednisolone
N-Acetylprocainamide	Dextromethorphan	Loperamide	D/L-Propranolol
Aminopyrine	Diflunisal	Meperidine	D-Propoxyphene
Ampicillin	Diphenhydramine	Meprobamate	D-Pseudoephedrine
Apomorphine	Diclofenac	Methylphenidate	Quinacrine
Atropine	Digoxin	Methoxyphenamine	Quindine
Acetophenetidin	Ecgonine methylester	Nalidixic acid	Quinine
Acetylsalicylic acid	L-Ψ-Ephedrine	Naloxone	Ranitidine
Amoxicillin	Estrone-3-sulfate	Naproxen	Salicylic acid
L-Ascorbic acid	[1R,2S] (-)-Ephedrine	Nifedipine	Sulfamethazine
Asparfame	Erythromycin	D-Norpropoxyphene	Serotonin
Benzoic acid	β-Estradiol	Naltrexone	Sulindac
Bilirubin	Ethyl-p-aminobenzoate	Niacinamide	Tetracycline
Benzilic acid	L(-)-Epinéphrine	Norethindrone	Tetrahydrozoline
Benzphetamine*	Fenoprofen	Noscapine	Thiamine
D/L-Brompheniramine	Furosemide	D/L-Octopamine	Tetrahydrocortisone 3-acetate
Caffeine	Genitilic acid	Oxolinic acid	
Chloralhydrate	Hemoglobin	Oxalic acid	Tetrahydrocortisone 3 (β-D-glucuronide)
Chlorothiazide	Hydrochlorothiazide	Oxymetazoline	
Chlorpromazine	O-Hydroxyhippuric acid	Papaverine	D/L-Tyrosine
Cholesterol	p-Hydroxytyramine	Pentazocine hydrochloride	Triamterene

Cortisone	Hydralazine	Phenelzine	Trimethoprim
Creatinine	Hydrocortisone	L-Phenylephrine	D/L-Tryptophan
Cannabidol	p-Hydroxyamphetamine	Phenylpropanolamine	Thioridazine
Chloramphenicol	Ibuprofen	Prednisone	Tolbutamide
D/L-Chloropheniramine	Ironiazid	Penicillin-G	Trifluoperazine
Chloroquine	Isoxsuprine	Perphenazine	Tryptamine
Clonidine	D/L-Isoproterenol	Trans-2-phenylcyclopropylamine hydrochloride	Tyramine
L-Cotinine	Ketoprofen		Uric acid
β-Phenylethylamine	Verapamil	Zomepirac	

*Parent compound only; metabolizes amphetamine and methamphetamine in urine.

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	Do not reuse		For in vitro diagnostic use only
	Store between 4-30°C		Consult instructions for use
	Caution		Lot number
	Use by		Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
	Authorized representative in the European Community		

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