

Rapid Multi-drug Test Cup

Catalogue No.: DTPM-13PCW

Instruction of use for testing of any combination of the following drugs:

AMP/ BAR/ BUP/ BZO/ COC/ MDMA

MET/ MOP/ MTD/ OXY/ PCP/ TCA/ THC

Include Specimen Validity Tests (S.V.T.): OX/ SG/pH/NI/GLU/CR

Rapid Multi-drug Test Cup is a rapid, screening test for the qualitative detection of multiple drugs and drug metabolites in human urine at specified cut off levels.

For professional use only. For in vitro test use only.

INTENDED USE

Rapid Multi-drug Test Cup is an immuno-chromatographic assay for the qualitative determination of the presence of drugs listed in the table below.

Drug(Identifier)	Calibrator	Cut-off level
Amphetamine (AMP)	d-Amphetamine	1000ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Buprenorphine(BUP)	Buprenorphine	10 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoyllecgonine	300 ng/mL
Methylenedioxymethamphetamine - ecstasy (MDMA)	3,4-Methylenedioxymethamphetamine HCl (MDMA)	500 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000ng/mL
Morphine300 (MOP)	Morphine	300ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000ng/mL
Marijuana (THC)	11-nor- Δ 9-THC-9-COOH	50 ng/mL

The test you purchased may test for any combination of drugs listed in the table above. This assay provides only a preliminary analytical test result. Gas Chromatography/Mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

Amphetamine (AMP)

Amphetamine and the structurally related "designer" drugs are sympathomimetic amines whose biological effects include potent central nervous system (CNS) stimulation, anorectic, hyperthermic, and cardiovascular properties. They are usually taken orally, intravenously, or by smoking. Amphetamines are readily absorbed from the gastrointestinal tract and are then either deactivated by the liver or excreted unchanged in the urine. Methamphetamine is partially metabolized to amphetamine and its major active metabolite. Amphetamines increase the heart rate and blood pressure, and suppress the appetite. Some studies indicate that heavy abuse may result in permanent damage to certain essential nerve structural in the brain. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. It can be detected in the urine for 1 to 2 days after use.

BARBITURATES (BAR)

Barbiturates are central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Barbiturates range from short-acting (approximately 15 minutes, such as secobarbital) to long-acting (24 hours or longer, such as Phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged. Barbiturates produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Barbiturate could develop tolerance and physiological dependency and lead to its abuse.

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.

BENZODIAZEPINES (BZO)

Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsants and sedative hypnotics. Benzodiazepines manifest their presence by analgesia, drowsiness, confusion, diminished reflexes, lowering of body temperature, respiratory depression, blockade of adrenocortical response, and a decrease in peripheral resistance without an impact on the cardiac index. The major pathways of elimination are the kidneys (urine) and the liver where it is conjugated to glucuronic acid. Large doses of Benzodiazepines could develop tolerances and physiological dependency and lead to its abuse. Only trace amounts (less than 1%) of Benzodiazepines are excreted unaltered in the urine, most of Benzodiazepines in urine is conjugated drug. Oxazepam, a common metabolite of many benzodiazepines, remains detectable in urine for up to one week, which makes Oxazepam a useful marker of Benzodiazepines abuse.

Cocaine (COC)

Cocaine derived from leaves of coca plant, is a potent central nervous system stimulant and a local anesthetic. Among the psychological effects induced by using cocaine are euphoria, confidence and a sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Cocaine is excreted in urine primarily as benzoyllecgonine in a short period of time.

Methylenedioxymethamphetamine - ecstasy (MDMA)

MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphetamine). They all share the amphetamine-like effects. MDMA is a stimulant with hallucinogenic tendencies described as an empathogen as it releases mood-altering chemicals, such as cartoning and L-dopa, and may generate feelings of love and friendliness. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia and insomnia. MDMA is administered either by oral ingestion or intravenous injection. The effects of MDMA begin 30 minutes after intake, peak in an hour and last for 2 – 3 hours.

Methamphetamine (MET)

Methamphetamine is a potent sympathomimetic agent with therapeutic applications. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, and a sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behavior, and cardiac dysrhythmias. The pattern of psychosis which may appear at half-life of about 15 hours is excreted in urine as amphetamine and oxidized as deaminated and hydroxylated derivatives. However, 40% of methamphetamine is excreted unchanged. Thus the presence of the parent compound in the urine indicates methamphetamine use.

Morphine(MOP300)

Opiates refer 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. Opiates exert their effects on the central nervous system and organs containing smooth muscle. Opiates manifest their presence by analgesia, drowsiness, euphoria, lowering of body temperature, respiratory depression, blockade of adrenocortical response. The major pathways of elimination are kidneys (urine) and the liver where it is conjugated to glucuronic acid. Opiates and their metabolites can be detected in urine as result of heroin, morphine, codeine or poppy seed intake.

Methadone (MTD)

Methadone is a narcotic analgesic prescribed for the management of moderate to severe pain and for the treatment of opiate dependence (Heroin, Vicodin, Percocet, Morphine). It is administered either orally, or by intravenous or intra-muscular injection. The duration of effect of methadone is 12 – 24 hours. Its major urinary excretion products are methadone, EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine), and EMDP (2-ethyl-5-methyl-3,3-diphenylpyrrolidine).

Opiate(MOP2000)

See Morphine(MOP300) for the summary.

Oxycodone (OXY)

Oxycodone is an analgesic, which works by depressing the central nervous system. Oxycodone is abused for its opiate-like effects. In addition to its equal potency to morphine in analgesic effects, it is also equipotent to morphine in relieving abstinence symptoms from chronic opiate (heroin, morphine) use. For this reason, it is often used to alleviate or prevent the onset of opiate withdrawal by street users of heroin and methadone. The drug is most often administered orally. Like other opiates, Oxycodone can also depress the respiratory system resulting in suffocation and death when overdosed. Oxycodone is very addictive, both physically and psychologically. Some physical indications of Oxycodone abuse include extreme loss of appetite and weight, cramps, nausea, vomiting, excessive scratching and complaint of itching, excessive sweating, constipation, pin-point pupils and watery eyes, reduced vision, drowsiness, euphoria, trance-like states, excessive thirst, tremors, twitching, irritability, hallucinations and lethargy.

Phencyclidine (PCP)

Phencyclidine, commonly known as PCP or "angel dust" is used primarily as recreational drug due to its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. The effects of PCP are very much dose related. Small amounts of Phencyclidines (PCP) are central nervous system stimulants that produce alertness, wakefulness, increased energy, increased heart rate, and decreased sense of pain and touch, and an overall feeling of well being. Large doses of Phencyclidine (PCP) can result in death due to convulsions, heart and lung failure and coma. Large repeated doses of Phencyclidine (PCP) could develop tolerances and physiological dependency and lead to its abuse. PCP can be found in urine within 4 to 6 hours after use and will remain in urine for 7 to 14 days. Phencyclidine is excreted in the urine as an unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%).

Tri-cyclic Antidepressants (TCA)

Tricyclic Antidepressants are a group of antidepressant drugs that are commonly used for treatment of depressive disorders. TCAs can be taken orally or by intramuscularly injection (IM). The symptoms of TCAs overdoses include agitation, confusion, hallucinations, hypertonicity, seizures, and EKG changes. The half-life of TCA varies from a few hours to several days. The commonly used TCAs are excreted with a very low percentage of unchanged drugs in the urine. Therefore, detection of the metabolites of TCAs in human urine has been used for screening the abuse of TCAs.

Marijuana (THC)

Marijuana is a hallucinogenic agent derived from the flowering portion of the hemp plant. The active ingredients in Cannabinoids, THC & Cannabinol can be metabolized and excreted as 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of Cannabinoids/cannabis. Higher doses used by abusers produce central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short-term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate. A tolerance to the cardiac and psychotropic effects can occur, and withdrawal syndrome produces restlessness, insomnia, anorexia and nausea.

PRINCIPLE

Rapid Multi-drug Test Cup is a competitive immunoassay that is used to screen for the presence of various drugs *and drug metabolites* in urine. It is chromatographic absorbent device in which, drugs within a urine sample, competitively combined to a limited number of drug monoclonal antibody (mouse) conjugate binding sites.

When the test is activated, the urine is absorbed into each test strip by capillary action, mixes with the respective drug monoclonal antibody conjugate, and flows across a pre-coated membrane. When drug within the urine sample is below the detection level of the test, respective drug monoclonal antibody conjugate binds to the respective drug-protein conjugate immobilized in the Test Region (T) of the test strip. This produces a colored Test line in the Test Region (T) of the strip, which, regardless of its intensity, indicates a negative test result.

When sample drug levels are at or above the detection level of the test, the free drug in the sample binds to the respective drug monoclonal antibody conjugate, preventing the respective drug monoclonal antibody conjugate from binding to the respective drug-protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a preliminary positive result.

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

WARNINGS AND PRECAUTIONS

- Immunoassay for *in vitro* test use only.
- Do not use after expiration date.
- The test cup should remain in the sealed pouch until use.
- The used test cup should be discarded according to local regulations.

CONTENTS OF THE KITS

- Drug Test Cup.
- Desiccant.
- Leaflet with instruction for use.

ADDITIONAL REQUIREMENTS

- Timer (watch or clock)
- External controls

STORAGE AND STABILITY

- Store at 39 ~ 86 °F (4 ~ 30 °C) in the sealed pouch up to the expiration date.
- Keep away from direct sunlight, moisture and heat.

SPECIMEN COLLECTION AND PREPARATION

- Urine collected at any time of the day may be used.
- For best results, test specimens immediately following collection.
- Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours.
For longer storage, freeze the samples (-20°C or below).
- Bring frozen or refrigerated samples to room temperature before testing.

HOW TO PERFORM THE TEST?

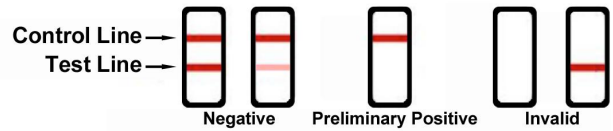
Test must be in room temperature (15°C to 30°C)

1. After the urine has been collected, tighten lid to the indicator, and place the test cup on a flat surface.
2. Read temperature immediately to verify that urine temperature is within the acceptable range. 90 – 100°F (32 – 38°C)
3. Peel off label and read the results. The drug test results should be read at 5 minutes. **The drug test results remain stable for up to thirty minutes.**

READING THE RESULTS

Preliminary positive (+)

A rose-pink band is visible in each control region. If no color band appears in the appropriate test “T” region, a preliminary positive result is indicated for the corresponding drug of that specific test zone.



Negative (-)

If a rose-pink band is visible in each control region and the appropriate test “T” region, it indicates that the concentration of the corresponding drug of that specific test zone is absent or below the detection limit of the test.

Invalid

If a color band is not visible in the control “C” region or a color band is only visible in the test “T” region, the test is invalid. Another test should be opened and run to re-evaluate the specimen. If test still provides an invalid result, please contact the distributor from whom you purchased the product. When calling, be sure to provide the lot number for the test.

Note: There is no meaning attributed to line color intensity or width. Any visible line is considered to be a line.

Certain lines may appear lighter or thinner than other lines. ANY COLORED LINE VISIBLE IN THE TEST “T” REGION, NO MATTER HOW DARK OR FAINT, SHOULD BE INTERPRETED AS A NEGATIVE RESULT.

IMPORTANT: This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS is the preferred confirmatory method. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug test result, particularly when preliminary positive results are indicated.

What Is A False Positive Test?

The definition of a false positive test would be an instance where a substance is identified incorrectly by Rapid Multi-drug Test Cup. The most common causes of a false positive test are cross reactants. Certain foods and medicines, diet plan drugs and nutritional supplements may cause a false positive test result with this product.

What Is A False Negative Test?

The definition of a false negative test is that the initial drug is present but isn't detected by Rapid Multi-drug Test Cup. Diluted or adulterated urine specimens may cause a false negative result.

TEST LIMITATIONS

1. This test has been developed for testing urine samples only. No other fluids have been evaluated. DO NOT use this device to test substances other than urine.
2. There is a possibility that technical or procedural errors, as well as interfering substances in the urine specimen may cause erroneous results.
3. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analyte. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, cup.
4. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
5. A positive result does not indicate level or intoxication, administration route or concentration in urine.
6. 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.

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. Quality control should be run with each new lot, and every 30 days to check storage stability. Positive and negative control should give the expected results. Users can commercially obtain control materials (For example from Sigma-Aldrich Corporation).The concentration of drug(s) in positive and negative controls are approximately 50% above and below the cutoff concentration of the assay.

INDEX OF SYMBOLS

	Consult instructions for use		Sufficient for		Date of manufacture
	In vitro diagnostic medical device		Use by		Do not reuse
	Store between 4 ~ 30 °C		Batch code		Catalogue number
	Keep away from sunlight		Keep dry		Authorised Representative in the EU

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