DRUGFOR

Multi-Drug Screen Test Kit
Reference Number: VDDOA03 IVD IFU CE
AMP/BAR/BZO/BUP/COC/THC/MET/MTD/MDMA/MOP/OXY/PCP/PPX/TCA/K2/OPI/TRA/EDDP/FTY/COT/ETG/KET/MQL

INTENDED USE

DrugFor™ Multi-Drug Screen Test Kit uses immuno-chromatographic assay for the qualitative determination of the presence of drugs listed in the table below in human urine.

Drug (Identifier)	Calibrator	Cut-off level
Amphetamine (AMP)	d-Amphetamine	1000 ng/mL
		500 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
		150 ng/mL
Buprenorphine (BUP)	Buprenorphine	10 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
		150 ng/mL
Marijuana (THC)	11-nor-Δ9-THC-9-COOH	50 ng/mL
Methamphetamine (MET)	d-Methamphetamine	1000 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Methylenedioxymethamphetamine-ecstasy (MDMA)	3,4-Methylenedioxymethamp hetamine HCl (MDMA)	500 ng/mL
Morphine (MOP)	Morphine	300 ng/mL
		150 ng/mL
Oxycodone (OXY)	Oxycodone	100 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Propoxyphene (PPX)	Propoxyphene	300 ng/mL
Tri-cyclic Antidepressants (TCA)	Nortriptyline	1000 ng/mL
Synthetic Cannabis (K2)	JWH-018	50 ng/mL
	JWH-073	25 ng/mL
Opiate (OPI2000)	Morphine	2000ng/mL
Tramadol (TRA)	Cis-Tramadol HCl	100 ng/mL
Methadone Metabolite (EDDP)	2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine(EDDP)	100 ng/mL
		300 ng/mL
Fentanyl (FTY)	Norfentany	20 ng/mL
Cotinine (COT)	Cotinine	200 ng/mL
Ethyl Glucuronide (ETG)	Ethyl Glucuronide	500 ng/mL
		300 ng/mL
Ketamine (KET)	Ketamine HCl	1000 ng/mL
Methaqualone (MQL)	Methaqualone	300 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.

Benzodiazepines (BZO)
Benzodiazepines are a class of drugs that are often therapeutically used as anxiolytics, anti-convulsant 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.

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 the 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 drug are available. The drug has been diverted from legitimate channels through theft, doctor shopping, and fraudulent prescriptions, and been abused via intravenous, sublingual, intranasal and inhalation routes.

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

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-Δ9-tetrahydro cannabinol-9-carboxylic acid with a half-life of 24 hours. It can be detected for 1 to 5 days after use. Smoking is the primary method of use of 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.

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.

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-diphenylprryolidine), and EMDP (2-ethyl-5-methy-3, 3-diphenylpyrrolidine).

Methylenedioxymethamphetamine - ecstasy (MDMA)
MDMA belongs to a family of man-made drugs. Its relatives include MDA (methylenedioxyamphetamine), and MDEA (methylenedioxyethylamphet amine). 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 cartooning 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.

Morphine (MOP)
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. Multi-Drug Screen Test Kit yields a positive result when the concentration of Opiates in urine exceeds 300ng/mL.

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 heat rate, and decreased sense of pain and touch, and an overall feeling of wellbeing. 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%).

Propoxyphene (PPX)
Propoxyphene is a narcotic pain reliever and cough suppressant but is weaker than morphine, codeine, and hydrocodone. The precise mechanism of action is not known but may involve stimulation of opioid (narcotic) receptors in the brain. The recommended adult dose is 1 capsule (65 mg) or 1 tablet (100 mg) every 4 hours as needed for relief of pain. The common side effects for Propoxyphene use are shallow breathing, slow heartbeat, feeling light-headed, fainting, confusion, hallucinations, unusual thoughts or behavior, seizure(convulsions) and jaundice (yellowing of the skin or eyes). The shelf life of Propoxyphene is ranged from 6 to 12 hours; however the shelf life of its derivatives can last up for 36 hours.

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 intramuscular 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.

Synthetic Cannabis (K2): Synthetic cannabis is a psychoactive designer drug derived of natural herbs sprayed with synthetic chemicals that, when consumed, allegedly mimic the effects of cannabis, It is best known by the brand names K2 and Spice. Synthetic cannabis act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. A large and complex variety of synthetic cannabis most often cannabicyclohexanol, JWH-018, JWH-073, or HU-210, are used in an attempt to avoid the laws that make cannabis illegal, making synthetic cannabis a designer drug Although synthetic cannabis does not produce positive results in drug tests for cannabis, it is possible to detect its metabolites in human urine. The synthetic cannabinoids contained in synthetic cannabis products have been made illegal in many European countries. On November 24, 2010, the U.S. Drug Enforcement Administration announced it would use emergency powers to ban many synthetic cannabinoids within a month. As of March 1, 2011, five cannabinoids, JWH-018, JWH-073, CP-47,497, JWH-200, and cannabicyclohexanol are now illegal in the US.

Opiate (OPI2000)
Multi-Drug Screen Test Kit yields a positive result when the concentration of Opiates in urine exceeds 2000ng/mL.

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. 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 an unchanged drug, whereas 60% is excreted as metabolites. The major pathways appear to be N- and O-demethylation, glucuronidation or sulfation in the liver.

Methadone Metabolite (EDDP)
The EDDP is the metabolite of Methadone (substitution treatment against heroin addictions), so EDDP is the molecule obtained after the human body has modified the basic molecule of Methadone in order to eliminate it.

Fentanyl (FTY)
Fentanyl is a potent synthetic opioid drug approved by the Food and Drug Administration for use as an analgesic (pain relief) and anesthetic. It is approximately 100 times more potent than morphine and 50 times more potent than heroin as an analgesic.

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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 an 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 cutoff level of 200 ng/mL is expected to be up to 2-3 days after nicotine use.

Ethyl glucuronide (ETG)
Ethyl glucuronide (ETG) is a metabolite of ethanol that is formed in the body through glucuronidation due to ethanol produced after drinking alcoholic beverages. It is used as a biomarker to test ethanol use and monitor alcohol withdrawal in situations where alcohol use is prohibited, such as the military, alcohol treatment programs, professional monitoring programs (healthcare professionals, lawyers, airline pilots recovering from addiction), schools, liver transplant clinics or recovering alcoholic patients.

Ketamine (KET)
Ketamine was developed in the 1960s to replace phencyclidine (PCP) as an anesthetic agent and is most used in veterinary medicine today. In addition to rohypnol (add hyperlink to page) and GHB, it is also considered a club drug, and may be used in drug-facilitated sexual assault situations. It is odorless, tasteless and usually swallowed in powder form or injected. Once taken, it is very short-acting and shows effects within minutes. Under federal law, ketamine is classified as a Schedule III drug, meaning it has approved medical use, but still possesses a high potential for abuse.

Methaqualone (MQL)
Metaqualone is a sedative-hypnotic drug with similar action to barbiturates, a general central nervous system depressant. Sedative-hypnotic activity was first recorded by Indian researchers in the 1950s, and in 1962 metaqualone itself was patented in the US by Wallace and Tiernan. It was popularized in the early 1970s as a hypnotic, sedative and muscle relaxant used for insomnia. It was also used illegally as a recreational drug, commonly known as Quaaludes, Sopors, Ludes or Mandrax (especially in North America in the 1970s), depending on the manufacturer. Since 2001, it has been widely used in South Africa, where it is commonly referred to as "smarties" or "geluk-tablette" (meaning happy tablets). Clandestinely produced methaqualone is still seized by government agencies and police forces around the world.

PRINCIPLE OF THE PROCEDURE
Multi-Drug Screen Test Kit 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.

REAGENTS AND MATERIALS SUPPLIED

Component	**25 Tests/box**
Test card	25 Test card
Package insert	1 instruction for use

Materials Required but Not Provided
- Timer or stopwatch
- Urine cup

STORAGE AND STABILITY
The kit has a 24-month shelf life from the date of manufacture. Store the unused kits at 4°C~30°C. If stored refrigerated, ensure that the sealed pouch is brought to room temperature (2°C~30°C) before opening for testing.

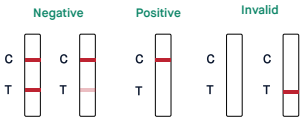
WARNINGS AND PRECAUTIONS
1.For in vitro diagnostic use only. Do not reuse the test device.
2.The instructions must be followed exactly to achieve accurate results. Any individual performing an assay with this product must be trained in its use and must be experienced in laboratory procedures.
3.All positive results must be confirmed by an alternate method.
4.Devices used for testing should be autoclaved before disposal.
5.Do not use kit materials beyond their expiration dates.
6.Do not eat or smoke while handling specimens.

SAMPLE COLLECTION AND STORAGE
Collect urine sample with a clean, dry container. Urine collected at any time of the day may be used.
DO NOT REFREEZE.
For best results, test specimens immediately following collection.
Urine specimens may be refrigerated (2°C~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.

TEST PROCEDURE
Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 15 minutes.
1.Allow all kit components and specimens to reach room temperature between 2°C~30°C prior to testing.
2.Remove the test card from the foil pouch and place on a clean dry surface.
3.Identify the test card for each specimen.
4.Test operation:
Collect the urine and bring out the test card.
With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds.
Place the test on a non-absorbent flat surface.
5.Interpret test results within **5 minutes**. Do not interpret the result after 10 minutes.

Caution: Use a clean urine cup for every sample to avoid cross-contamination.

INTERPRETATION OF TEST RESULTS



Negative (-)
If a color 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.

Positive (+)
A color band is visible in each control region. If no color band appears in the appropriate test "T" region, a positive result is indicated for the corresponding drug of that specific test zone.

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 open and run to re-evaluate the specimen.

QUALITY CONTROL
Though there is an internal procedural control line in the test device of Control Region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay

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 analyze. If a sample is suspected of being adulterated, obtain a new sample in a different, unused, device.
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.
7.Although the test is very accurate, a low incidence of false results may occur, so all positive results must be confirmed by an alternative method.

SYMBOLS USED

COMPONENT	Material Included	TUBE	Tube
TEST CARD	Test Card	IFU	Instruction for Use
	Consult Instruction for Use		Expiration Date
2°C 30°C	Store at 2℃ ~ 30℃		Manufacturer
	Keep Dry		Date of Manufacture
LOT	Lot Number		Do Not Reuse
DILUENT	Sample Buffer	REF	Reference Number
	Keep Away from Sunlight	Σ	Tests per Kit
IVD	In Vitro Diagnostic Medical Device		Do not use it if the package is damaged
%40 %60	Store between 40%-60% humidity		
CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device		

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