

Drug Abuse Rapid Test Kit

Instruction for use

(AMP, BAR, BZO, BUP, COC, COD, COT, EDDP, ETG, FYL, K2, KET, MET, MOP, MDMA, MTD, OPI, OXY, PCP, PPX, PQ, TCA, THC, TRA,6-MAM)

【Product Name】 Drug Abuse Rapid Test Kit

【REF】 A10036001B, A10036001C, A10036001D, A10036001E

【Specification】 1 test/kit, 5 tests/kit, 10 tests/kit, 25 tests/kit

【Intended Use】

The Drug Abuse Rapid Test Kit is a rapid, qualitative, competitive immunoassay for the determination of Drug-of-Abuse (DOA) and/or their metabolites in human urine. The strip allows the detection of multiple drugs in one simple step. The Drug Abuse Rapid Test Kit is intended to be used in Professional Medical & Forensic laboratories.

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

【Summary】

Amphetamine(AMP) is central nervous system stimulants that produce alertness, wakefulness, increased energy, reduced hunger, and an overall feeling of well being. Large doses of Amphetamine could cause the development of tolerances and physiological dependency and lead to its abuse.

Barbiturates(BAR) are a group of prescription drugs that are frequently abused. An acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives, and glucuronide conjugates. The presence of Barbiturates in the urine indicates Barbiturates use in the past 24 to 48 hours. Urinary concentrations are dependent on the time of sample collection and frequency of drug use.

Oxazepam (BZO) is a medication classified as a benzodiazepine. It is primarily used to treat anxiety disorders, insomnia, and withdrawal symptoms from alcohol and other substances. Oxazepam works by enhancing the effects of a neurotransmitter called gamma-aminobutyric acid (GABA) in the brain, which helps to reduce anxiety and promote relaxation. Oxazepam may cause drowsiness, dizziness, and impaired coordination. This medication can also interact with alcohol and other central nervous system depressants, leading to increased sedation and potential health risks. In summary, oxazepam (BZO) is a benzodiazepine medication commonly used to treat anxiety disorders, insomnia, and withdrawal symptoms. It should be used according to the prescribed dosage and under medical supervision due to the potential for dependence and side effects.

Buprenorphine(BUP) 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 detection window for the parent drug in urine is thought to be approximately 3 days. The BUP Rapid Test Kit is a rapid urine screening test that can be performed without the use of an instrument.

Cocaine(COC) is derived from the leaves of the cocoa plant and is a potent central nervous system stimulant as well as a local anesthetic. Some of the psychological effects induced by Cocaine are: euphoria, confidence and sense of increased energy, accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating. Continued ingestion of Cocaine could induce tolerances and physiological dependency which lead to its abuse. Cocaine is rapidly absorbed, almost completely metabolized by the liver and excreted in the urine as Benzoylcegonine. Benzoylcegonine has a biological half-life of 5 to 8 hours, which is much longer than that of Cocaine (0.5 to 1.5 hours), and can be generally detected 12-72 hours after cocaine use or exposure.

Codeine(COD) is an opioid medication used to treat mild to moderate pain and to relieve cough. It works by acting on the central nervous system to alter the perception of pain and reduce the urge to cough. Codeine is metabolized in the liver, where a portion is converted to morphine, providing pain relief through its effect on opioid receptors. Common side effects include drowsiness, constipation, nausea, vomiting, and dizziness. Serious side effects may include respiratory depression, addiction, and overdose. As an opioid, codeine carries

a risk of dependence, abuse, and withdrawal symptoms. It is classified as a controlled substance in many countries.

Cotinine(COT) is a metabolite of nicotine that can be detected in the body through various tests, such as urine, blood, or saliva. It is used as a biomarker to determine tobacco or nicotine exposure. Cotinine has a longer half-life than nicotine, making it a more reliable indicator of smoking habits. Levels of cotinine can also be influenced by factors like secondhand smoke exposure or the use of nicotine replacement therapies. Overall, a cotinine test can provide valuable information about an individual's tobacco or nicotine use, which is important for assessing health risks and monitoring smoking cessation efforts.

EDDP (2-ethylidene-1, 5-dimethyl-3, 3-diphenylpyrrolidine) is the metabolite of methadone, and testing for EDDP is used to determine the effective intake of Methadone when it is used as patient substitution treatment during use cessation. Methadone metabolizes in the liver into EDDP and EMDP. However, the rates of metabolism vary between individuals. The detection of EDDP in place of Methadone avoids the problems related to the metabolic differences of each person.

Ethyl Glucuronide(EtG) is a direct metabolite of alcohol. Presence in urine may be used to detect recent alcohol intake, even after alcohol is no longer measurable. Traditional laboratory methods detect the actual alcohol in the body, which reflects current intake within the past few hours (depending on how much was consumed). The presence of EtG in urine is a definitive indicator that it can be detected in the urine for 3 to 4 days after drinking alcohol, even alcohol is eliminated from the body. Therefore, EtG is a more accurate indicator of the recent intake of alcohol than measuring for the presence of alcohol itself. The EtG test can aid in the diagnosis of drunk driving and alcoholism, which has important significance in the forensic identification and medical examination.

Fentanyl(FYL) is a potent, synthetic narcotic analgesic with a rapid onset and short duration of action. It was first synthesized by Janssen Pharmaceutica (Belgium) in the late 1950s, and it is approximately 100 times more potent than morphine. Fentanyl is a strong agonist at the μ -opioid receptors. Historically it has been used to treat breakthrough pain and is commonly used in pre-procedures as a pain reliever as well as an anesthetic in combination with a benzodiazepine. Fentanyl is frequently given intrathecally as part of spinal anesthesia or epidurally for epidural anesthesia and analgesia.

Synthetic cannabinoids(K2) are psychoactive designer drugs 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 cannabinoids act on the body in a similar way to cannabinoids naturally found in cannabis, such as THC. Although synthetic cannabinoids do not produce positive results in drug tests for cannabis, it is possible to detect its metabolites in human urine.

Ketamine(KET) hydrochloride ("Special K" or "K") was originally created for use as a human anaesthetic, and is still used as a general anaesthetic for children, persons of poor health, and in veterinary medicine. Ketamine belongs to a class of drugs called "dissociative anaesthetics," which separate perception from sensation. Other drugs in this category include PCP, DXM and nitrous oxide (laughing gas). Ketamine usually comes as a liquid in small pharmaceutical bottles, and is most often cooked into a white powder for snorting. At lower doses it has a mild, dreamy feeling similar to nitrous oxide. Users report feeling floaty and slightly outside their bodies. Numbness in the extremities is also common. Higher doses produce a hallucinogenic (trippy) effect, and may cause the user to feel very far away from their bodies.

Methamphetamine(MET) 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. Large doses of methamphetamine could cause the development of tolerances and physiological dependency and lead to its abuse.

Morphine(MOP) have been a preferred drug for the management of pain in advanced cancer. Large doses of Morphine could cause the development of tolerances and physiological dependency and lead to its abuse. Morphine and its metabolites detected in urine may be present as a result of Heroin, Morphine, Codeine, or poppy seed intake.

Methylenedioxymethamphetamine(MDMA) has many street names including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. It is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartoning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heartstroke. **Methadone(MTD)** is excreted in the urine in unchanged forms, diphenylpyrrolidine derivatives, methadol, normethadol and conjugates. The MTD Rapid Test Kit is based on the principle of the highly specific immunochemical reactions of antigens and antibodies which are used for the analysis of specific compounds in biological fluids.

Opiates(OPI) have been a preferred drug for the management of pain in advanced cancer. Large doses of Morphine could cause the development of tolerances and physiological dependency and lead to its abuse. Morphine and its metabolites detected in urine may be present as a result of Heroin, Morphine, Codeine, or

poppy seed intake.

Oxycodone(OXY) is known as Oxycontin and Roxicodone. It is an ingredient of Percodan, Percocet, Roxicet and Tylox. Oxycodone is a semi-synthetic opiates derived from opium. Like other opiates, Oxycodone is characterized by its analgesic properties, and the tendency for users to form a physical dependency and develop tolerance with extended use. Oxycodone is usually administered in combination with non-opiate analgesics such as acetaminophen and salicylates for the relief of moderate to severe pain. Oxycodone is a central nervous system depressant that may cause drowsiness, dizziness, lethargy, weakness and confusion. Toxicity in an overdose of Oxycodone can lead to stupor, coma, muscle flaccidity, severe respiratory depression, hypotension, and cardiac arrest. Oxycodone is metabolized by N- and O-demethylation. One of the metabolites, oxymorphone, is a potent narcotic analgesic, while the other, noroxycodone, is relatively inactive. Between 33 to 61% of a single dose of Oxycodone is excreted in a 24-hour urine collection and consists of 13-19% free Oxycodone, 7-29% glucuronide conjugated Oxycodone, 13-14% glucuronide conjugated oxymorphone and an unknown amount of noroxycodone. The detection time window of Oxycodone is 1-3 days following use.

Phencyclidine(PCP) is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as "angel dust" and "crystal cyclone," etc. phencyclidine can be administered orally, by nasal ingestion, smoking, or by intravenous injection. It is metabolized in the liver and excreted through the kidneys in urine in unchanged form and oxidized metabolites with a half-life of about 12 hours. Suction and urinary acidification in the treatment of overdose typically reduces its half-life from three days to one day.

Propoxyphene(PPX) a synthetic opiate agonist, is structurally similar to methadone. Propoxyphene is a narcotic analgesic used to relieve mild to moderate pain. The principal metabolites are norextropropoxyphene. The combination usage of propoxyphene, aspirin, acetaminophen or other sedatives can lead cooperative interaction. Abuse of propoxyphene can lead nausea, vomit, striction, illusion, hallucination, heart poisoning, lung dropsy and even death. Propoxyphene is metabolized in the liver and excreted in urine as norextropropoxyphene. Thus the presence of the propoxyphene or its metabolites in the urine indicates propoxyphene use.

Paraquat non-selective, contact herbicide (bipyridylum compound), widely used for weed control in agriculture. Extremely toxic when ingested (median lethal dose, LD50: 3-5 g for humans); survival is rare with doses exceeding 20 mg/kg body weight. Critical for emergency departments to rapidly confirm paraquat exposure, enabling timely treatment. Paraquat detection via colloidal gold test strips offers a rapid, accessible solution for poisoning screening and residue monitoring, Negative results do not rule out poisoning (especially low-dose or early-stage cases).

Nortriptyline(TCA) is a tricyclic antidepressant medication used to treat depression and certain types of neuropathic pain. It works by increasing the levels of certain neurotransmitters in the brain, which can help improve mood and reduce pain. Nortriptyline is typically taken in tablet form and is generally well-tolerated, but it can have potential side effects such as dry mouth, constipation, dizziness, and drowsiness. It may also interact with other medications, so it's important to consult with a doctor before taking nortriptyline. Overall, nortriptyline is an effective treatment option for depression and neuropathic pain when used under medical supervision.

Cannabinoids(THC) are a group of chemical compounds found in the cannabis plant, with delta-9-tetrahydrocannabinol (THC) being the most well-known and psychoactive compound. THC is responsible for the "high" sensation associated with marijuana use. THC interacts with cannabinoid receptors in the brain and other parts of the body, leading to various effects. It can cause relaxation, euphoria, altered perception of time and space, increased appetite, and distorted sensory experiences. It may also have therapeutic properties, such as pain relief and anti-inflammatory effects. Overall, THC and cannabinoids have complex effects on the body and mind, and their use should be approached with caution, especially in individuals with a history of mental health issues or substance abuse. It is important to consult with a healthcare professional for personalized guidance and advice.

Tramadol(TRA) is a synthetic codeine analogue with weak affinity for opioid receptors. By inhibiting the reuptake of norepinephrine by neuronal synapses and increasing the concentration of serotonin outside neurons, pain transmission is affected, resulting in analgesic effects. The intensity of its action is 1/10-1/8 of morphine. No respiratory inhibition, low dependence, and significant analgesic effect. It has a cough relieving effect, with an intensity of 50% that of codeine. It does not affect histamine release and has no effect on causing smooth muscle spasms. Both oral and injection absorption are good, and the analgesic effect is the same. After oral administration, it takes 10-20 minutes to take effect and lasts for 4-8 hours. Metabolized in the liver, 80% is excreted from the urine in its original form and metabolites within 24 hours.

6-Monoacetylmorphine (6-MAM) is a metabolite of heroin (diacetylmorphine) and is an intermediate substance that occurs during the metabolic breakdown of heroin in the body. It is primarily noted for its role in opioid pharmacology and its presence in forensic toxicology. As an opioid, it binds to and activates the mu-opioid receptors in the brain, leading to effects such as analgesia, euphoria, and sedation. Because it is a metabolite of heroin, its presence indicates heroin use, which is associated with high abuse potential and addiction risk.

6-MAM is often tested for in drug screening and forensic investigations, particularly in cases involving heroin use, since it can indicate recent heroin consumption. 6-MAM is generally classified under controlled substances regulations due to its relation to heroin and its potential for abuse.

【Test Principle】

The Drug Abuse Rapid Test Kit is a strip composed of multiple chromatographic strips designed to detect various (as per the format) individual drugs of abuse. Each strip consists of a sample pad treated with antibody colloidal gold conjugate and membrane treated with drug conjugate and control reagent. Urine sample initially reacts with the antibody gold conjugate, and then migrates up the strip, by capillary action, to the test area. If sufficient drug is present in the urine, it binds with the conjugate, preventing it from binding to the drug conjugate immobilized on the membrane in the test region. Any unbound conjugate continues to migrate up the strip to the control region where it binds to the control reagent producing a pink/purple band. The control band indicates that the result is valid.

【Main Components】

Materials Provided:

Specification Material	1 test/kit	5 tests/kit	10 tests/kit	25 tests/kit
Test Cassette	1	5	10	25
Instruction for Use	1	1	1	1

Materials Required but Not Provided:

- 1.Timer
- 2.Urine cups

【Storage Conditions and Validity】

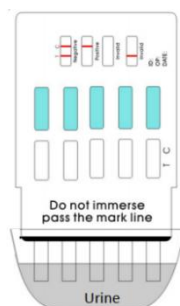
- 1.This product should be stored in a dark and dry place at 2~30°C. The validity period of the kit is 24 months.
- 2.After unpacking the aluminum foil bag of the test cassette, It should be used in the specified environment (Temperature 2-35°C, Humidity 40%-90%) within 1 hour.
- 3.Please see label for the information about the date of manufacture and shelf life.

【Samples Collection Handing】

1. Urine specimens should be collected in a clean, dry container. Randomly collected specimens can be used. If not tested immediately, Specimens may be refrigerated (2°C - 8°C) and stored up to 72 hours prior to testing. If specimens are refrigerated, they must be brought to room temperature before testing.
2. Urine samples exhibiting visible precipitates or turbidity should be centrifuged or allowed to settle so a clear aliquot may be sampled for this assay.
3. Collection of samples may require mandatory procedures and custody and control records. Poppy seed ingestion has been associated with positive test results in some samples.

【Test Method】

1. Bring all materials and specimens to room temperature.
2. Remove test cassette from the sealed foil pouch.
3. Immerse the bottom end of the test strips (the sample pads), keep the level of urine sample below the bottom of plastic strip.
4. Hold the strips in the urine until the red liquid moves in the result display area, wait for 10-15 seconds and then remove the test strip and place it on a flat surface of clean non-adsorbent material.
5. The result(s) should be read at 5 minutes. However, negative results may be read and reported as early as 3 minutes but positive results must be reported at 5 minutes only. Do not interpret the result(s) after 8 minutes after the addition of sample.

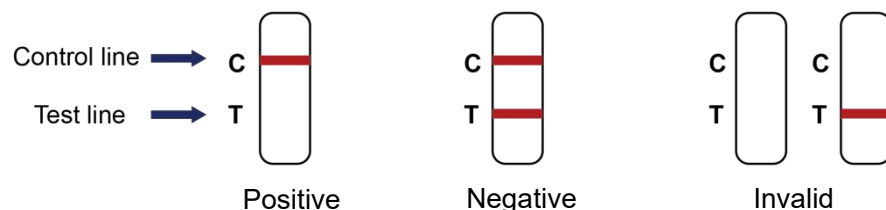


【Interpretation of Test Results】

Positive test: One (1) pink/purple band appears in the control region. No band is found in the test region. This is an indication that the drug level is above the detection sensitivity level.

Negative test: Two (2) pink/purple bands form. In addition to the control band, a pink/purple band also appears in the test region.

Invalid: If there is no pink/purple band in the control area of the strip, the test result is invalid. Retest the sample using a new device.



【Limitation of The Test】

1. This product is designed to be used for the detection of DOA and/or their metabolites in human urine only.
2. Although the Drug Abuse Rapid Test Kit is very accurate in detecting the urine drug levels, there is a possibility of false results due to the presence of interfering substances in the urine.
3. The test is a qualitative screening assay and is not suggested for determining the quantitative level of DOA in urine.
4. Adulterants, such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen.

【Performance Characteristics】

1. Sensitivity

Drug	Calibrator	Cut-off Level
Amphetamine(AMP)	d-Amphetamine	500ng/mL
Secobarbital(BAR)	Secobarbital	300ng/mL
Oxazepam(BZO)	Oxazepam	300ng/mL
Buprenorphine(BUP)	Buprenorphine	10ng/mL
Cocaine(COC)	Cocaine	150ng/mL
Codeine(COD)	Codeine	300ng/mL
Cotinine(COT)	Cotinine	200ng/mL
EDDP	2-ethylidene-1,5-dimethyl-3, 3-diphenyl-pyrrolidine	100ng/mL
Ethyl Glucuronide(EtG)	Ethyl Glucuronide	500ng/mL
Fentanyl(FYL)	Fentanyl	20ng/mL
Synthetic cannabinoids(K2)	JWH-018 Pentanoic Acid JWH-073 Butanoic Acid	50ng/mL

Ketamine(KET)	Ketamine	1000ng/mL
Methamphetamine(MET)	D(+)-Methamphetamine	1000ng/mL
Morphine(MOP)	Morphine	300ng/mL
Methylenedioxymethamphetamine(MDMA)	3,4-Methylenedioxymethamphetamine	500ng/mL
Methadone(MTD)	Methadone	300ng/mL
Opiates(OPI)	Morphine	2000ng/mL
Oxycodone(OXY)	Oxycodone	100ng/mL
Phencyclidine(PCP)	Phencyclidine	25ng/mL
Propoxyphene(PPX)	Propoxyphene	300ng/mL
Paraquat(PQ)	Paraquat	100ng/mL
Nortriptyline (TCA)	Tricyclic Antidepressants	1000ng/mL
Cannabinoids (THC)	11-nor- Δ -9-THC-9-COOH	50ng/mL
Tramadol(TRA)	Tramadol	100ng/mL
6-Monoacetylmorphine (6-MAM)	6-Monoacetylmorphine (6-MAM)	10ng/mL

2. The clinical performance of Drug Abuse Rapid Test Kit was evaluated in comparison to a commercial DOA test using clinical specimens. The results are shown in the following tables.

(1) AMP

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	83(a)	1(b)	84(a+b)
Negative	1(c)	93(d)	94(c+d)
Total	84(a+c)	94(b+d)	178(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.81%	93.54%~99.97%	
Clinical specificity	98.94%	94.22%~99.97%	
Total coincidence rate	98.88%	96.00%~99.86%	

(2) BAR

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	80(a)	1(b)	81(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	81(a+c)	96(b+d)	177(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.77%	93.31%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.87%	95.98%~99.86%	

(3) BZO

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	77(a)	1(b)	78(a+b)
Negative	1(c)	105(d)	106(c+d)
Total	78(a+c)	106(b+d)	184(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.72%	93.06%~99.97%	
Clinical specificity	99.06%	94.86%~99.98%	
Total coincidence rate	98.91%	96.13%~99.87%	

(4) BUP

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	81(a)	1(b)	82(a+b)
Negative	1(c)	89(d)	90(c+d)
Total	82(a+c)	90(b+d)	172(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.78%	93.39%~99.97%	
Clinical specificity	98.89%	93.96%~99.97%	
Total coincidence rate	98.84%	95.86%~99.86%	

(5) COC

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	69(a)	2(b)	81(a+b)
Negative	1(c)	119(d)	120(c+d)
Total	80(a+c)	121(b+d)	201(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.75%	93.23%~99.97%	
Clinical specificity	98.35%	94.16%~99.80%	
Total coincidence rate	98.51%	95.70%~99.69%	

(6) COD

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	80(a)	1(b)	81(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	81(a+c)	96(b+d)	177(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.77%	93.31%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.87%	95.98%~99.86%	

(7) COT

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	82(a)	1(b)	83(a+b)
Negative	1(c)	93(d)	94(c+d)
Total	83(a+c)	94(b+d)	177(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.80%	93.47%~99.97%	
Clinical specificity	98.94%	94.22%~99.97%	
Total coincidence rate	98.87%	95.98%~99.86%	

(8) EDDP

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	80(a)	1(b)	81(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	81(a+c)	96(b+d)	177(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.77%	93.31%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.87%	95.98%~99.86%	

(9) ETG

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	77(a)	1(b)	78(a+b)
Negative	1(c)	97(d)	98(c+d)
Total	78(a+c)	98(b+d)	176(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.72%	93.06%~99.97%	
Clinical specificity	98.98%	94.45%~99.97%	
Total coincidence rate	98.86%	95.96%~99.86%	

(10) FYL

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	88(a)	1(b)	82(a+b)
Negative	1(c)	89(d)	90(c+d)
Total	89(a+c)	90(b+d)	172(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.88%	93.90%~99.97%	
Clinical specificity	98.89%	93.96%~99.97%	
Total coincidence rate	98.88%	96.02%~99.86%	

(11) K2

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	73(a)	2(b)	75(a+b)
Negative	1(c)	124(d)	125(c+d)
Total	74(a+c)	126(b+d)	200(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.65%	92.70%~99.97%	
Clinical specificity	98.41%	94.38%~99.81%	
Total coincidence rate	98.50%	95.68%~99.69%	

(12) KET

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	73(a)	2(b)	75(a+b)
Negative	1(c)	113(d)	114(c+d)
Total	74(a+c)	115(b+d)	189(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.65%	92.70%~99.97%	
Clinical specificity	98.26%	93.86%~99.79%	
Total coincidence rate	98.41%	95.43%~99.67%	

(13) MET

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	83(a)	1(b)	84(a+b)
Negative	1(c)	99(d)	100(c+d)
Total	84(a+c)	100(b+d)	184(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.81%	93.54%~99.97%	
Clinical specificity	99.00%	94.55%~99.98%	
Total coincidence rate	98.91%	96.13%~99.87%	

(14) MOP

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	79(a)	1(b)	80(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	80(a+c)	96(b+d)	176(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.75%	93.23%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.86%	95.96%~99.86%	

(15) MDMA

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	97(a)	1(b)	98(a+b)
Negative	1(c)	99(d)	100(c+d)
Total	98(a+c)	100(b+d)	198(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.98%	94.45%~99.97%	
Clinical specificity	99.00%	94.55%~99.98%	
Total coincidence rate	98.99%	96.40%~99.88%	

(16) MTD

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	69(a)	1(b)	70(a+b)
Negative	1(c)	104(d)	105(c+d)
Total	70(a+c)	105(b+d)	175(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.57%	92.30%~99.96%	
Clinical specificity	99.05%	94.81%~99.98%	
Total coincidence rate	98.86%	95.93%~99.86%	

(17) OPI

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	75(a)	2(b)	77(a+b)
Negative	1(c)	133(d)	134(c+d)
Total	76(a+c)	135(b+d)	211(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.68%	92.89%~99.97%	
Clinical specificity	98.94%	94.75%~99.82%	
Total coincidence rate	98.58%	95.90%~99.71%	

(18) OXY

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	80(a)	1(b)	81(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	81(a+c)	96(b+d)	177(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.77%	93.31%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.87%	95.98%~99.86%	

(19) PCP

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	81(a)	1(b)	82(a+b)
Negative	1(c)	95(d)	96(c+d)
Total	82(a+c)	96(b+d)	178(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.78%	93.39%~99.97%	
Clinical specificity	98.96%	94.33%~99.97%	
Total coincidence rate	98.88%	96.00%~99.86%	

(20) PPX

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	81(a)	1(b)	82(a+b)
Negative	1(c)	89(d)	90(c+d)
Total	82(a+c)	90(b+d)	172(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.78%	93.39%~99.97%	
Clinical specificity	98.89%	93.96%~99.97%	
Total coincidence rate	98.84%	95.86%~99.86%	

(21) PQ

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	88(a)	1(b)	89(a+b)
Negative	2(c)	70(d)	72(c+d)
Total	90(a+c)	71(b+d)	161(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	97.78%	92.20%~99.73%	
Clinical specificity	98.59%	92.40%~99.96%	
Total coincidence rate	98.14%	94.65%~99.61%	

(22) TCA

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	81(a)	1(b)	82(a+b)
Negative	1(c)	88(d)	89(c+d)
Total	82(a+c)	89(b+d)	171(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.78%	93.39%~99.97%	
Clinical specificity	98.88%	93.90%~99.97%	
Total coincidence rate	98.83%	95.84%~99.86%	

(23) THC

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	88(a)	1(b)	82(a+b)
Negative	1(c)	89(d)	90(c+d)
Total	89(a+c)	90(b+d)	172(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.88%	93.90%~99.97%	
Clinical specificity	98.89%	93.96%~99.97%	
Total coincidence rate	98.88%	96.02%~99.86%	

(24) TRA

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	77(a)	1(b)	78(a+b)
Negative	1(c)	97(d)	98(c+d)
Total	78(a+c)	98(b+d)	176(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.72%	93.06%~99.97%	
Clinical specificity	98.98%	94.45%~99.97%	
Total coincidence rate	98.86%	95.96%~99.86%	

(25) 6-MAM

Drug Abuse Rapid Test Kit	GC/MS		
	Positive	Negative	Total
Positive	83(a)	1(b)	84(a+b)
Negative	1(c)	99(d)	100(c+d)
Total	84(a+c)	100(b+d)	184(a+b+c+d)
Coincidence rate and 95% confidence interval			
	Coincidence	95% Confidence Interval	
Clinical sensitivity	98.81%	93.54%~99.97%	
Clinical specificity	99.00%	94.55%~99.98%	
Total coincidence rate	98.91%	96.13%~99.87%	

3. The following compounds did not interfere with the Drug Abuse Test.

Glucose	2000mg/dl	Uric Acid	10 mg/dl
Human Albumin	2000mg/dl	Urea	4000mg/dl
Hemoglobin	10mg/dl	Bilirubin	2 mg/dl

【Precautions】

1. Keep away from children and prolonged exposure to extreme storage conditions.
2. This test is designed for single in vitro diagnostic use only.
3. Do not use test kit beyond expiry date printed on package.
4. Tests results may vary for different individuals.
5. Confirm all test results with a qualified specialist

【Bibliography】

1. Ambre, J.J., Anal. Toxicol., 9:241-5, (1985).
2. Baselt, R.C., Disposition of Toxic Drugs and Chemicals in Man, 2nd Ed., Biomedical Publ., Davis, CA, p. 488, 1982.
3. Huang, W., Andollo, W., and Hearn W.L., J. Anal. Toxicol., 16: 307-310 (1992).
4. Cone, E.J., Dickerson, S., Paul, B.D., and Mitchell, J.M., J. Anal. Toxicol., 17: 156-164 (1993).
5. Glare, P.A., Walsh, T.D., and Pippenger, C.E., Therapeutic Drug Monitoring, 13: 226-232 (1991).
6. Walsh, T. D., and Cheater, F.M., Pharmaceutical J.,10: 525527 (1983).
7. Mitchell, J.M., Paul, B.D., Welsh, P.,and Cone, E.J.,J. Anal. Toxicol., 15: 49-53 (1991).
8. Tietz, Norbert W.,Textbook of Chemistry, W.B. Saunders Company, 1986, p.1735.
9. Stewart, D.J.,Inoba T.,Ducassen, M.,and Kalow, W.,Clin. Pharmacol. Ther. 25:264 (1979).
10. Department of Health and Human Services, Fed. Regist., 53: (69): 11970-11989(1988).
11. Urine Testing for Drugs of Abuse, NIDA, Research Monograph 73, 1986
12. Glass, IB. The International Handbook of Addiction Behavior. Routledge Publishing, New York, NY. 1991, 216
13. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Davis, CA.,129, 2002.
14. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.

【Index of Symbols】

	In vitro diagnostic medical device		Do not re-use
	Authorized representative in the European Union		Consult instructions for use or consult electronic instructions for use
	Caution		Manufacturer
	Temperature limit		Batch code
	Use-by date		Keep dry
	Keep away from sunlight		Catalog number
	Date of manufacture		Contains sufficient for <n> tests
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Do not use if package is damaged and consult instructions for use

【Basic Information】

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Lotus NL B.V.
 Add:Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
 Email: info@lotusnl.com

Instructions For Use Version: Rev V3.1
Date issued: 2026.07.01

