

SCREEN

DROGA TEST

Screen Drug Test Surface/Solid

Amphetamine - Cocaine - Ketamine - Marijuana/THC - MDMA/Ecstasy -
Methamphetamine - Morfine
(Surface or Solid)
Package Insert

REF: 970791760

English

Instructions for the use of any test combination to test any combination of the following drugs of abuse: Acetaminophen, Barbiturates, Benzodiazepines, Buprenorphine, Cocaine, Marijuana/THC, Methadone, Methamphetamine, Amphetamine, Ketamine, MDMA/Ecstasy, Morphine, Methaqualone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, Tramadol, Oxycodone, Cotinine, EDDP, Fentanyl

PRECAUTIONS

- **Not for medical or diagnostic use.**
 - Do not use after expiration date.
 - Test device should remain sealed until ready for use.
 - All specimens must be considered potentially dangerous and, therefore, should be handled using precautions for potentially infective products.
 - Used testing materials should be discarded in accordance with local regulations.
- Keep the sealed pouch at a temperature between 2° and 30°C. The test is stable until expiration date printed on the pouch label. The test must be kept in the sealed pouch until use. Do not freeze. Do not use after the expiration date.

INTENDED USE AND SUMMARY

The Screen Drug Surface/Solid Test is a rapid immunochromatographic test for the qualitative detection of multiple drugs at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Acetaminophen (ACE)	Acetaminophen	5,000
Amphetamine (AMP)	d-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoyllecgonine	300
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50/10,000
Methadone (MTD)	Methadone	300
Methamphetamine (MET)	d-Methamphetamine	1,000
Methylenedioxyamphetamine(MDMA)	d,l- Methylenedioxyamphetamine	500
Morphine (MOP)	Morphine	300
Methaqualone(MQL)	Methaqualone	300
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TML)	Cis-Tramadol	100
Ketamine (KET)	Ketamine	1,000
Oxycodone (OXY)	Oxycodone	100
Cotinine(COT)	Cotinine	200
2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine	300
Fentanyl (FYL)	Fentanyl	200

With this surface test, you can test:

1. Minimal traces of drugs adhering to surfaces such as furniture, utilitarian objects etc. as residues.
 2. Solid substances such as tablets and powder.
 3. Urine samples, which can be used to detect drug use.
 4. Liquids from ampoules or other containers that may contain suspicious substances.
- Configurations of the Multi-Drug Surface Test Panel come with any combination of the above listed drug analytes. This assay 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 spectrometry (GC/MS) is the preferred confirmatory method.

SUMMARY

The Screen Drug Surface/Solid Test is a rapid test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs on surfaces and solids.

Acetaminophen (ACE)

Acetaminophen is one of the most commonly used drugs, yet it is also an important cause of serious liver injury. Acetaminophen is the generic name of a drug found in many common brand name over-the-counter (OTC) products, such as Tylenol, and Prescription (Rx) products, such as Vicodin and Percocet. Acetaminophen is an important drug, and its effectiveness in relieving pain and fever is widely known. Unlike other commonly used drugs to reduce pain and fever (e.g., non steroidal anti-inflammatory drugs (NSAIDs), such as aspirin, ibuprofen, and naproxen), at recommended doses acetaminophen does not cause adverse effects, such as stomach discomfort and bleeding, and acetaminophen is considered safe when used according to the directions on its OTC or Rx labeling. However, taking more than the recommended amount can cause liver damage, ranging from abnormalities in liver function blood tests, to acute liver failure, and even death. Many cases of overdose are caused by patients inadvertently taking more than the recommended dose (i.e., 4 grams a day) of a particular product, or by taking more than one product containing acetaminophen (e.g., an OTC product and an Rx drug containing acetaminophen).

Amphetamine (AMP)

Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine®) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system 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.

Barbiturates (BAR)

Barbiturates are CNS 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 can produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Benzodiazepines (BZO)

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, benzodiazepines have replaced 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.

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.

Cocaine (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, oversensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking.

Marijuana (THC)

THC (A9-tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette.

Methamphetamine (MET)

Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion.

Ecstasy (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.

Morphine (MOP)

Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the central nervous system. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin.

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 1956.¹⁰ 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.

Phencyclidine (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations.

PCP is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. PCP is most commonly administered by inhalation but can be used intravenously, intra-nasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of PCP.

Propoxyphene (PPX)

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Peak plasma concentrations of propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, propoxyphene blood concentrations can reach significantly higher levels.

In humans, propoxyphene is metabolized by N-demethylation to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

Tricyclic Antidepressants (TCA)

TCA (Tricyclic Antidepressants) are commonly used for the treatment of depressive disorders. TCA overdoses can result in profound CNS depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from prescription drugs. TCAs are taken orally or sometimes by injection. TCAs are metabolized in the liver.

Tramadol (TML)

Tramadol (TML) 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.

Ketamine (KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained.

Oxycodone (OXY)

Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form.

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.

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

Methadone is an unusual drug in that its primary urinary metabolites (EDDP and EMDP) are cyclic in structure, making them very difficult to detect using immunoassays targeted to the native compound.¹⁰ Exacerbating this problem, there is a subsection of the population classified as "extensive metabolizers" of methadone. In these individuals, a urine specimen may not contain enough parent methadone to yield a positive drug screen even if the individual is in compliance with their methadone maintenance. EDDP represents a better urine marker for methadone maintenance than unmetabolized methadone.

Fentanyl (FYL)

Fentanyl, belongs to powerful narcotics analgesics, and is a μ special opiates receptor stimulant. Fentanyl is one of the varieties that been listed in management of United Nations "Single Convention of narcotic drug in 1961". Among the opiates agents that under international control, fentanyl is one of the most commonly used to cure moderate to severe pain. After continuous injection of fentanyl, the sufferer will have the performance of protracted opioid abstinence syndrome, such as ataxia and irritability etc, which presents the addiction after taking fentanyl in a long time. Compared with drug addicts of amphetamine, drug addicts who take fentanyl mainly have got the possibility of higher infection rate of HIV, more dangerous injection behavior and more lifelong medication overdose.

PRINCIPLE

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

REAGENTS

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

PRECAUTIONS

- Single use.
- Do not touch the free edges of the strips to avoid contamination.
- Do not immerse the support beyond the maximum level indicated.
- Do not spill the samples on the reaction area.
- Samples can be potentially infectious and should be handled and discarded appropriately.
- Do not use Multi Drug test beyond expiration date.
- Do not use the test if the package is damaged.
- Use the test immediately after opening.
- Please take into account specificity and cross-reaction when evaluating the test.
- Store and transport the test always at 2-30°C.
- **Strong acid, alkali, oxidation and corrosion liquid is not suitable for this test, thick, oily liquid is not suitable for this test.**

STORAGE AND STABILITY

Store as packaged in the closed canister either at 2-30°C. Keep out of direct sunlight. The test is stable through the expiration date printed on the canister label. Test must remain in its sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

MATERIALS

Materials Provided

- Test device
- Package Insert

Materials Required But Not Provided

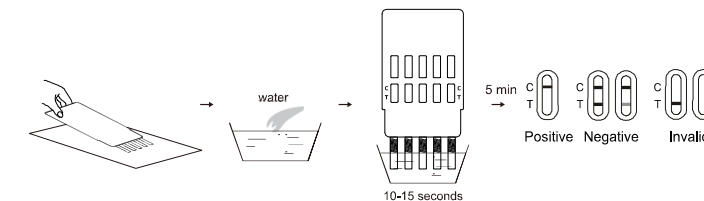
- Specimen collection container
- Timer

DIRECTION FOR USE

Test device (in its sealed pouch), samples and controls must be brought at room temperature (15-30°C) before testing. Do not open the package until ready to perform the test.

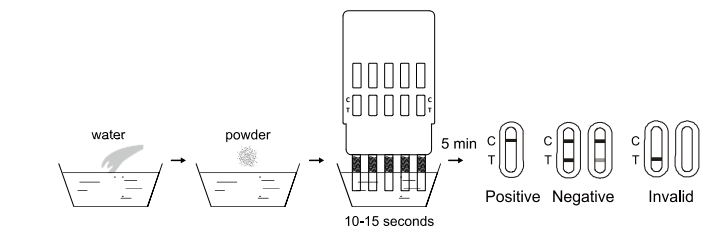
FOR SURFACES:

1. Remove the panel cap and wipe with the panel over the surface in which the drugs are suspected.
2. With the arrow pointing toward the water, **immerse the test panel vertically in the water for at least 10 to 15 seconds.** Immerse the strips to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored line(s) to appear. **The test result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



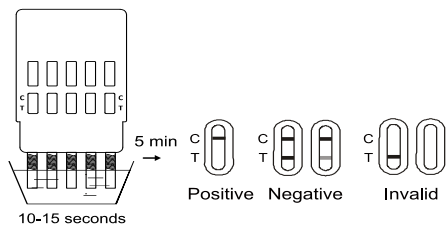
FOR SOLIDS:

1. Prepare specimen collection containers and solid sample
2. For solid sample into the specimen collection containers.
3. At least **1mg solid diluted with 5mL water** (1 mineral water bottle cap=5mL). Shake to mix well.
4. Remove the panel cap with the arrow pointing toward the water immerse the test panel vertically in the water specimen for at least 10 to 15 seconds. **Immerse the strips to at least the level of the wavy lines, but not above the arrow on the test Panel.**
5. Wait for the colored lines to appear, **read the results after 5 minutes** and do not interpret the result after 10 minutes.



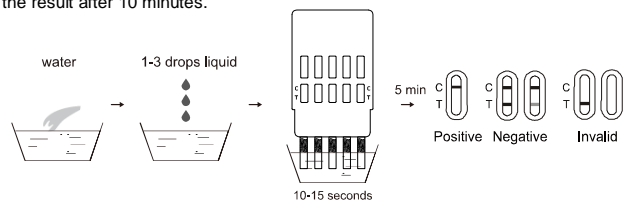
FOR URINE:

1. Collect urine in a clean and dry container.
2. Remove the panel cap, with the arrow pointing toward the specimen, **immerse the test panel vertically in the specimen for at least 10 to 15 seconds.** Immerse the strips to at least the level of the wavy lines, but not above the arrow on the test panel.
3. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



FOR LIQUIDS:

1. Prepare specimen collection containers and liquid sample.
2. Pour **one to three drops of suspicious liquid into 5mL water** (1 mineral water bottle cap=5mL). Shake to mix well.
3. Remove the panel cap, with the arrow pointing toward the specimen, **immerse the test panel vertically in the specimen for at least 10 to 15 seconds**. Immerse the strips to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Wait for the colored lines to appear, **read the results at 5 minutes** and do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

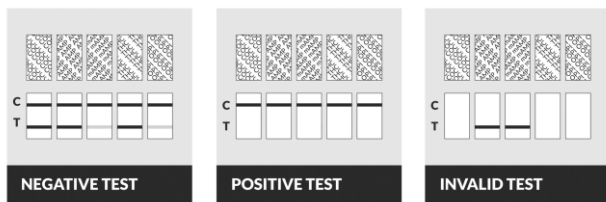
(Please refer to the illustration below)

NEGATIVE:* A colored line appears in the Control region (C) and colored lines appear in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cut-off levels for a particular drug tested.

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

POSITIVE: A colored line appears in the Control region (C) and NO line appears in the Test region (T). The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for a specific drug.

INVALID: No line appears in the Control region (C). Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for Control line failure. Read the directions again and repeat the test with a new test card. If the result is still invalid, contact your manufacturer.



NEGATIVE TEST
Absence of drugs on surfaces and dusts

POSITIVE TEST
Presence of Amphetamine on surfaces and dusts

INVALID 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.

LIMITATIONS

1. The Screen Drug Surface/Solid Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. A negative result may not necessarily indicate drug-free specimen. Negative results can be obtained when drug is present but below the cut off level of the test.
3. This test does not distinguish between drugs of abuse and certain medications.

Distributed by:

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