

DRUG ALERT Street Drugs Test

DRUG ALERT Cut-Off Levels meet Australian/New Zealand Standards:
AS/NZ 4308:2008

In home one step drug screen test panel.
Instruction leaflet for multi drug screen test panel
for any combination of the following drugs:

Marijuana THC
Cocaine COC
Opiates OPI (Opium & Heroin)
Amphetamines AMP (Speed)
Methamphetamine MET (Crystal)
Methylenedioxyamphetamine MDMA (Ecstasy)

A rapid, one step screening test
for simultaneous, qualitative detection of
multiple drugs and drug metabolites in human urine.
For in vitro diagnostic use only.

INTENDED USE

The Drug Alert test panel is a lateral flow chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off
Marijuana (THC)	11-nor- Δ^9 -THC-9 COOH	50 ng/mL
Cocaine (COC)	Benzoyllecgonine	300 ng/mL
Opiates (OPI)	Morphine	300 ng/mL
Amphetamine (AMP)	D-Amphetamine	300 ng/mL
Methamphetamine (mAMP/MET)	D-Methamphetamine	300 ng/mL
Methylenedioxyamphetamine (MDMA) Ecstasy	D,L Methylenedioxyamphetamine	500 ng/mL

Configurations of the test panel can consist of 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. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY

The Drug Alert test panel is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine.

MARIJUANA THC

THC (Δ^9 -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. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- Δ^9 -tetrahydrocannabinol-9-carboxylic acid (Δ^9 -THC-COOH). The test panel yields a positive result when the concentration of THC-COOH in urine exceeds 50 ng/mL. This is the suggested screening cut-off for positive specimens set by **Australian/New Zealand Standards: AS/NZ 4308:2008**

COCAINE COC

Cocaine is a potent central nervous system (CNS) stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as Benzoyllecgonine. Benzoyllecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure. The test panel yields a positive result when the cocaine metabolite in urine exceeds 300 ng/mL. This is the suggested screening cut-off for positive specimens set by **Australian/New Zealand Standards: AS/NZ 4308:2008**

OPIATES OPI (Opium & Heroin)

The test panel yields a positive result when the morphine in urine exceeds 2,000 ng/mL. This is the suggested screening cut-off for positive specimens set by **Australian/New Zealand Standards: AS/NZ 4308:2008**

AMPHETAMINE AMP (Speed)

Amphetamine is a Schedule II controlled substance available by prescription and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of Amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives. The test panel yields a positive result when Amphetamines in urine exceed 1,000 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

METHAMPHETAMINE MET (Crystal)

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

behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine as amphetamine and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level. The test panel yields a positive result when the Methamphetamine in urine exceeds 1,000 ng/mL.

METHYLENEDIOXYMETHAMPHETAMINE MDMA (ECSTASY)

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 Oberlender, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws. The Methylenedioxyamphetamine test panel yields a positive result when the Methylenedioxyamphetamine in urine exceeds 500 ng/mL.

PRINCIPLE

The Drug Alert test panel is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region of the specific drug strip. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains a membrane strip coated with drug-protein conjugates (purified bovine albumin) on the test line, a goat polyclonal antibody against gold-protein conjugate at the control line, and a dye pad which contains colloidal gold particles coated with mouse monoclonal antibody specific to Amphetamine, Cocaine, Methamphetamine, Methylenedioxyamphetamine, Marijuana or Opiates.

PRECAUTIONS

- For in vitro diagnostic use only. Do not use after the expiration date.
- The test panel should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in

the same manner as an infectious agent.

STORAGE and STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through to the expiration date printed on the sealed pouch. The test devices must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

SPECIMEN COLLECTION and PREPARATION

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

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

MATERIALS

Materials Provided

- Test panel

Materials Needed but not Provided

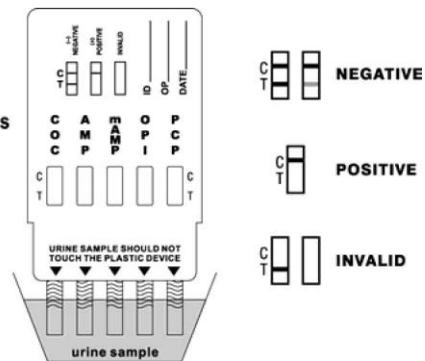
- Timer
- Specimen Collection Container

DIRECTIONS FOR USE

Allow the test panel and urine specimen to equilibrate to room temperature (15-30°C) prior to testing.

- 1 Bring the pouch to room temperature before opening it. Remove the test card from the sealed pouch and use it as soon as possible.
- 2 Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strips of the test card vertically in the urine specimen for at least 10-15 seconds. **Immerse the test card to at least the level of the wavy lines on the strips, but keep other part of the test panel away from the specimen. Refer to the illustration below.**
- 3 Place the test card on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The results should be read at 5 minutes. Results remain stable for up to four hours after test initiation.

Note: This illustration shows a 5-drug test card



INTERPRETATION of RESULTS

(Please refer to the illustration above)

NEGATIVE: * **Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line adjacent should be in the test region

(T). This negative result indicates that the drug concentration is below the detectable level. ***NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

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

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test panel. If the problem persists, discontinue using the lot immediately and contact your supplier.

QUALITY CONTROL

A procedural control is included in the test. A red 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 Drug Alert test panel 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. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A Positive result does not indicate level or intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

WEB ADDRESS

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