

SCREEN

DROGA TEST

Screen Drug Test Urine 10

ethamphetamine – Methadone – Amphetamine – Barbiturates – Tricyclic antidepressants – Phencyclidine – Cocaine – Marijuana – Opiates – Benzodiazepines (Urine) Package Insert

REF: 927972327

English

Instructions for use for every combination of tests for the following drugs: methamphetamine, methadone, amphetamine, barbiturates, tricyclic antidepressants, phencyclidine, cocaine, marijuana, opiates, benzodiazepines. One-step assay for the simultaneous qualitative detection of drugs of abuse and their metabolites in human urine.

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.

The kit should be stored at 2-30°C in its sealed pouch. The reactive strips panel is stable until the expiration date printed on the label of the pouch. The reactive strips panel should be stored in its sealed pouch until use. Do not freeze. Do not use after expiration date.

INTENDED USE AND SUMMARY

Screening test for the simultaneous detection of different drugs of abuse. The rapidity and sensitivity of immunoassays made them the most accepted among urine screening tests for the simultaneous detection of drugs of abuse. The one-step strips panel test (Urine) is a rapid immunochromatographic test with lateral flow to qualitatively determine the following drugs, without any further equipment:

Test	Calibrator	Cut-off (ng/ml)
Methamphetamine (mAMP)	d-methamphetamine	1.000
Methadone (MTD)	Methadone	300
Amphetamine (AMP)	d-amphetamine	1.000
Barbiturates (BAR)	Secobarbital	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1.000
Phencyclidine (PCP)	Phencyclidine	25
Cocaine (COC)	benzoylecgonine	300
Marijuana (THC)	11-nor- Δ^9 -THC-9-COOH	50
Opiates (OPI)	morphine	2.000
Benzodiazepines (BZO)	Oxazepam	300

This assay provides only a preliminary result. In order to obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) is the preferred confirmation method. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result.

The Urine SCREEN DROGA TEST for MET / MDMA / MTD / AMP / BA / TCA / PCP / COC / THC / OPI / BZO and their metabolites is a rapid urine assay not requiring any particular equipment. The assay uses antibodies to selectively determine high levels of specific

substances in the human urine.

The permanence times are approximated for each substance, as they vary based on the frequency of usage, body mass, age, health, tolerance to drugs and urine PH. The Urine SCREEN DROGA TEST detects the presence of drugs of abuse in urine only after their metabolization.

COCAINE (COC)

Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. It is often self-administered through inhalation or intravenous injection or by base-smoking.

AMPHETAMINE (AMP)

Amphetamine is a substance often used for therapeutic use. It is often self-administered through inhalation or ingestion. High doses induce a potent stimulation of the central nervous system and cause euphoria, alertness, reduction of appetite, sense of increased energy and power. Acute responses can include anxiety, paranoia, hallucinations and psychotic behavior.

METHAMPHETAMINE (MET/MDMA)

Methamphetamine is a potent stimulant, chemically linked to amphetamine, but with a major capability of stimulating the central nervous system. The substance is often self-administered through inhalation, smoking or ingestion.

MARIJUANA (THC)

Tetrahydrocannabinol is the active component of cannabis. When ingested or smoked, it produces euphoric effects. Abusers exhibit impaired short term memory and learning, they can also show episodes of confusion and anxiety. Long-term relatively high usage can be associated to behavior disorders.

OPIATES (OPI)

Opiates include any of the substances deriving from the opium poppy, included natural products as morphine, codeine and semi-synthetic substances as heroin. Opiates act on pain central depressing the central nervous system. Dependence symptoms can include sweating, shakings, nausea and irritability. Opiates can be taken orally or through intravenous, intramuscular or subcutaneous injection. Users can also take the substance intravenously or through inhalation.

METHADONE (MTD)

Methadone is a narcotic analgesic prescribed for pain treatment from severe to moderate and for the treatment of opioids addiction (heroin, Vicodin, Percocet, Morphine). Methadone is a long-action analgesic producing effects that last from twelve to forty-eight hours.

BARBITURATES (BAR)

Barbiturates are used in medicine as sedatives, hypnotics and anticonvulsants. Barbiturates are almost always assumed orally in the form of capsules or tablets. The effects are similar to those of an alcohol intoxication. The chronic use of barbiturates induces tolerance and physical dependence.

BENZODIAZEPINES (BZO)

Benzodiazepines are medications frequently prescribed for the symptomatic treatment of anxiety and sleeping disorders. They act through specific receptors involving a neurochemical substance called gamma aminobutyric acid (GABA). For their greater safety and effectiveness, benzodiazepines have replaced barbiturates in the treatment of anxiety and insomnia. Benzodiazepines are also used as sedatives before surgical and medical operations and for the treatment of epileptic seizures and alcohol withdrawal.

PHENCYCLIDINE (PCP)

Phencyclidine, also known as PCP or Angel Dust, is a hallucinogen used as dust, capsules and tablets. The dust is inhaled or smoked mixed with marijuana or vegetal substances. PCP is commonly administered through inhalation but can be also used intravenously, intranasally or orally. After small doses, the user thinks and acts fast and experiments humor alterations from euphoria to depression. Self-destructive behavior is one of PCP's effects.

TRICYCLIC ANTIDEPRESSANTS (TCA)

TCAs (tricyclic antidepressants) are commonly used for the treatment of depressive disorders. Overdoses of TCA can cause a deep depression, cardiotoxicity and anticholinergic effects. TCA overdose is the main cause of death by medicines. TCAs are taken orally or sometimes by injection.

PRINCIPLE

The one-step assay (Urine) strips panel is a rapid immunochromatographic test based on the competitive binding principle. The drugs that may be present in the urine sample compete with the related conjugate for the same antibody binding sites. During the test, the urine sample migrates on the membrane by capillary action. A drug, if present in the urine sample, under the cut-off concentration, won't be able to saturate all the binding sites of the particles tied to the related antibodies present on the strip. The particles tied to the antibodies will be caught by the immobilized conjugate and a visible colored line will appear in the test line area of the corresponding strip. The colored line won't form in the corresponding area if the drug level is over the cut-off concentration, as all the corresponding antibodies binding sites will be saturated. A urine sample positive to the corresponding drug won't cause the formation of the colored line because of the drug competition, while a drug negative sample or a sample containing a drug concentration below the cut-off level will cause the formation of the colored line in the specific test area. As procedure! contrai, a colored line will appear in the corresponding area, indicating a sufficient sample volume has been used and migration on the membrane has occurred.

REAGENT

Each panel strip contains monoclonal mouse antibodies bound to particles and the corresponding, the strip pane for the one-step assay (Urine) is a rapid immunochromatographic test with lateral flow conjugated for each drug. Goat antibodies are used for the contrai line.

SPECIMEN COLLECTION AND PREPARATION

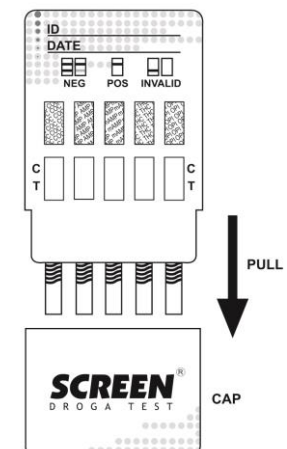
Collect the urine sample in a clean and dry container. Urine samples of any time of the day can be used. urine samples with evidence of precipitate must be centrifuged, filtered or left to deposit in order to get a clear sample to perform the test. Urine samples can be stored at 2-8°C for a maximum of 48 hours. For longer storage samples can be frozen under -20°C. Before usage, let the samples thaw and mix them accurately.

PACKAGE COMPOSITION

SCREEN Drug Test Urine, directions for use.

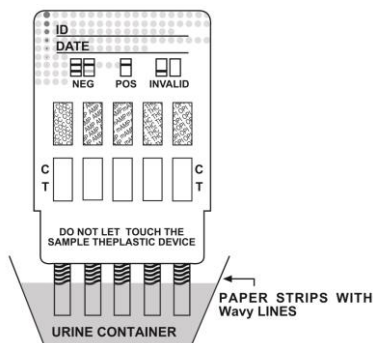
DIRECTIONS FOR USE

1 Before opening the sealed pouch, bring it to room temperature. Take the SCREEN DROGA TEST out of the pouch and use it as soon as possible.

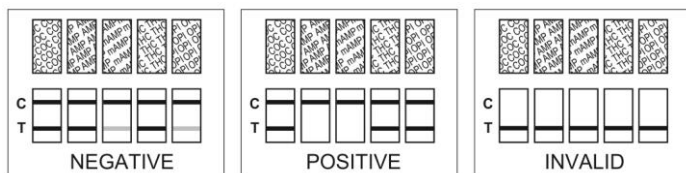


2 Remove the cap from the strips. Dip the SCREEN DROGA TEST vertically in the direction of the arrows in the urine sample for at least 10/15 seconds.

Dip the SCREEN DROGA TEST up to the wavy lines level on the strips, but not over them (see illustration below).



3. Put the cap back on the cassette and lay on a horizontal flat non-absorbent surface the SCREEN DROGA TEST. Read the results after 5 minutes. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

NEGATIVE: *A colored line appears at the control region (C) and a colored line appears at the test region (T) for each drug indicating a negative result. The negative test result indicates that the drug concentration in the urine is under the cut-off level detectable for that specific drug.

*NOTE: The intensity of the color in the test region (T) may vary, but any shade of color in the test region should be considered negative.

POSITIVE: A colored line appears in the control region and no colored line appears at a specific drug test region indicating a positive result. The positive result indicates that the concentration of that particular drug in the urine is above the cut-off level detectable for that specific drug.

INVALID: No control (C) line appears. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

In case the test result is positive, please avoid aggressive behavior and reasonably search for dialogue with the tested subject. Ask for advice to your physician, a psychologist or the competent service in your area.

QUALITY CONTROL

The test includes an internal procedural control, the red band appearing in the control region (C). The appearance of this band confirms the test has been carried out correctly with a sufficient specimen volume, membrane wicking and correct procedural technique.

Standard controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The one-step strips panel assay (Urine) only provides a preliminary qualitative analytic result. This assay provides only a preliminary result. A more specific alternate chemical method is needed. Gas Chromatography/Mass Spectroscopy (GC/MS) are the preferred confirmation methods, particularly when the preliminary result is positive.
2. It is possible 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 indicates presence of the drug or its metabolites but does not indicate level of 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 containing the same substance. False positive results can be caused by some medications.

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