

# SCREEN

## DROGA TEST

### Screen Drug Test Urine 1

Rapid Test One Drug  
(Urine)

Package Insert

REF: 911151672	English
REF: 911151696	English
REF: 911151708	English
REF: 911151658	English
REF: 927972315	English
REF: 921455770	English
REF: 911151684	English
REF: 911151660	English
REF: 988717017	English

Instructions for use for every combination of tests for the following drugs: amphetamine, benzodiazepine, cocaine, marijuana, methylenedioxyamphetamin, ketamine, opiates, synthetic marijuana k2/spice and fentanyl.

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:

**This assay provides only a preliminary result. 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.**

Test	Calibrator	Cut-Off (ng/ml)
Cocaine (COC)	Benzoilecgonine	300
Amfetamine (AMP)	d-amfetamine	1000
Methylenedioxyamphetamin (MDMA)	d,l-Methylenediossietamfetamine	500
Marijuana (THC)	11-nor- $\Delta^9$ -THC-9 COOH	50
Opiates (OPI)	Morfine	2000
Benzodiazepine (BZO)	Oxazepam	300
Ketamine (KET)	Ketamine	1000
Marijuana synthetic k2/spice	jwh-018 e jwh-073	50
Fentanyl (FYL)	Norfentanil	20

The Urine SCREEN DROGA TEST for COC / AMP / MDMA / THC / OPI / BZO / KET / K2 / SPICE/FYL and their metabolites is a rapid urine assay not requiring any 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.

#### METHYLENEDIOXYMETHAMPHETAMINE

Ecstasy is a stimulant, even if it shares with amphetamines the capability of rising blood pressure and heart rate. It induces some changes in perception, as major sensibility to light, hard focusing, blurred vision. The most common effect in almost all its users is jaw clenching.

#### 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 control 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.

#### BENZODIAZEPINE (BZO)

These drugs are frequently prescribed for the symptomatic treatment of anxiety, sleeping disorders, epileptic seizures, and alcohol withdrawal symptoms. The sudden interruption can induce symptoms as sleeping and gastrointestinal disorders, loss of appetite, sweating, shaking, weakness, anxiety and altered perceptions.

#### KETAMINE (KET)

Ketamine is a dissociative anesthetic for human and veterinary use. In Italy it is commercialized under the trade names of Ketalar, Ketanest and Ketaset and, for human use, it is classified as "H" drug and should be used only in hospitals by a trained anesthetist. As for all neuroleptic and psychotropic substances, it can be abused and used for voluptuary purposes as a drug of abuse (which is forbidden and sanctioned by the Law).

#### SYNTHETIC MARIJUANA K2/SPICE (K2/SPICE)

Synthetic Marijuana or K2 is a psychoactive herb and a chemical product that, if used, imitates the effects of Marijuana. Mostly known through the trade names K2 and Spice, they are both largely used to refer to any synthetic product of Marijuana.

#### FENTANYL (FYL)

Fentanyl is a powerful narcotic analgesic, abuse of which leads to addiction or dependence. It is primarily a mu-opioid agonist. Norfentanil is also used as an adjuvant to general anaesthetics and as an induction and maintenance anaesthetic.

#### 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 procedural control, a colored line will appear in the corresponding area, indicating a sufficient sample volume has been used and migration on the membrane has occurred.

#### REAGENTS

Each panel strip contains monoclonal mouse antibodies bound to particles and the corresponding, the strip panel for the one-step assay (Urine) is a rapid immunochromatographic test with lateral flow.

#### SPECIMEN COLLECTION AND PREPARATION

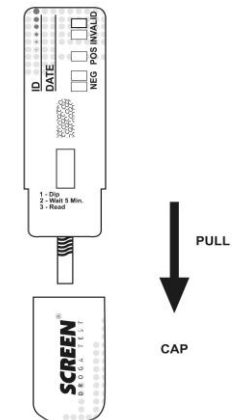
Collect the urine sample in a clean and dry container. Urine samples of any time of the day can be used, urine samples with evidence of precipitate must be centrifuged, filtered or left to deposit in order to get a clear sample to perform the test. Urine samples can be stored at 2-8°C for a maximum of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

#### COMPOSITION OF THE PACKAGE

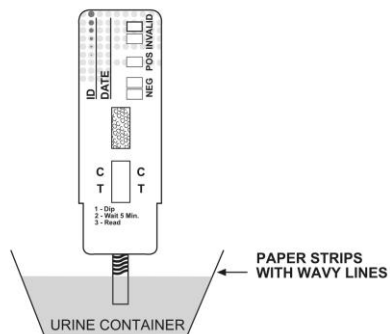
SCREEN Drug Test Urine, directions for use.

#### 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.



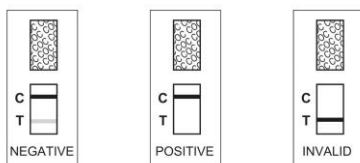
2. Remove the cap from the strips. Dip the SCREEN DROGA TEST vertically in the direction of the arrows in the urine sample for at least 10/15 seconds. Dip the SCREEN DROGA TEST up to the wavy lines level on the strips, but not over them (see illustration below).



- 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 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

- 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.
- 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.

Distributed by:

**Screen Italia Srl**

Via dell'Artigianato, 16

06089 - Torgiano - Perugia - Italia

[www.screenpharma.it](http://www.screenpharma.it) - [info@screenpharma.it](mailto:info@screenpharma.it)