

Materials Provided

- One Step Drug Screen Test Card
- Package insert

Precautions

- For healthcare professionals including professionals at point of care sites.
- For in vitro diagnostic use only. Do not use after the expiration date.
- The test card 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.
- The used test device should be discarded according to federal, state and local regulations.

Storage and Stability

Store as packaged in the sealed pouch at 2-30°C (36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

Specimen Collection and Preparation

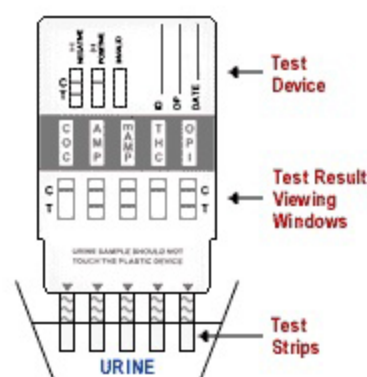
The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Urine specimens may be stored at 2-8°C (36-46°F) for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C (-4°F). Frozen specimens should be thawed and mixed well before testing.

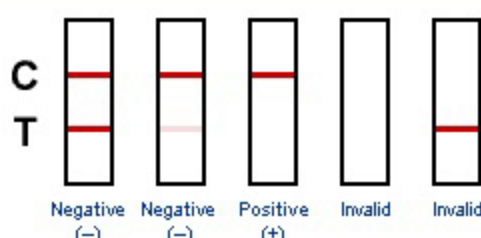
Directions for Use

Allow the test card, urine specimen and/or controls to equilibrate to room temperature (15-30°C (59-86°F)) prior to testing.

1. Remove the test card from the sealed pouch and use it as soon as possible. Remove the cap from the end of the test card. With arrows pointing toward the urine specimen, immerse the strip(s) 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 strip(s), but not above the arrow(s) on the test card.
2. Replace cap and place the test card on a non-absorbent flat surface. The results should be read at 5 minutes.



Interpretation of Results



NEGATIVE*: Two lines appear. A colored line appears in the Control region (C) and a colored line appears in the Test region (T). This negative result means that the concentrations in the urine sample are below the designated cutoff 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 cutoff 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.

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

- The One Step Drug Screen Test Card 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.
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cutoff level of the test.
- This test does not distinguish between drugs of abuse and certain medications.
- A positive test result may be obtained from certain foods or food supplements.