One Step Drug Urine Screening Test Kit
Instruction leaflet for any test card and strip of the following drugs
AMP/BAR/BZO/COC/mAMP/MDMA MOP/MTD/OPI/PCP/TCA/THC

INTENDED USE

This One-step Drug Abuse Test is a lateral flow chromatographic immunoassay for the qualitative detection of drugs and drug metabolites in urine at the following cut-off concentrations:

ab.	Drug to Be Tested	Calibrator	Cut-off
AMP	Amphetamine	D-Amphetamine	1,000 ng/mL
BAR	Barbiturates	Secobarbital	300 ng/mL
BZO	Benzodiazepines	Oxazepam	300 ng/mL
COC	Cocaine	Benzoylecgonine	300 ng/mL
MET/mAMP	Methamphetamine	D-Methamphetamine	1,000 ng/mL
MDMA	Methylenedioxymeth-amphetamine (Ecstasy)	D,L Methylenedioxymeth-amphetamine	500 ng/mL
MOP/MOR	Morphine	Morphine	300 ng/mL
MTD	Methadone	Methadone	300 ng/mL
OPI	Opiates	Morphine	2,000 ng/mL
PCP	Phencyclidine	Phencyclidine	25 ng/mL
TCA	Tricyclic Antidepressants	Nortriptyline	1,000 ng/mL
THC	Marijuana	11-nor-Δ9-THC-9 COOH	50 ng/mL

This assay provides only a preliminary analytical testing 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.

PRINCIPLE

One-step Drug Rapid Test 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 under capillary effect. The 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.

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, Methylenedioxymethamphetamine, Morphine, THC, Phencyclidine, Benzodiazepine, Methadone, Barbiturate or Tricyclic Antidepressants, depending on the drug to be tested.

PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For in vitro diagnostic use only.
- Do not use after the expiration date.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test card should be discarded according to the local regulations.

STORAGE and STABILITY

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

SPECIMEN COLLECTION and PREPARATION

The urine specimen must be collected in a clean and dry container. The test can be tested with urine samples taken at any time of the day. 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 totally before testing.

MATERIALS

Materials Provided

- Test Cassette or Strip
- Package insert;
- Specimen collection container

Materials Needed but not Provided

- Timer
- External controls

INSTRUCTION FOR USE

1 Allow the sealed test cassette or strip, urine specimen, and/or controls come to room temperature (15-30°C) prior to testing.

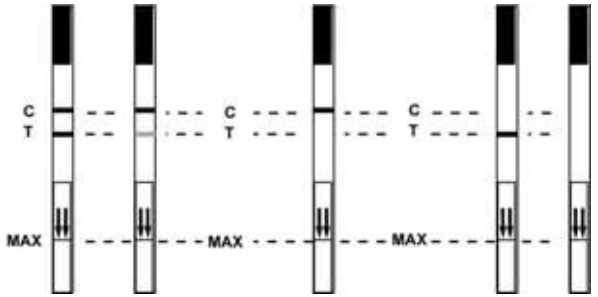
2 Remove the test cassette or strip from the sealed pouch and use it as soon as possible, according to the steps listed below.

3 Adding samples:

For Strip:

Holding the handler of the strip, Immerge the other end with arrows vertically into the urine specimen for at least 10-15 seconds. Don't immerge beyond the maximum line (MAX) on the test strip. Refer to the Illustration 1 below.

Illustration 1. Testing Procedure of Strip

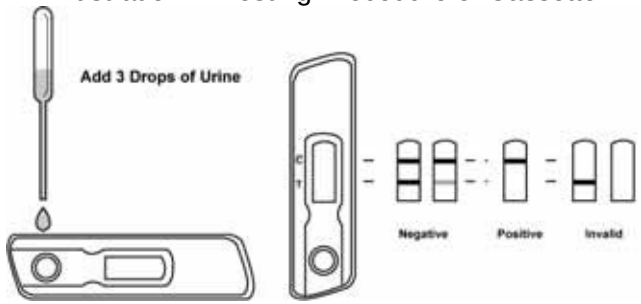


Negative Positive Invalid

For Cassette:

Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100µl) to the specimen well of the test cassette. Avoid trapping air bubbles in the specimen well (S). Refer to the Illustration 2 below.

Illustration 2. Testing Procedure of Cassette



4 Place the test cassette or the strip 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.

INTERPRETATION of RESULTS

(Please refer to the Illustration 1 and Illustration 2 above)

NEGATIVE:* Two lines appear. One red line appear in the control region (C), and another apparent red or weak pink line adjacent appear 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 cassette or strip. 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. One Step Drug Screen 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. 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.

MANUFACTURER

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