

and Oberlender, 1990). The most pervasive effect of MDMA, occurring in nearly 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 OF THE PROCEDURE

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.

WARNINGS AND 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.
- For testing human urine only
- Do not reuse the test device.

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 between 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

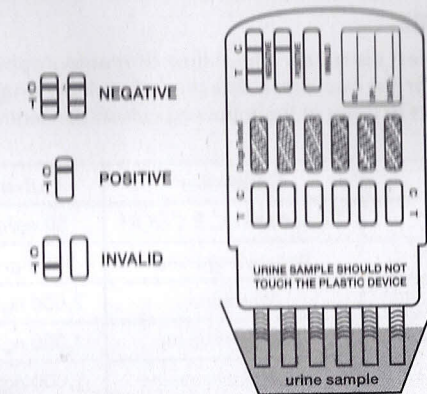
Allow the test panel and urine specimen to equilibrate to room temperature (15-30°C) prior to testing.

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 in the next column.

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.



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.