

Psilocybin Rapid Test Dipstick (Urine)

Package Insert

A rapid test for the qualitative detection of metabolite of Psilocybin (PY) in human urine.

For forensic use only.

【INTENDED USE】

The Psilocybin Rapid Test Dipstick (Urine) is a rapid immunochromatographic assay for the qualitative detection of metabolite of Psilocybin in human urine at a cut-off concentration of 500 ng/mL. This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test 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 used.

【SUMMARY】

Psilocybin is the major psychoactive alkaloid of some species of mushrooms distributed worldwide. Psilocybin-containing mushrooms are one of the major hallucinogenic drugs of abuse today. In a medium dosage (12–20 mg p.o.), psilocybin was found to produce a well-controllable altered state of consciousness. This state is marked by stimulation of affect, enhanced ability for introspection and altered psychological functioning in the direction of Freudian primary processes, known otherwise as hypnagogic experience and dreams. Especially noteworthy are perceptual changes such as illusions, synaesthesias, affective activation, and alterations of thought and time sense. The effects last from 3 to 6 hours¹.

Both psilocin (at 90-97%) and psilocybin (3-10%), are detectable in human urine, unmodified (only 3-10%) and in particular conjugated with glucuronic acid. The majority is excreted within 3 hours after oral administration and is completely eliminated from the body within 24 hours².

The Psilocybin Rapid Test Dipstick (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of Psilocin in urine. The Psilocybin Rapid Test Dipstick (Urine) yields a positive result when Psilocin in urine exceeds 500 ng/mL.

【PRINCIPLE】

The Psilocybin Rapid Test Dipstick (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.

During testing, a urine specimen migrates upward by capillary action. Psilocin, if present in the urine specimen below 500 ng/mL, will not saturate the binding sites of antibody-coated particles in the test device. The antibody-coated particles will then be captured by immobilized PY conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the Psilocin level exceeds 500 ng/mL because it will saturate all the binding sites of anti-PY antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line 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 dipstick contains mouse monoclonal anti-PY antibody-coupled particles and PY-protein conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】

- For forensic use only. Do not use after the expiration date.
- The test 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 should be discarded according to local regulations.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

NOTE: Once the canister has been opened, the remaining test(s) are stable for 50 days only.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

【MATERIALS】

Materials Provided

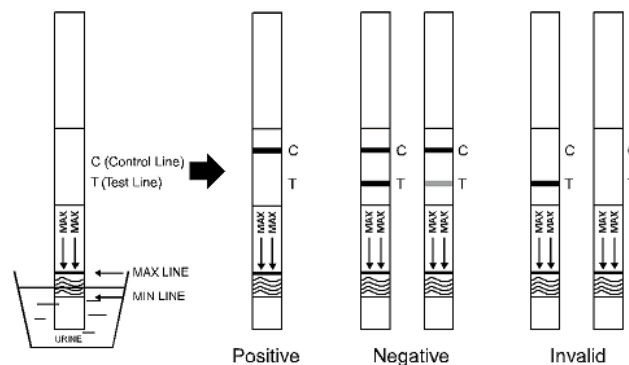
- Test Dipsticks
- Package Insert
- Specimen Collection Containers
- Timer

Materials Required But Not Provided

【DIRECTIONS FOR USE】

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

1. Bring the pouch or canister to room temperature before opening it. Remove the test dipstick from the sealed pouch or canister and use it within one hour.
2. With arrows pointing toward the urine specimen, **immerse the test dipstick vertically in the urine specimen for at least 10-15 seconds.** Do not pass the maximum line (MAX) on the test dipstick when immersing the strip. See the illustration below.
3. Place the test dipstick on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another colored line should be in the test line region (T). A negative result indicates that the Psilocin concentration is below the detectable level (500 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line

appears in the test line region (T). A positive result indicates that the Psilocin concentration exceeds the detectable level (500 ng/mL).

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. If the problem persists, discontinue using the lot immediately and contact your local distributor.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line 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 testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Psilocybin Rapid Test Dipstick (Urine) 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. 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.

【BIBLIOGRAPHY】

1. Passie T, Seifert J, Schneider U, et al. The pharmacology of psilocybin[J]. *Addiction Biology*, 2002, 7(4):357-64
2. Tylš F, Páleníček T, Horáček J. Psilocybin – Summary of knowledge and new perspectives[J]. *European Neuropsychopharmacology*, 2014, 24(3), 342–356

Number:
Revision date: 2023-06-05