Psilocybin (PY) Rapid Test Panel (Urine)
Package Insert

A rapid test for the qualitative detection of the metabolite of Psilocybin in human urine.
For forensic use only.

【INTENDED USE】

The Psilocybin (PY) Rapid Test Panel (Urine) is a rapid chromatographic immunoassay for the detection of psilocin, the metabolite of psilocybin in human urine at a cut-off concentration of 500ng/mL.

This assay provides only a qualitative, preliminary 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, synaestesias, affective activation, and alterations of thought and time sense. The effects last from 3 to 6 hours.[1]

Both psilocin (at 90-97%) and psilocybin (3-10%), are detectable in human urine, unmodified (only 3-10%) and in particular conjugated with glucoronic acid. The majority is excreted within 3 hours after oral administration and is completely eliminated from the body within 24 hours.[2]

The Psilocybin (PY) Rapid Test Panel (Urine) is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of psilocin in urine. The Psilocybin (PY) Rapid Test Panel (Urine) yields a positive result when the psilocin in urine exceed the cut-off level.

【PRINCIPLE】

The Psilocybin (PY) Rapid Test Panel (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 the cut-off level, will not saturate the binding sites of the antibody in the test. The antibody coated particles will then be captured by immobilized psilocybin-protein 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 the cut-off level, because it will saturate all the binding sites of anti-psilocybin antibody.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, 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 contains mouse monoclonal anti-psilocybin antibody coupled particles and psilocybin-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 in the sealed pouch either at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【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 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 before testing.

【MATERIALS】

Materials Provided

- Test Panels
- Package Insert

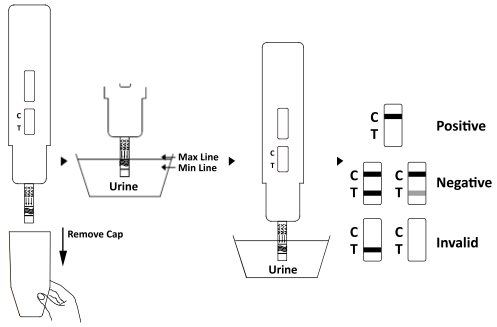
Materials Required but Not Provided

- Specimen Collection Containers
- Timer

【DIRECTIONS FOR USE】

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

1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for **at least 10 to 15 seconds**. **Immerse the strip to at least the level of the wavy lines, but not above the arrow on the test panel.**
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. **The result should be read at 5 minutes.** Do not interpret the result after 10 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

NEGATIVE: **Two colored 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). This negative result indicates that the psilocin concentration is below the detectable cut-off level.

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). This positive result indicates that the psilocin concentration exceeds the detectable cut-off 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 with a new test. If the problem persists, discontinue using the test kit 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 (PY) Rapid Test Panel (Urine) provides only a qualitative, preliminary 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.

【PERFORMANCE CHARACTERISTICS】

Accuracy

A side-by-side comparison was conducted using the Psilocybin (PY) Rapid Test Panel (Urine) and GC/MS at the cut-off of 500ng/mL. Testing was performed on clinical specimens previously collected from subjects present for Drug Screen Testing. The following results were tabulated:

Method		GC/MS		Total Results
Psilocybin (PY) Rapid Test Panel	Results	Positive	Negative	
	Positive	28	1	29
	Negative	2	55	57
Total Results		30	56	86
% Agreement		93.3%	98.2%	96.5%

Analytical Sensitivity

A drug-free urine pool was spiked with psilocin at the following concentrations: 0ng/mL, 250ng/mL, 375ng/mL, 500ng/mL, 625ng/mL, 750ng/mL and 1,500ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Psilocin Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
250	-50%	30	30	0
375	-25%	30	27	3
500	Cut-off	30	15	15
625	+25%	30	4	26
750	+50%	30	0	30
1,500	3X	30	0	30

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Psilocybin (PY) Rapid Test Panel (Urine) at 5 minutes.

Compound	Concentration(ng/mL)
Psilocin	500

Effect of Urinary Specific Gravity

Fifteen urine specimens of normal, high and low specific gravity ranges were spiked with 250ng/mL and 750ng/mL of psilocin. The Psilocybin (PY) Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH

The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with psilocin to 250ng/mL and 750ng/mL. The spiked, pH-adjusted urine was tested with the Psilocybin (PY) Rapid Test Panel (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or psilocin positive urine. The following compounds show no cross-reactivity when tested with the Psilocybin (PY) Rapid Test Panel (Urine) at a concentration of 100 μg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	Thiamine	Levetiracetam
Acetophenetidin	Tyramine	Trihexyphenidyl
Acetylsalicylic acid	Verapamil	Ibuprofen
Amitriptyline	Dicyclomine	Olanzapine
Amobarbital	Trazodone	mirtazapine
Ascorbic acid L-Ascorbic acid	Theophylline	Bisulepini hydrochloridum
Amoxcillin	Nalorphine	Norfloxacin
(±)-Amphetamine	Lithium acetoacetate	Venlafaxine Hydrochloride
(R)-Apomorphine hydrochloride hemihydrate	(±)Isoproterenol hydrochloride[(-)isoprenaline]	(+)3,4-Methylendioxyme-thamphetamine
Atropine	Hydroxyzine	Hydrocodone
Benzoylecgonine	Guaiacol Glyceryl Ether carbamate	a-Hydroxymidazolam
Cannabidiol	Chlorprothixene	Methylone HCl
Chloramphenicol	Orphenadrine	Fexofenadine
Chlordiazepoxide	Ephedrine	Methedrone
Clomipramine	Kanamycin	MDPBP HCl
Clonidine Hydrochloride	Fluoxetine	Itraconazole
Cocaine	Fentanyl	R(-)-Selegiline [(-)-Deprenyl]
Codeine	Buprenorphine	Nalbuphine HCl
Dextromethorphan	Clozapine	Risperidone
Diazepam	Amikacin	Acamprosate Calcium

Diclofenac sodium salt	Dimenhydrinate	Topiramate
propranolol HCl	Insulin	lormetazepam
Ecgonine methyl ester	Atenolol	5-pentanoic acid
1S,2R(+)-Ephedrine HCl	Cephalexin	Fenofibrate
β-Estradiol Estradiol	Dexamethasone	Melatonine
Estrone	Protriptyline	losartan potassium
Furosemide	Haloperidol	Bisoprolol Fumarate
Hydrocortisone	Paroxetine	sulfasalazine
p-Hydroxymethamphetamine	Sertraline	carbamide
Imipramine	Heroin	Valproate
Cyclobenzaprine	Nefopam	Lamotrigine
Meprobamate	Epitestosterone	$FeSO_4$
Methoxyphenamine	(±)-Phenylpropanolamine HCl	Normeperidine
(±)3,4-Methylendioxyam-phetamine	7-Aminonitrazepam	Simvastatin
Desoxypipradrol HCl	Triazolam	Betahistine
Methylphenidate HCl	Estazolam	Norbuprenorphine
Morphine-6-β-D-Glucuronide	Clobazam	Glutamine
Morphine-3-β-D-Glucuronide	Nitrazepam	Lisdexamfetamine
Nalidixic acid	Cocaethylene	R(+)-Methcathinone HCl
Naltrexone	6-Acetylcodeine	S(-)-Cathinone HCl
Nifedipine	Nordiazepam	Disulfiram
Norethindrone Norethisterone	Desipramine	R(+)-Cathinone HCl
Sodium oxalate	Nordoxepin	Tilidine HCl
Oxycodone	α-Hydroxyalprazolam	Norcocaine HCl
Promazine	11-nor-Δ^9-THC-9COOH	Difenidol Hydrochloride
Pentobarbital	n-Desmethyl-cis-tramadol	Telmisartan
Phenobarbital	Ciprofloxacin Hydrochloride	Phenytoin
2-Phenylethylamine	Tramsdol Hydrochloride	Demoxepam
Procaine	Sildenafil Citate	Butabarbital
Salicylic acid	Tizanidine HCl	Flurazetam
Tetrahydrozoline	Gabapentin	Atorvastatin
Thebaine	Escitalopram	Alimemazine Tartrate
Amlodipine	Lamivudine	tenofovir Disopoxil fumarate

【BIBLIOGRAPHY】

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