



PHENCYCLIDINE

Rapid Test (PCP) strip

Introduction

The PCP Rapid Test Dipstick (Urine) is a Rapid chromatographic immunoassay for qualitative detection of Phencyclidine in human urine at a cut-off concentration of 25 ng/mL which is only utilized for in vitro diagnostics (IVD). It merely provides a preliminary result, therefore, an alternative method with more specificity is recommended to be used to confirm the initial results, in which case, the most preferred method is gas chromatography-mass spectrometry (GC-MS). For substance abuse cases, clinical considerations must be taken into account, especially when test results are positive.

Summary

Phencyclidine is a dissociative hallucinogenic drug that was introduced to the market as an anesthetic for surgery in the 50s. However, in the late 60s, due to its side effects such as hallucination and delirium, it was more abused than used. The substance is taken in the form of powder, capsules, and tablets. Generally, its effect starts in the very first seconds of consumption which include sedative and anesthetic states. Since phencyclidine has the greatest effect on the brain, it can change an individual's perceptions and has dangerous consequences. The effects this drug has on the body are similar to the symptoms of schizophrenia, paranoia, disorganized thinking, and confusion. People abusing phencyclidine suffer from slurred speech in the long term.

Phencyclidine could be detected in the urine after being taken within 4 to 6 hours for 7 to 14 days, depending on factors like the metabolic rate, user's age, weight, activity and diet. It is excreted in urine as an unchanged drug (4-19%) and conjugated metabolites (25-30%).

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Function Method Basis

Rapid phencyclidine urine test employs an immunochromatographic method based on competitive binding. During the test, the urine specimen flows upward via capillary action. If the amount of phencyclidine in the urine is below 25 ng/mL, it does not bind to the binding sites of the antibodies conjugated with gold nanoparticles. Consequently, the conjugated antibody will be absorbed by the phencyclidine on the surface of the membrane and will leave a colored line in the test area (T). Should the amount be greater than 25 ng/mL, no colored line will appear in the T area, since all the binding sites of the phencyclidine antibodies are occupied. So, if the presence of phencyclidine in the urine specimen is positive, no colored line will be formed in the test area (T) due to drug competition, whereas if the urine specimen contains phencyclidine amounts lower than the desired level in the test, a colored line will appear in this area. In order to have a procedural control, a colored line always appears in the area of the control line (C), indicating the appropriate volume of the specimen added to the membrane.

Compounds

The test strip contains anti-phencyclidine monoclonal antibody particles and a combination of conjugated protein-phencyclidine. The secondary antibody prepared in goat species is also employed for the control line.

+ **Caution:** for in vitro diagnostic use only.

Do not use after the expiration date. The test must remain in its package until use. All specimens must be considered infectious and all precautions and safety measures for handling and use must be taken.

Storage

The package should be stored at room temperature or in refrigerator (2-30 °C). The test is valid only until the expiration date printed on the package. Keep from freezing.

Specimen Collection and Preparation

+ **Urine collection:** The urine specimen must be collected in a clean and dry container. It could be collected at any time of the day.

+ **Specimen storage:** The urine specimen can be stored at 2-8 °C for more than 48 hours, and frozen for long-term storage at -20 °C. Frozen specimens must be thawed and mixed well before testing.

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Contents and Required Supplies

Items found in the kit: + Brochure + Test strip

Required items not included in the kit: + Specimen collection container + Timer

User Manual

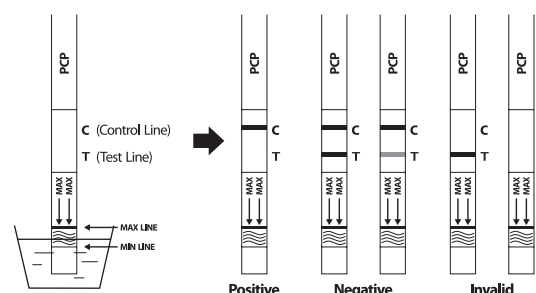
Before testing, let the test strip and the urine specimen reach room temperature (18-30 °C).

• Bring the pouch to room temperature, before opening it. Remove the test strip from the sealed pouch, and use it as soon as possible.

• Dip the test strip vertically into the urine specimen in the direction indicated by the arrows up to the MAX line, and hold it for at least 10-15 seconds (See illustration).

• Place the test strip on a flat, non-absorbent surface, set the timer and wait for the colored line to appear. Interpret the results within 5 minutes.

+ Do not interpret the results after 10 minutes.



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Result Interpretation

Negative: Two lines appear, one line should be in the control area (C) and another colored line should appear in the test area (T). This negative result indicates that the phencyclidine concentration is below the detectable level of 25 ng/mL.

+ **Attention:** The color shade in the testing area may vary, but it should be considered negative whenever there is even a faint colored line.

Positive: A colored line should appear in the control area (C) and no line should be seen in the test area (T). This positive result shows that the concentration of phencyclidine is above the detectable level of 25 ng/mL.

Invalid: The control line (C) is not formed. 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 is not solved, stop using the strip and contact the after-sales service immediately.

Quality Control

The quality control of the method is included in the test, and the colored line appearing in the control area (C) is considered as an inner controller which confirms the sufficient volume of the specimen and the correct execution of the test. The test strip does not come with control standards. It is recommended to do the test with positive and negative controls in an accredited laboratory to confirm the method and the correctness of the test.

Limitations

1. Phencyclidine Rapid Test strip provides only preliminary analytical and qualitative results, and therefore, a secondary analytical method must be employed to confirm the results. For the confirmation of the results of this test, gas chromatography-mass spectrometry (GC-MS) is preferred.

2. There is a possibility of error in this technique. As some interfering substances in the urine specimen may lead to wrong results.

3. Adding substances like bleaches or white alum in the urine specimen may cause a wrong result, despite the analytical method used, and should the substances remain, the test should be performed with another urine specimen.

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4. A positive result indicates the presence of substances or its metabolites. A negative result, on the other hand, may not necessarily indicate the absence of substances in the urine. The drug level may be lower than the level detectable by the test.

5. The test is not able to detect the abuse of certain therapeutic cases.

+ **Expected values:** if phencyclidine concentration is less than 25 ng/mL, the result will be negative and if the concentration is greater than 25 ng/mL, the result will be positive. The cut-off value of the test is 25 ng/mL.

Executive Feature

Accuracy: The results obtained from Hana Gene's Phencyclidine Rapid Test strip were compared with those of an available commercial kit. In a study on 95 urine specimens (38 positive and 57 negative), Hana Gene's kit detected 38 of the specimens positive and 57 negative. The results are presented in table below:

Method		other PCP Rapid Test		Total Result
The PCP Rapid Test Dipstick	Results	Positive	Negative	
	Positive	38	0	38
	Negative	0	57	57
Total Result		38	57	95

Sensitivity: > 99% Specificity: > 99%
Accuracy: > 99% 95% Confidence Intervals

In order to compare the results of Hana Gene's PCP Rapid test kit, using GC/MS method, 250 clinical specimens (92 positive; 158 negative) were collected, and Hana Gene's kit detected 85 positive and 153 of the specimens negative. The results are shown in the table below:

Method		GC/MS		Total Result
The PCP Rapid Test Dipstick	Results	Positive	Negative	
	Positive	85	5	90
	Negative	7	153	160
Total Result		92	158	250

Sensitivity: 92.4% Specificity: 96.8%
Accuracy: 95.2% 95% Confidence Intervals

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Analytical Sensitivity:

Some amount of drug-free urine specimens was prepared in the following concentrations of phencyclidine:

0 ng/mL, 12.5 ng/mL, 18.75 ng/mL, 25 ng/mL, 31.25 ng/mL, 37.5 ng/mL and 75 ng/mL. The results show more than 99% accuracy in 50% of specimens greater than the cut-off level, and 50% below cut-off value. This information is summarized in the table below:

PCP Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
12.5	-50%	30	30	0
18.75	-25%	30	26	4
25	Cut-off	30	15	15
31.25	+25%	30	3	27
37.5	+50%	30	0	30
75	3X	30	0	30

Analytical Features:

The following table shows the compounds positively identified by the phencyclidine test strip in the urine specimen within 5 minutes.

Compound	Concentration (ng/mL)
4-Hydroxyphencyclidine	12,500
Phencyclidine	25

Precision

A study was carried out in three different centers by untrained people making use of three different lots of the product in order to evaluate the intra-rater, inter-rater, and inter-individual reliability.

A panel of coded specimens containing certain phencyclidine concentrations with GC/MS method was used in each center, at 0 ng/mL, 25% above and below the minimum detection limit, and 50% above and below the minimum detection limit of 25 ng/mL.

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PCP Concentration (ng/mL)	n per site	LOT A		LOT B		LOT C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
12.5	10	10	0	10	0	10	0
18.75	10	8	2	9	1	9	1
31.25	10	1	9	1	9	1	9
37.5	10	0	10	0	10	0	10

Effect of Urinary Specific Gravity

Phencyclidine with concentrations of 12.5 ng/mL and 37.5 ng/mL was added to 15 urine specimens with low, normal, and high specific gravity. Then pure specimens and specimens with certain phencyclidine concentrations were checked by the test strip. The results show that the specific weight and gravity do not affect the test results.

Effect of Urinary pH

The pH of the negative diluted urine specimen was changed from 5 to 9, and the specimens were given phencyclidine concentrations of 12.5 ng/mL and 37.5 ng/mL. The adjusted pH of the urine was done in a duplicate rapid phencyclidine test whose results show that the pH range does not interfere with the test.

Cross Reactivity

In order to assess the interferences with positive and negative phencyclidine test results, a study was carried out. The following compounds did not show any interference in the test results with 100 µg/ml phencyclidine concentration:

Zomepirac, Acetaminophen, Creatinine, Meperidine, Prednisolone, Acetophenetidin, Deoxycorticosterone, Meprobamate, Prednisone, N-Acetylprocainamide, Dextromethorphan, Methadone, Procaine, Acetylsalicylic acid, Diazepam, Methoxyphenamine, Promazine, Aminopyrine, Diclofenac, (+) 3,4-Methylenedioxy-, Promethazine, Amitriptyline, Diflunisal, Amphetamine

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D,L-Propanolol, Amobarbital, Digoxin, (+) 3,4-Methylenedioxy-, D-Propoxyphene, Amoxicillin, Diphenhydramine, methamphetamine, D-Pseudoephedrine, Ampicillin, Doxylamine, Morphine-3-Quinidine, L-Ascorbic acid, Ecgonine hydrochloride, β-D glucuronide, Quinine, D,L-Amphetamine, Ecgonine methylester, Morphine Sulfate, Ranitidine, Apomorphine, (-)-ψ-Ephedrine, Nalidixic acid, Salicylic acid, Aspartame, Erythromycin, Naloxone, Secobarbital, Atropine, β-Estradiol, Naltrexone, Serotonin, Benzilic acid, Estrone-3-sulfate, Naproxen (5-Hydroxytyramine), Benzoic acid, Ethyl-p-aminobenzoate, Niacinamide, Sulfamethazine, Benzoyllecgonine, Fenoprofen, Nifedipine, Sulindac, Benzphetamine, Furosemide, Norcodein, Temazepam, Bilirubin, Gentisic acid, Norethindrone, Tetracycline (±) - Brompheniramine, Hemoglobin, D-Norpropoxyphene, Tetrahydrocortisone, Caffeine, Hydralazine, Noscapine, 3-Aacetate, Cannabidiol, Hydrochlorothiazide, D,L-Octopamine, Tetrahydrocortisone, Cannabinol, Hydrocodone, Oxalic acid, 3-(β-D glucuronide), Chloralhydrate, Hydrocortisone, Oxazepam, Tetrahydrozoline, Chloramphenicol, O-Hydroxyhippuric acid, Oxolinic acid, Thiamine, Chlordiazepoxide, p-Hydroxy-, Oxycodone, Thioridazine, Chlorothiazide, Methamphetamine, Oxymetazoline, D, L-Tyrosine (±) Chlorpheniramine, 3-Hydroxytyramine, Papaverine, Tolbutamide, Chlorpromazine, Ibuprofen, Penicillin-G, Triamterene, Chlorquine, Imipramine, Pentazocine hydrochloride, Trifluoperazine, Cholesterol, Iproniazid, Pentobarbital, Trimethoprim, Clomipramine (±), Isoproterenol, Perphenazine, Trimipramine, Clonidine, Isoxsuprine, Phenelzine, Tryptamine, Cocaine hydrochloride, Ketamine, Phenobarbital, D, L-Tryptophan, Codeine, Ketoprofen, Phentermine, Tyramine, Cortisone, Labetalol, L-Phenylephrine, Uric acid, (-) Cotinine, Loperamide, β-Phenylethylamine, Verapamil, Maprotiline, Phenylpropanolamine, Zomepirac, Acetaminophen

References

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