One Step Phencyclidine Urine Test

One Step Phencyclidine Urine Test is a rapid one step test for the qualitative detection of Phencyclidine and its principal metabolites in human urine at specified cut-off level.
For in vitro diagnostic use only. For professional use only.

INTENDED USE

One Step Phencyclidine Urine Test is a lateral flow chromatographic immunoassay for the detection of Phencyclidine in human urine at the cut-off concentration of 25 ng/ml. This assay provides only a qualitative, 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

Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilzer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as "angel dust" and "crystal cyclone," etc. phencyclidine can be administered orally, by nasal ingestion, smoking, or by intravenous injection. It is metabolized in the liver and excreted through the kidneys in urine in unchanged form and oxidized metabolites with a half life of about 12 hours. Suction and urinary acidification in the treatment of overdose typically reduces its half-life from three days to one day.

PRINCIPLE

One Step Phencyclidine Urine Test is a competitive immunoassay that is used to screen for the presence of Phencyclidine in urine. It is chromatographic absorbent device in which Phencyclidine and its metabolites in a sample competitively combined to a limited number of anti-phencyclidine monoclonal antibody (mouse) conjugate binding sites.
When add four drops of the urine specimen to the sample well, the urine is absorbed into the device by capillary action, mixes with the phencyclidine monoclonal antibody conjugate, and flows across the pre-coated membrane. When sample drug levels are zero or below the target cut off (the detection sensitivity of the test), anti-phencyclidine monoclonal antibody (mouse) conjugate binds to the phencyclidine-protein (duck egg) conjugate immobilized in the Test Region (T) of the device. This produces a colored Test line that, regardless of its intensity, indicates a negative result.
When sample drug levels are at or above the target cutoff, the free drug in the sample binds to the phencyclidine monoclonal antibody conjugate preventing the phencyclidine monoclonal antibody conjugate from binding to the phencyclidine -protein conjugate immobilized in the Test Region (T) of the device. This prevents the development of a distinct colored band in the test region, indicating a potentially positive result.
To serve as a procedure control, a colored line will appear at the Control Region (C), where the Goat anti mouse IgG polyclonal antibody immobilized in, if the test has been performed properly.

WARNINGS AND PRECAUTIONS

1. This kit is for external use only. Do not swallow.
2. Discard after first use. The test cannot be used more than once.
3. Do not use test kit beyond expiry date.
4. Do not use the kit if the pouch is punctured or not well sealed.
5. Keep out of the reach of children.
6. Do not read after 5 minutes
7. This kit is for in vitro diagnostic use.

CONTENT OF THE KIT

1. 25 tests per kit., one test in one pouch.
2. One pouch containing a test and a desiccant. The only desiccant is for storage purposes only, and is not used in the test procedures.
3. Leaflet with instructions for use.
4. Dropper.

STORAGE AND STABILITY

Store at 4 ~ 30 ºC in the sealed pouch up to the expiration date.
Keep away from direct sunlight, moisture and heat.
DO NOT FREEZE.

SPECIMEN COLLECTION AND PREPARATION

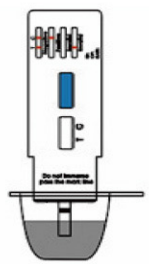
Collect a urine sample in the supplied urine cup. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below). Bring frozen or refrigerated samples to room temperature before testing. Previously frozen or refrigerated samples should be well mixed before analysis. Cloudy specimens should be centrifuged before analysis. Use only clear aliquots for testing.

TEST PROCEDURE

Test must be in room temperature (18ºC to30° C)

1. Open the sealed pouch by tearing along the notch. Remove the test device from the pouch.
2. Hold the one side of the device with one hand. Use the other hand to pull out the cap and expose the absorbent end.
3. Immerse the absorbent end into the urine sample about 10 seconds. Make sure that the urine level is not above the "MAX" line printed on the front of the device.
4. Lay the device flat on a clean, dry, non-absorbent surface.
5. Read the result at 5 minutes. **Do not read after 5 minutes.**

6.



INTERPRETATION OF RESULTS

Positive (+)

A rose-pink band is visible in the control region. No color band appears in the appropriate test region. It indicates a positive result for the corresponding drug of that specific test zone.

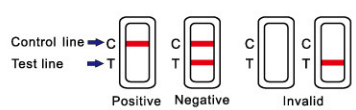
Negative (-)

A rose-pink band is visible in the control region and the appropriate test region. It indicates that the concentration of the corresponding drug of that specific test zone is below zero or the detection limit of the test.

Invalid

If a color band is not visible in the control region or a color band is only visible in the test region, the test is invalid. Another test should be run to re-evaluate the specimen. Please contact the distributor or the store, where you bought the product, with the lot number.

Note: There is no meaning attributed to line color intensity or width.



QUALITY CONTROL

Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.
Though there is an internal procedural control line in the test device of Control region, the use of external controls is strongly recommended as good laboratory testing practice to confirm the test procedure and to verify proper test performance. Positive and negative control should give the expected results. When testing the positive and negative control, the same assay procedure should be adopted.

LIMITATIONS OF PROCEDURE

1. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
2. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
3. This test is a qualitative screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication

PERFORMANCE CHARACTERISTICS

Accuracy

Eighty clinical urine specimens were analyzed by GC-MS and by One Step Phencyclidine Test. Each test was read by three viewers. Samples were divided by concentration into four categories: less than half the cutoff, near cutoff negative, near cutoff positive, and high positive. Results were as follows:

Viewer A:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	15	22
Negative	23	17	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77%- 100%)

% agreement among negatives is100% (95% Confidence Interval 84.5%- 100%)

Viewer B:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	0	17	22
Negative	23	17	1	0

% agreement among positives is 97.5% (95% Confidence Interval 82%- 100%)

% agreement among negatives is 100% (95% Confidence Interval 84.5%- 100%)

Viewer C:

Result	Less than half the cutoff concentration by GC/MS analysis	Near Cutoff Negative (Between 50% below the cutoff and the cutoff concentration)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration)	High Positive (greater than 50% above the cutoff concentration)
Positive	0	1	15	22
Negative	23	16	3	0

% agreement among positives is 92.5% (95% Confidence Interval 77%- 100%)

% agreement among negatives is 97.5% (95% Confidence Interval 82%- 100%)

From the results of the above tables, the total results are showed as below:
The average positive agreement is 94.2%
The average negative agreement is 99.2%

Precision and Sensitivity

To investigate the precision and sensitivity, samples were analyzed at the following concentrations: cutoff - 50%, cutoff - 25%, cutoff, cutoff +25%, and the cutoff + 50%. All concentrations were confirmed with GC-MS. Each concentration was tested using three different lots. Thirty samples were analyzed at each concentration, and each result was read by three viewers, for a total of 90 results per concentration per lot.

Lot 1

Approximate concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
13	90	90/0
17	90	83/7
25	90	47/43
32	90	14/76
38	90	0/90

Lot 2

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
13	90	90/0
17	90	83/7
25	90	47/43
32	90	14/76
38	90	0/90

Lot 3

Approximate Concentration of sample (ng/mL)	Number of determinations	Results Negative/ Positive
13	90	90/0
17	90	83/7
25	90	47/43
32	90	14/76
38	90	0/90

Specificity and cross reactivity

To test the specificity of the test, the test device was used to test Phencyclidine, drug metabolites and other components of the same class that are likely to be present in urine, All the components were added to drug-free normal human urine. These concentrations below also represent the limits of detection for the specified drugs or metabolites.

Component	Concentration (ng/ml)
Phencyclidine	25
4-Hydroxyphencyclidine	12,500
Phencyclidine morpholine	50

Effect of Urinary Specific Gravity

5 urine samples with density ranges (1.000-1.035) are collected and spiked with Phencyclidine at 50% below and 50% above cutoff level. One step Phencyclidine urine test was tested in duplicate. The results demonstrate that varying ranges of urinary specific gravity do not affect the test result.

Effect of Urinary PH

The pH of an aliquot negative urine pool is adjusted to a pH range of 4 to 9 in 1 pH unit increments and spiked with Phencyclidine at 50% below and 50% above cutoff levels. One step Phencyclidine urine test was tested in duplicate. The result demonstrate that varying ranged of PH do not interfere with the performance of the test.

Interfering substances

Clinical urine samples may contain substances that could potentially interfere with the test. The following compounds were added to drug-free urine, urine with a Phencyclidine concentration 50% below the cutoff, and urine with a Phencyclidine concentration 50% above the cutoff. All potential interferents were added at a concentration of 100 µg/mL. None of the urine samples showed any deviation from the expected results.

Acetaminophen
Acetophenetidin
N-Acetylprocainamide
Acetylsalicylic acid
Aminopyrine
Amitryptyline
Amobarbital
Amoxicillin
Ampicillin
Ascorbic acid
D,L-Amphetamine
Apomorphine acid
Aspartame
Atropine
Benzilic acid
Benzoic acid
Benzoylecgonine
Benzphetamine
Bilirubin
Brompheniramine
Caffeine
Cannabidiol
Cannabinol
Chloralhydrate
Chloramphenicol
Chlordiazepoxide
Chlorothiazide
(±) Chlorpheniramine
Chlorpromazine
Chlorquine
Cholesterol
Clomipramine
Clonidine
Cocaine hydrochloride
Codeine
Cortisone
Meperidine
Meprobamate
Methadone
Methoxyphenamine
(+) 3,4-Methylenedioxyamphetamine
(+)3,4-Methylenedioxymethamphetamine
Morphine-3-β-D glucuronide
Morphine Sulfate
Nalidixic acid
Naloxone
Naltrexone
Naproxen
Niacinamide
Nifedipine
Norcodein
Norethindrone
D-Norpropoxyphene
Noscapine
D,L-Octopamine
Oxalic acid
Oxazepam
Oxolinic acid
Oxycodone
Oxymetazoline
Papaverine
Penicillin-G
Pentazocine hydrochloride
Pentobarbital
Perphenazine
Phenelzine
Phenobarbital
Phentermine
L-Phenylephrine
β-Phenylethylamine
Phenylpropanolamine
Prednisolone
(-) Cotinine
Creatinine
Deoxycorticosterone
Dextromethorphan
Diazepam
Diclofenac
Diflunisal
Digoxin
Diphenhydramine
Doxylamine
Ecgonine hydrochloride
Ecgonine methylester
(-) Y Ephedrine
Erythromycin
β-Estradiol
Estrone-3-sulfate
Ethyl-p-aminobenzoate
Fenoprofen
Furosemide
Gentisic acid
Hemoglobin
Hydralazine
Hydrochlorothiazide
Hydrocodone
Hydrocortisone
O-Hydroxyhippuric
p-Hydroxymethamphetamine
3-Hydroxytyramine
Ibuprofen
Imipramine
Iproniazid
(±) - Isoproterenol
Isoxsuprine
Ketamine
Ketoprofen
Labetalol
Loperamide
Maprotiline
Prednisone
Procaine
Promazine
Promethazine
D,L-Propanolol
D-Propoxyphene
D-Pseudoephedrine
Quinidine
Quinine
Ranitidine
Salicylic acid
Secobarbital
Serotonin (5-Hydroxytyramine)
Sulfamethazine
Sulindac
Temazepam
Tetracycline
Tetrahydrocortisone, 3 acetate
Tetrahydrocortisone3 (β-D glucuronide)
Tetrahydrozoline
Thiamine
Thioridazine
D, L-Tyrosine
Tolbutamide
Triamterene
Trifluoperazine
Trimethoprim
Trimipramine
Tryptamine
D, L-Tryptophan
Tyramine
Uric acid
Verapamil
Zomepirac

BIBLIOGRAPHY OF SUGGESTED READING

Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
Ellenhorn, M.J. and Barceloux, D. G Medical Toxicology. Elservier Science Publishing Company, Inc., New York, 1988
Gilman, A. G., and Goodman, L. S. The Pharmacological Fluids, in Martin WR(ed): Drug Addiction I, New York, Spring – Verlag, 1977.
Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
Hawwks RL, CN Chiang. Urine Testing for drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monography 73, 1986
Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
McBay, A. J. Clin. Chem. 33,33B-40B, 1987.

Index of Symbols

IVD	For *in vitro* diagnostic use only	4 ~ 30 °C	Store between 4 ~ 30 °C
	Do not reuse		Manufacturer
	Keep away from sunlight		Keep dry