274 mm x 218mm

CE Insight | PCP

DEVICE

Rapid Competitive Immunochromatographic Assay for the detection of Phencyclidine in human urine

DEVICE

INTENDED USE

INSIGHT-PCP is a rapid, qualitative, immunochromatographic assay for the detection of phencyclidine in human urine. This test is used to screen the phencyclidine intoxication. For healthcare professional use only.

SUMMARY

Phencyclidine is central nervous system (CNS) depressants. Phencyclidine, also known as PCP, is a hallucinogen that was first marketed as a surgical anesthetic in the 1950's. It was removed from the market because patients receiving it became delirious and experienced hallucinations. Phencyclidine is used in powder, capsule, and tablet form. The powder is either snorted or smoked after mixing it with marijuana or vegetable matter. Phencyclidine is most commonly administered by inhalation but can be used intravenously, intranasally, and orally. After low doses, the user thinks and acts swiftly and experiences mood swings from euphoria to depression. Self-injurious behavior is one of the devastating effects of Phencyclidine. Phencyclidine is excreted in the urine as unchanged drug (4% to 19%) and conjugated metabolites (25% to 30%) with a half-life of about 12 hours.

INSIGHT-PCP detects the presence of phencyclidine in human urine specimens, qualitatively, at concentrations as low as 25 ng/ ml.

PRINCIPLE

INSIGHT-PCP is based on the principle of agglutination of antibodies/ antisera with respective antigen in a competitive immuno-chromatography format along with use of nano gold particles as agglutination. The conjugate pad is impregnated with two components - Agglutinating sera for Phencyclidine conjugated to colloidal gold and rabbit globulin conjugated to colloidal gold. As the test specimen flows through the membrane assembly of the device, the Agglutinating sera for Phencyclidine - colloidal gold conjugate complexes with the Phencyclidine present in the test specimen and travels on the membrane due to capillary action along with the rabbit globulin-colloidal gold conjugate. This complex moves further on the membrane to the test region (T) where it is not immobilized by Phencyclidine conjugated to BSA coated on the membrane, therefore forming no band. The absence of this band in the test region (T) indicates a positive result. In absence of Phencyclidine in the test specimen, the Agglutinating sera for Phencyclidine -colloidal gold conjugate and along with rabbit globulin-colloidal gold conjugate moves further on the membrane to the test region (T) where it is immobilized by the Phencyclidine conjugated to BSA coated on the membrane, forming a pink coloured band indicating a negative result.

The rabbit globulin colloidal gold conjugate and unbound complex if any move further on the membrane and are subsequently immobilized by the Agglutinating sera for rabbit globulin coated on the membrane at the control region (C) forming a pink coloured band. This control band acts as a procedural control and serves to validate the test results.

REAGENTS AND MATERIALS SUPPLIED

A. Each INSIGHT-PCP kit contains individual pouches each containing a
   1. DEVICE : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Phencyclidine and rabbit globulin, Phencyclidine conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions
   2. PIPETTE : Sample applicator.
   3. Desiccant pouch.

B. Package insert.

REF	10811010	10811050
Σ	10	50

OPTIONAL MATERIAL REQUIRED

Precision micropipette capable of delivering 50 µl specimen, stopwatch.

STORAGE AND STABILITY

The sealed pouches in the test kit and the kit components may be stored between 4 - 30°C till the duration of the shelf life as indicated on the pouch/carton. DO NOT FREEZE.

NOTE s

1. For in vitro diagnostic and professional use only. NOT FOR MEDICINAL USE.
2. Do not use beyond the expiry date and do not reuse the test device.
3. Read the instructions carefully before performing the test.
4. Handle all specimen as if potentially infectious.
5. Follow standard biosafety guidelines for handling and disposal of potentially infectious material.

6. If desiccant colour at the point of opening the pouch has turned from blue to pink or colourless, another test device must be run.
7. Contact with the contents of desiccant pouch containing, among other substances, cobalt chloride (CAS# 7646-79-9) should be kept to a minimum. Inhalation / swallowing may cause harm.

SPECIMEN COLLECTION AND PREPARATION

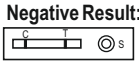
1. INSIGHT-PCP uses human urine as specimen.
2. No special preparation of the patient is necessary prior to specimen collection by approved techniques.
3. A clean dry plastic or glass container may be used for specimen collection.
4. Though fresh specimen is preferable, in case of delay in testing, it may be stored at 2-8°C for maximum up to 24 hours.
5. Refrigerated specimens must be brought to room temperature prior to testing.
6. Repeated freezing and thawing of the specimen should be avoided.
7. Specimen containing precipitates or particulate matter must be centrifuged and the clear supernatant only used for testing.

TESTING PROCEDURE

1. Bring the kit components of INSIGHT-PCP device to room temperature before testing.
2. Open a foil pouch by tearing along the "notch".
3. Remove the testing device and the sample applicator.
4. Check the colour of the desiccant pouch. It should be blue. If the desiccant has turned colourless or pink, discard the test device and use another device. *Once opened, the device must be used immediately.*
5. Label the device with specimen identity.
6. Place the testing device on a flat horizontal surface.
7. Holding the sample applicator vertically, carefully dispense exactly two drops of the test specimen into the specimen port (S). Alternatively, using a micropipette, carefully dispense exactly 50 µl of test specimen into the specimen port (S).
8. Start the stopwatch. Read the results at the end of 5 minutes. Do not interpret the results beyond 10 minutes.

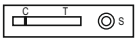
INTERPRETATION OF RESULTS

Negative Result:



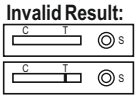
Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of phencyclidine in the specimen.

Positive Result:



One pink coloured band appears at the control region (C). This indicates that the specimen contains detectable amount of phencyclidine.

Invalid Result:



The test result is invalid if no band appears either at the control region (C) or test region (T). In such cases, verify the test procedure and repeat the test with a INSIGHT-PCP device.

Note: A negative test result indicates that the analyte (drug) is either absent or is present below the detection threshold of the test kit.

REMARKS

1. The deliberate slow reaction kinetics of INSIGHT-PCP is designed to maximize and enhance reaction time between sample capture and tracer elements to improve test sensitivity.
2. Most positive results develop within 5 minutes. However, certain samples may take a longer time to flow. Therefore, negatives should be confirmed only at 8 minutes. Do not interpret the results beyond 10 minutes.
3. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.
4. The assay is designed for use with human urine only.
5. A preliminary positive result indicates only the presence of phencyclidine and does not indicate or measure intoxication.
6. There is a possibility that technical/or procedural errors as well as other substances or factors not listed may interfere with the test and cause false results. See specificity section, for the list of substances that shall produce positive results, or that do not interfere with the test performance.
7. If adulteration is suspected, the test should be repeated with a new sample.
8. Certain over the counter or prescription medications (or certain foods) may cause false results.
9. The length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half life, the user's age, weight, activity and diet.
10. **This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry**

(GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

PERFORMANCE CHARACTERISTICS

1. **Sensitivity** : INSIGHT-PCP detects phencyclidine and it's metabolites at concentrations equal to or greater than 25 ng/ ml.
2. **Specificity** : Interference of substances that may be present in urine specimen, as well as effect of sample pH and specific gravity was also studied.
   a) Cross-reactivity of non-phencyclidine related compounds at concentrations much higher than normally found in the urine of people using or abusing them were tested using assay devices.
   b) No cross-reactivity was detected with the substances listed in table I. Table II lists phencyclidine -related substances and concentrations that produced results approximately equivalent to the cut-off level for phencyclidine.

Table I:

Following compounds has shown no cross reactivity when tested with INSIGHT-PCP at concentration of 100 microgram/ml:

Acetaminophen	(-) Cotinine	Loperamide
Acetophenetidin	Creatinine	Maprotiline
N-Acetylprocainamide	Deoxycorticosterone	Meperidine
Acetylsalicylic acid	Dextromethorphan	Meprobamate
Aminopyrine	Diazepam	Methadone
Amitryptyline	Diclofenac	Methoxyphenamine
Amobarbital	Diflunisal	(+) 3,4-Methylenedioxy-amphetamine
Amoxicillin	Digoxin	(+) 3,4-Methylenedioxy-methamphetamine
Ampicillin	Diphenhydramine	Morphine-3-β-D glucuronide
Ascorbic acid	Doxylamine	Morphine Sulfate
D,L-Amphetamine	Ecgonine hydrochloride	Nalidixic acid
Apomorphine	Ecgonine methylester	Naloxone
Aspartame	(-) Y Ephedrine	Naltrexone
Atropine	Erythromycin	Naproxen
Benzilic acid	β-Estradiol	Niacinamide
Benzoic acid	Estrone-3-sulfate	Nifedipine
Benzoylecgonine	Ethyl-p-aminobenzoate	Norcodein
Benzphetamine	Fenoprofen	Norethindrone
Bilirubin	Furosemide	D-Norpropoxyphene
Brompheniramine	Gentisic acid	Noscapine
Caffeine	Hemoglobin	D, L-Octopamine
Cannabidiol	Hydralazine	Oxalic acid
Cannabinol	Hydrochlorothiazide	Oxazepam
Chloralhydrate	Hydrocodone	Oxolinic acid
Chloramphenicol	Hydrocortisone	Oxycodone
Chlordiazepoxide	O-Hydroxyhippuric acid	Oxymetazoline
Chlorothiazide	p-Hydroxy-methamphetamine	Papaverine
(±) Chlorpheniramine	3-Hydroxytyramine	Penicillin-G
Chlorpromazine	Ibuprofen	Pentazocine hydrochloride
Chlorquine	Imipramine	Pentobarbital
Cholesterol	Iproniazid	Perphenazine
Clomipramine	(±) - Isoproterenol	Phenelzine
Clonidine	Isoxsuprine	Phenobarbital
Cocaine hydrochloride	Ketamine	Phentermine
Codeine	Ketoprofen	L-Phenylephrine
Cortisone	Labetalol	β-Phenylethylamine

Phenylpropanolamine	Salicylic acid	Thioridazine
Prednisolone	Secobarbital	D, L-Tyrosine
Prednisone	Serotonin (5-Hydroxytyramine)	Tolbutamide
Procaine	Sulfamethazine	Triamterene
Promazine	Sulindac	Trifluoperazine
Promethazine	Temazepam	Trimethoprim
D, L-Propanolol	Tetracycline	Trimipramine
D-Propoxyphene	Tetrahydrocortisone, 3 acetate	Tryptamine
D-Pseudoephedrine	Tetrahydrocortisone 3 (β-D	D, L-Tryptophan
Quinidine	glucuronide)	Tyramine
Quinine	Tetrahydrozoline	Uric acid
Ranitidine	Thiamine	Verapamil
		Zomepirac

Table II:
The following table listed the concentration of the compounds (ng/ml) those are detected positive with INSIGHT PCP.

Compound	Concentration
4 - Hydroxyphecyclidine	12,000
Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Levophanol	50,000
Naloxone	37,000
Naltrexone	37,000
Oxymorphone	200

WARRANTY

This product is designed to perform as described on the label and the package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

(1) Wu. AH, Onigbhinde TA, Wong SS, Johnson KG, Evaluation of full scanning GC/ion trap MS of NIDA drugs of abuse urine testing in urine. J. Anal. Toxicol. 1992, May, Jun; 16(3) pgs 202-206. (2) www. drug detection. net/drug. html . (3) Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature Limitation	Consult Instructions for use	Date of Manufacture	Do not reuse
Manufacturer	IVD — *In vitro* Diagnostic Medical Device	This side up	PS — Production site
Use by	REF — Catalogue Number	DEVICE — Device	EC REP — Authorised Representative in the European Community
Σ — Contains sufficient for <n> tests	LOT — Batch Number / Lot Number	PIPETTE — Disposable Plastic Sample Applicator	

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PS

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