

274 mm x 218mm



Insight | PPX

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

DEVICE

DEVICE

#### INTENDED USE

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

#### SUMMARY

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, Propoxyphene can be 50-75% as potent as oral codeine. Peak plasma concentrations of Propoxyphene are achieved from 1 to 2 hours post dose. In the case of overdose, Propoxyphene blood concentrations can reach significantly higher levels. In humans, Propoxyphene is metabolized by N-demethylation in liver to yield Norpropoxyphene. Norpropoxyphene has a longer half-life (30 -36 hours) than parent Propoxyphene (6 - 12 hours). The accumulation of Norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

INSIGHT-PPX detects the presence of propoxyphene and its metabolites in human urine specimens, qualitatively, at concentrations as low as 300 ng/ml.

#### PRINCIPLE

INSIGHT-PPX 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 Propoxyphene 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 Propoxyphene - colloidal gold conjugate complexes with the Propoxyphene 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 Propoxyphene 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 Propoxyphene in the test specimen, the Agglutinating sera for Propoxyphene -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 Propoxyphene 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-PPX kit contains individual pouches each containing a

1. **DEVICE** : Membrane test assembly impregnated with colloidal gold conjugated to the Agglutinating sera for Propoxyphene and rabbit globulin, Propoxyphene conjugated to BSA and Agglutinating sera for rabbit globulin at the respective regions
2. **PIPETTE** : Sample applicator.
3. Desiccant pouch.

B. Package insert.

REF	10812010	10812050
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

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.

Insight

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-PPX 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-PPX 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:



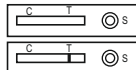
Two pink coloured bands appear at the control region (C) and test region (T). This indicates absence of propoxyphene in the specimen.

##### Positive Result:



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

##### 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-PPX 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-PPX 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 propoxyphene 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-PPX detects propoxyphene and its metabolites at concentrations equal to or greater than 300 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-propoxyphene 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 propoxyphene-related substances and concentrations that produced results approximately equivalent to the cut-off level for propoxyphene.

**Table I:**

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

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

Pentobarbital	D-Pseudoephedrine	Thiamine
Perphenazine	Quinidine	Thioridazine
Phenelzine	Quinine	D, L-Tyrosine
Phenobarbital	Ranitidine	Tolbutamide
Phentermine	Salicylic acid	Triamterene
L-Phenylephrine	Secobarbital	Trifluoperazine
$\beta$ -Phenylethylamine	Serotonin (5-Hydroxytyramine)	Trimethoprim
Phenylpropanolamine	Sulfamethazine	Trimipramine
Prednisolone	Sulindac	Tryptamine
Prednisone	Temazepam	D, L-Tryptophan
Procaine	Tetracycline	Tyramine
Promazine	Tetrahydrocortisone, 3 acetate	Uric acid
Promethazine	Tetrahydrocortisone 3 ( $\beta$ -D glucuronide)	Verapamil
D, L-Propanolol	Tetrahydrozoline	Zomepirac

**Table II:**

The following table listed the concentration of the compounds (ng/ml) those are detected positive with INSIGHT-PPX.

Compound	Concentration
d-Propoxyphene	300
d-Norpropoxyphene	300
















#### 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). www. drug detection. net/drug. html (2). Klabunde R.E., Cardiovascular Pharmacology Concepts; Beta Adrenoceptor Antagonists (Beta Blockers), Sympathomimetics, 2006. (3). 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. (4). Drugs and Human Performance, FACT SHEETS Cannabis, Amphetamines. (5). Kreek M.J. and Hartmann N. Chronic use of opioids and anti psychotic drugs, side effects , effects of endogenous opioids and toxicity; Annals New York academy of Science pgs 151-172. (6). Drugs of Abuse, Drug Enforcement Administration ( DEA) Barbiturates pg 52, Benzodiazepines pg 53, Cocaine pg 45. (7) Data on file: Tulip Diagnostics (P) Ltd.

#### SYMBOL KEYS

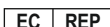
 Temperature Limitation	 Consult instructions for use	 Date of Manufacture	 Do not reuse
 Manufacturer	 In vitro Diagnostic Medical Device	 This side up	 Production site
 Use by	 Catalogue Number	 Device	 Authorised Representative in the European Community
 Contains sufficient for <n> tests	 Batch Number / Lot Number	 Disposable Plastic Sample Applicator	

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