

# One Step

## Propoxyphene Test Strip Package Insert

*A rapid, one step test for the qualitative detection of Propoxyphene in human urine.*

*For healthcare professionals including professionals at point of care sites.*

For professional *in vitro* diagnostic use only.

### INTENDED USE

The One Step Propoxyphene Test Strip is a lateral flow chromatographic immunoassay for the qualitative detection of Propoxyphene in human urine at a cut-off concentration of 300 ng/mL. It is a prescription assay intended for use by healthcare professionals including those at point of care sites.

**This assay provides only a 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

Propoxyphene (PPX) is a narcotic analgesic compound bearing structural similarity to methadone. As an analgesic, propoxyphene can be from 50-75% as potent as oral codeine. Darvocet™, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. 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 to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than parent propoxyphene (6 to 12 hours). The accumulation of norpropoxyphene seen with repeated doses may be largely responsible for resultant toxicity.

The One Step Propoxyphene Test Strip yields a positive result when the concentration of Propoxyphene or Norpropoxyphene in urine exceeds 300 ng/mL. At present, the Substance Abuse and Mental Health Services Administration (SAMHSA) does not have a recommended screening cutoff for propoxyphene positive specimens.

### PRINCIPLE

The One Step Propoxyphene Test Strip 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. Propoxyphene, if present in the urine specimen below 300 ng/mL, will not saturate the binding sites of antibody-coated particles in the test strip. The antibody-coated particles will then be captured by immobilized Propoxyphene 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 Propoxyphene level exceeds 300 ng/mL because it will saturate all the binding sites of anti-Propoxyphene antibodies.

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 strip contains mouse monoclonal anti-Propoxyphene antibody-coupled particles and Propoxyphene-protein conjugate. A goat antibody is employed in the control line system.

### PRECAUTIONS

- For healthcare professionals including professionals at point of care sites.
- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip 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 strip should be discarded according to federal, state and local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test strip is stable through the expiration date printed on the sealed pouch. The test strip 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 assay. For long-term storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

### MATERIALS

#### Materials Provided

- Test strips
- Package insert

#### Materials Required But Not Provided

- Specimen collection container
- Timer
- External controls (recommended target concentration of +/-50% of cutoff)

### DIRECTIONS FOR USE

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

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, immerse the test strip vertically in the urine specimen for at least 10 to 15 seconds. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the following illustration.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be read at 5 minutes and up to 1 hour after test initiation.

### INTERPRETATION OF RESULTS

(Please refer to illustration below)

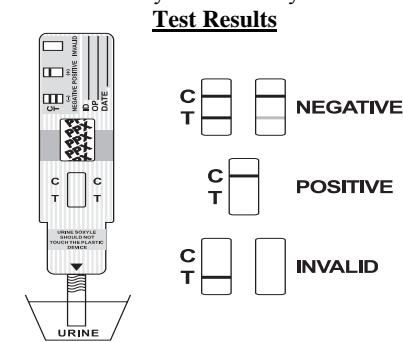
**NEGATIVE:\* Two lines appear.** One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative

result indicates that the Propoxyphene concentration is below the detectable level (300 ng/mL).

\* **NOTE:** The shade of red in the test line region (T) will vary, but it should be considered negative whenever there is even a faint pink line.

**POSITIVE: One red line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Propoxyphene concentration exceeds the detectable level (300 ng/mL).

**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 using a new test strip. If the problem persists, discontinue using the lot immediately and contact your local distributor.



#### Test Results

C T **NEGATIVE**

C T **POSITIVE**

C T **INVALID**

### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal positive 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 practice to confirm the test procedure and to verify proper test performance. Users should follow local, state, and federal guidelines for testing QC materials. Controls should be tested the same way as urine specimens, refer to the “Direction for Use” and “Interpretation of Results” sections above.

### LIMITATIONS

1. The One Step Propoxyphene Test Strip provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) are the preferred confirmatory methods.<sup>1,2</sup>
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 or 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 cutoff level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result might be obtained from certain foods or food supplements.

## PERFORMANCE CHARACTERISTICS

### Accuracy

A side-by-side comparison was conducted using the One Step Propoxyphene Test Strip and a leading commercially available PPX rapid test. Testing was performed on 314 clinical and diluted clinical specimens. Presumptive positive samples were confirmed by GC/MS. The following results were tabulated:

Method		Other PPX Rapid Test		Total Results	
PPX One Step Test strip	Results	Positive	Negative		
		Positive	157	0	157
		Negative	0	157	157
Total Results		157	157	314	
% Agreement with this commercial kit		>99%	>99%	>99%	

A clinical study was conducted the One Step Propoxyphene Test Strip using 352 clinical and diluted clinical specimens. All specimens containing propoxyphene were analyzed with GC/MS; negative specimens were pooled and analyzed by GC/MS to limit of detection. Approximately 20% of the specimens containing propoxyphene fell between -50% or +50% of the assay cut-off concentration of 300 ng/mL. When compared to the GC/MS analysis data, the following results were tabulated:

Specimen Cutoff Range by GC/MS							
PPX Device		Negative	< -50% of cutoff		Cutoff to +50% of cutoff		Agreement with GC/MS (95% C.I.)*
			-50% to cutoff	>+50% of cutoff			
PPX Device	Positive	0	0	2	7	158	94% (90%-97%)
	Negative	152	5	18	10	0	99% (96%-99%)

\* 95% Confidence Interval

The test comparison data demonstrate that the One Step Propoxyphene Test Strip can qualitatively detect urine Propoxyphene at the cutoff level of 300 ng/mL with a high degree of confidence.

### Analytical Sensitivity

A drug-free urine pool was spiked with Propoxyphene at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL, 450 ng/mL and 600 ng/mL. The result demonstrates >99% accuracy at 50% above and 50% below the cut-off concentration of 300 ng/mL. The data are summarized below:

Propoxyphene Concentration (ng/mL)	Percent of Cutoff	n	Visual Result	
			Negative	Positive
0	0%	30	30	0
150	-50%	30	30	0
225	-25%	30	24	6
300	Cutoff	30	17	13
375	+25%	30	7	23
450	+50%	30	0	30
600	+100%	30	0	30

### Analytical Specificity

The following table lists compounds that are positively detected in urine by the One Step Propoxyphene Test Strip at 5 minutes.

Compound	Concentration (ng/mL)	% Cross Reactivity
D-Propoxyphene	300	100%
D-Norpropoxyphene	300	100%

### Precision

A study was conducted at 3 physician's offices by untrained operators using 3 different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing no Propoxyphene, 25% Propoxyphene above and below the cut-off, and 50% Propoxyphene above and below the 300 ng/mL cut-off were provided to each site. The results are given below:

Propoxyphene concentration (ng/mL)	n	Site A		Site B		Site C	
		-	+	-	+	-	+
0	45	15	0	15	0	15	0
150	45	15	0	15	0	14	1
225	45	10	5	8	7	7	8
375	45	0	15	0	15	1	14
450	45	0	15	0	15	0	15

### Effect of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.007 to 1.029) were spiked with 150 ng/mL and 450 ng/mL of Propoxyphene respectively. The One Step Propoxyphene Test Strip was tested in duplicate using the fifteen neat and spiked urine samples. The results demonstrate that varying ranges of urinary specific gravity does not affect the test results.

### Effect of the 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 Propoxyphene to 150 ng/mL and 450 ng/mL. The spiked, pH-adjusted urine was tested with the One Step Propoxyphene Test Strip in duplicate. The results demonstrate that varying ranges of pH does 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 drug-free urine or Propoxyphene containing urine samples at +50% and -50% cutoff levels. The following compounds show no cross-reactivity when tested with the One Step Propoxyphene Test Strip at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

4-Acetamidophenol	Erythromycin	Oxycodone
Acetophenetidin	β-Estradiol	Oxymetazoline
Acetone	Estrone-3-sulfate	Oxymorphone
N-Acetylprocainamide	Ethanol	Penicillin-G
Acetylsalicylic acid	Ethyl-p-aminobenzoate	Pentazocine
Albumin	Fenfluramine	Pentobarbital
Aminopyrine	Fenpropfen	Perphenazine
Amitriptyline	Furosemide	Phencyclidine
Amobarbital	Gentisic acid	Phenelzine
Amoxapine	D-Glucose	Pheniramine
Amoxicillin	Guaiacol Glyceryl Ether	Phenobarbital
Ampicillin	Hemoglobin	Phenothiazine
Ascorbic acid	Hydralazine	Phentermine
L-Amphetamine	Hydrochlorothiazide	L-Phenylephrine
Apomorphine	Hydrocodone	β-Phenylethylamine
Aspartame	Hydrocortisone	Phenylpropanolamine
Atropine	p-Hydroxyamphetamine	Prednisolone
Benzilic acid	O-Hydroxyhippuric acid	Prednisone
Benzoic acid	p-Hydroxymethamphetamine	5-β-Pregnane3α17α21triol

Benzoyllecgonine	p-Hydroxynorephedrine	Procaine
Benzphetamine	3-Hydroxytyramine	Promazine
Bilirubin	Hydroxyzine	Promethazine
Brompheniramine	Ibuprofen	DL-Propranolol
Bupirone	Imipramine	D-Pseudoephedrine
Caffeine	Iproniazid	Quinacrine
Cannabidiol	(-) Isoproterenol	Quinidine
Chloralhydrate	Isoxsuprine	Quinine
Chloramphenicol	Ketoprofen	Ranitidine
Chlordiazepoxide	Labetalol	Riboflavin
Chloroquine	Lidocaine	Salicylic acid
Chlorothiazide	Lithium Carbonate	Serotonin (5-Hydroxytyramine)
(±) Chlorpheniramine	Loperamide	
Chlorpromazine	Maprotiline	Secobarbital
Chlorprothixene	Meperidine	Sodium chloride
Cholesterol	Mephentermine	Sulfamethazine
Clomipramine	Meprobamate	Sulindac
Clonidine	D-Methamphetamine	Tetracycline
Cocaethylene	L-Methamphetamine	Tetrahydrocortisone, 3 Acetate
Cocaine hydrochloride	Methaqualone	
Codeine	Methadol	Tetrahydrocortisone 3 (β-D glucuronide)
Cortisone	Methoxyphenamine	Tetrahydrozoline
(-) Cotinine	Methylphenidate	
Creatinine	(+/-)-3,4-Methylene	Theophylline
Deoxycorticosterone	Dioxyamphetamine	Thiamine
(-)-Deoxyephedrine	Methyprylon	Thioridazine
Dextromethorphan	Nalidixic acid	L-Thyroxine
Diazepam	Naloxone	Tolbutamide
Diclofenac	Naltrexone	Trans-2-phenylcyclopropylamine
Diflunisal	α-Naphthaleneacetic acid	Trazodone
Digoxin	Naproxen	Trimethobenzamide
4-Dimethylaminoantipyrine	Niacinamide	Triamterene
Diphenhydramine	Nifedipine	Trifluoperazine
Doxylamine	Normorphone	Trimethoprim
Ecgoinine hydrochloride	Nimesulide	Trimipramine
Ecgoinine methylester	Norethindrone	Tryptamine
EDDP	Noscapine	DL-Tryptophan
EMDP	D,L-Octopamine	Tyramine
Ephedrine	Orphenadrine	DL-Tyrosine
(-) γ- Ephedrine	Oxalic acid	Uric acid
[1R,2S](-) Ephedrine	Oxazepam	Verapamil
(+/-) Epinephrine	Oxolinic acid	Zomepirac

## BIBLIOGRAPHY

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2. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

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