INSTANT-VIEW® Propoxyphene (PPX) Urine Test *(Cassette)* CE

One Step Assay
Rapid Visual Results
For Qualitative In Vitro Diagnostic Use

INTENDED USE
This device is a one-step immunoassay intended for use in the rapid qualitative detection of propoxyphene and its metabolite, norpropoxyphene, in human urine at a cutoff concentration of 300 ng/ml. It is for health care professional use only.

This assay provides only a preliminary 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 obtained.

SUMMARY AND EXPLANATION OF THE TEST
Propoxyphene is a prescription drug for the relief of pain. Propoxyphene hydrochloride (Darvon, Dolene, and others) is available in 32mg and 65mg capsules; propoxyphene napsylate (Darvon-N) is available in 100mg tablets or as a suspension. It is structurally related to methadone. Overdose of the drug can affect the brain region and cause euphoria as many opioids do. The progressive symptomatology of propoxyphene includes analgesia, stupor, respiratory depression, and coma, etc. The half-life of propoxyphene is 8-24 hours. Following oral administration, propoxyphene reaches its peak in 1 to 2 hours. There is great variability between subjects in the rate of clearance. The percentage of excreted unchanged propoxyphene in urine is less than 1%. The major metabolite of propoxyphene is norpropoxyphene. Therefore, the detection of norpropoxyphene is widely used for the testing of propoxyphene abuse. The half-life of norpropoxyphene is about 30 hours, and its accumulation with repeated doses may be responsible for some of the toxicity observed.

PRINCIPLE OF THE PROCEDURE
This assay is a one-step lateral flow chromatographic immunoassay. The test strip includes 1) a burgundy-colored conjugate pad containing mouse anti-propoxyphene antibodies coupled to colloidal gold; and 2) nitrocellulose membrane containing a Test (T) line and a Control (C) line. The Test line is coated with propoxyphene-BSA, and the Control line is coated with goat anti-rabbit IgG antibody.

This test is a competitive binding immunoassay. The propoxyphene and/or norpropoxyphene the urine specimen competes with the propoxyphene–BSA antigen coated on the nitrocellulose membrane for the limited binding sites of the conjugated anti-propoxyphene antibodies.

When an adequate amount of urine specimen is applied to the sample pad of the device, the urine specimen migrates by capillary action through the test strip. If the level of propoxyphene and/or norpropoxyphene in the urine specimen is below the cutoff (300 ng/ml), the Test line should appear as a visible burgundy line. If the level of propoxyphene and/or norpropoxyphene in the urine specimen is at or above the cutoff, no Test line develops.

The C line binds to the gold-conjugated rabbit IgG and forms a burgundy color line regardless of the presence of propoxyphene and/or norpropoxyphene.

REAGENTS AND MATERIALS SUPPLIED
- 25 test devices, each in a pouch with a dropper pipette.
- 1 package insert (Instructions for Use)

MATERIAL REQUIRED BUT NOT PROVIDED
- Specimen collection containers
- Timer

STORAGE AND STABILITY
Store the kit at room temperature 15-30°C (59-86°F). Each device may be used until the expiration date printed on the label if it remains sealed in its foil pouch.

Do not freeze and/or expose the kit to temperatures over 30°C (86°F). **15°C**  **30°C**

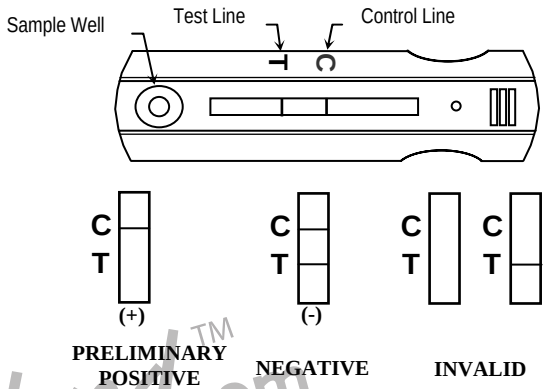
SPECIMEN COLLECTION
1. Each urine specimen must be collected in a clean container. Do not mix specimens.
2. Specimens may be kept at 15-30°C (59-86°F) for 8 hours, at 2-8°C for up to 3 days and at -20°C or lower for long term storage.

PRECAUTION
1. The instructions must be followed exactly to obtain accurate results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Do not use expired devices.
4. Dispose of all specimens and used assay materials as potentially biohazardous.

ASSAY PROCEDURE
1. Refrigerated specimens and other test materials, including devices, **must be equilibrated to room temperature before testing.**
2. Remove the test device from pouch and place it on a flat surface. Label the device with specimen identification.
3. Holding the dropper vertically, add four drops of the specimen to the sample well.
4. Read the test result between four (4) to seven (7) minutes after adding the specimen.

INTERPRETATION OF RESULTS

***IMPORTANT*: Do not read test results after seven (7) minutes. The T Line should always be interpreted independently of the C Line.**



Positive:
If only the C line appears, the test indicates that the propoxyphene and/or norpropoxyphene level in the sample is at a cutoff of 300 ng/ml or higher.
Samples with preliminary positive results should be confirmed with a more specific method before a positive conclusion is made.

Negative:
If both C line and T line appear, the test indicates that the propoxyphene and/or norpropoxyphene level is below 300 ng/ml.
Note: A faint T line should be considered negative.

Invalid:
If no C line develops within 5 minutes, repeat the assay with a new test device.

QUALITY CONTROL
- **Built-in Control Features**
  This test contains a built-in control feature, the C line. The presence of the C line indicates that an adequate sample volume was used and that the reagents migrated properly. If a C line does not form, the test is considered invalid. In this case, review the whole procedure and repeat the testing with a new device.
- **External Quality Control**
  Users should always follow the appropriate federal, state, and local guidelines concerning the running of external quality controls. SAMHSA recommends that the concentration of drug(s) in positive and negative controls be approximately 25% above and below the cutoff concentration of the assay.

LIMITATIONS
1. This test is for *professional in vitro* diagnostic use only.
2. Results obtained by this device provide only a preliminary qualitative result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result.
3. This product is designed for testing human urine only.
4. Adulterants such as bleach or other strong oxidizing agents may produce erroneous test results. When suspected, collect a fresh specimen and repeat the test with a new device.
5. Samples in which bacterial contamination is suspected should not be used. These contaminants may interfere with the test and cause false results.

EXPECTED VALUES
This test is capable of detecting PPX at a cutoff level of 300 ng/ml or higher.

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PERFORMANCE CHARACTERISTICS

1. Accuracy

The accuracy of this device was determined by a comparison study between the Propoxyphene (PPX) Urine Test and the GC/MS. This study was conducted in house, using one hundred (100) blind labeled clinical urine specimens. The detailed data is listed in this section.

The results agreed 100% with the GC/MS data of specimens at the levels below the cutoff (negative) and above 125% of the cutoff (positive). Two (2) discrepancies were observed on the specimens at the level between the cutoff and 125% of the cutoff.

The overall agreement was 98%.

		PPX Test		Total	Agreement
		Positive	Negative		
GC/MS (ng/ml)	Drug-free	0	40	40	100%
	<75% (0-225)	0	10	10	100%
	75%-Cutoff (225-300)	0	10	10	100%
	Cutoff-125% (300-375)	8	2	10	80%
	Positive (>375)	30	0	30	100%
Total		38	62	100	98%

2. Reproducibility

Off-site Evaluation

The reproducibility study on this device was performed off-site at three (3) Physician's Office Laboratories (POL) and a clinical reference laboratory by personnel with diverse educational backgrounds and working experiences. One hundred and twenty (120) propoxyphene-spiked urine samples consisting of six different levels of propoxyphene: 0, 110, 231, 332, 484, and 1069 ng/ml (determined with GC/MS), were used for this study. All samples were blind labeled.

The four evaluation sites had the same results for each of the ninety-five (95) samples at levels lower than 75% of the cutoff (0 and 110 ng/ml) and higher than the cutoff (332, 484, and 1069 ng/ml). Different results were obtained at the four sites for three (3) out of twenty-five (25) samples at the level around 75% of the cutoff (231 ng/ml), as shown in the following table. Therefore, the results from the four sites agreed 97.5% (117/120) with each other, indicating a high reproducibility of the test.

ID	Expected Result	Conc. (ng/ml)	POL #1	POL #2	POL # 3	Ref. Lab
2	-	231	-	-	+	+
23	-	231	+	-	+	-
103	-	231	-	-	-	+

In-house Evaluation

The precision of the device was determined by replicate assays with three different lots. Specimens used in this study were the same as used in the accuracy study. The devices were tested for five consecutive days five times each, for a total of 25 assays for each control. The results obtained indicate 100% precision for the replicate within each lot and no appreciable inter-lot variation occurred across the three different lots of devices.

3. Cross-Reactivity

Cross-reactivity of the propoxyphene structurally related compounds were evaluated with this device. The following compounds were spiked into known drug-free urine pools and then tested.

Propoxyphene and its major metabolite, norpropoxyphene, have a similar positive response at the concentration of 300 ng/ml. Other compounds tested produced positive responses at a very high concentration: methadone at 1,350,000 ng/ml and the metabolite of methadone (EDDP) at 200,000ng/ml.

Drugs or Compounds	Concentration
Propoxyphene	300 ng/ml
Norpropoxyphene	300 ng/ml
Methadone	1,350,000 ng/ml
2-ethyl-1,5-dimethyl-3,3-diphenylpyrroline (EDDP, Methadone Metabolite)	200,000 ng/ml

4. Interference

To determine the interference of structurally unrelated analytes, the following analytes were spiked into known drug-free urine pools, as well as the Norpropoxyphene positive urine pools (containing 300 ng/ml Norpropoxyphene), and then tested. Neither negative nor positive results were interfered by the analytes at the concentrations listed in the following table:

Compound	Conc.	Compound	Conc.
Acetaminophen	100 µg/ml	Nortriptyline	100 µg/ml
Acetylsalicylic Acid	100 µg/ml	Oxalic Acid	100 µg/ml
Amikacin	100 µg/ml	Oxazepem	100 µg/ml
Amitriptyline	100 µg/ml	Penicillin-G	100 µg/ml
Ampicillin	100 µg/ml	Pheniramine	100 µg/ml
Arterenal	100 µg/ml	Phencyclidine	100 µg/ml
Atropine	100 µg/ml	Phenylpropanalamine	100 µg/ml
Benzoic Acid	100 µg/ml	Ranitidine	100 µg/ml
Benzoylecgonine	100 µg/ml	Secobarbital	100 µg/ml
Caffeine	100 µg/ml	Salicylic Acid	100 µg/ml
(+)-Chlorpheniramine	100 µg/ml	11-nor-Δ^9-THC-9-COOH	100 µg/ml
(+/-)-Chlorpheniramine	100 µg/ml		
Cocaine	100 µg/ml	Thioridazine	100 µg/ml
Codeine	100 µg/ml	Trifluoperazine	100 µg/ml
Cortisone	100 µg/ml		
Cyclobenzaprine	400 µg/ml	Albumin	200 µg/ml
Desipramine	200 µg/ml	Bilirubin	100 µg/ml
Dextromethorphan	100 µg/ml	Creatine	100 µg/ml
Doxylamine	200 µg/ml	Glucose	100 µg/ml
Imipramine	200 µg/ml	Hemoglobin	200 µg/ml
Morphine	100 µg/ml	PH	4.5-8.5
Morphine-3-b-D-glucuronide	100 µg/ml	Vitamin C	100 µg/ml
		Uric Acid	100 µg/ml

There is a possibility that other substances and/or factors not listed may interfere with the test and cause false results.

Effect of Specific Gravity: Eight (8) human urine specimens with the specific gravity ranging from 1.002 to 1.035 g/ml were collected in house. Each was spiked with Norpropoxyphene to three levels, 225, 375, and 450ng/ml. All those specimens were tested with the Propoxyphene (PPX) Urine Test, separately. The results indicated that the specific gravity of urine, ranging from 1.002 to 1.035, did not affect the performance of the Propoxyphene (PPX) Urine Test.

REFERENCES

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- Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, Fed. Register. 53 (69): 11970 (1988).

15°C 30°C	Temperature limitation		Use by YYYY-MM
LOT	Batch/Lot code	IVD	*In vitro* diagnostic medical device
	Manufacturer	REF	Catalog number
Σ n	Contains sufficient for < n > tests		Consult instructions for use
	For IVD performance evaluation only	2	Do not reuse
	Caution, consult accompanying documents	CE	CE Mark

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San Diego, CA 92121
tel 858-481-5031
toll free 888-882-7739
www.cliawaived.com