DRI® Propoxyphene Assay

Thermo SCIENTIFIC

IVD **For In Vitro Diagnostic Use**

REF 10018510 (3 x 18 mL Kit)
0432 (100 mL Kit)
0433 (500 mL Kit)

Intended Use
The DRI® Propoxyphene Assay is intended for qualitative and semiquantitative determination of propoxyphene in human urine.

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) is the preferred confirmatory method.[1,2] Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Summary and Explanation of the Test
Propoxyphene (Darvon), a narcotic analgesic, is one of the most commonly prescribed drugs in the United States for the treatment of mild to moderate pain. It is also dispensed in a common formulation with other analgesics such as aspirin and acetaminophen. Use of propoxyphene can produce central nervous system depression effects similar to those of opioids. The side effects associated with the use of propoxyphene include nausea, vomiting, constipation, abdominal pain and drowsiness. Accidental or intentional overdose of propoxyphene may lead to convulsion, delusion, hallucination, confusion, cardiovascular collapse, respiratory depression, and in severe cases, may cause death.[1-3] When propoxyphene is ingested, it is rapidly metabolized and excreted into urine as norpropoxyphene with only about 20% reaching systemic circulation as unchanged drug.[4,5] Detection of propoxyphene or its metabolite in urine indicates use of propoxyphene.

Various assay techniques are available for propoxyphene determination.[6,7] However, these test methods are laborious and not suitable for high volume screening test application.

The DRI Propoxyphene Assay is a homogeneous enzyme immunoassay[8] using ready-to-use liquid reagents. The assay uses specific antibodies, which can detect propoxyphene in urine. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of drug from the sample, the specific antibody binds the drug-labeled G6PDH and the enzyme activity is inhibited. This phenomenon creates a relationship between drug concentration in urine and the enzyme activity. The enzyme G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Materials Provided
Antibody/Substrate Reagent:
Contains monoclonal anti-propoxyphene antibodies, glucose-6-phosphate (G6P) and nicotinamideadenine dinucleotide (NAD) in Tris buffer with sodium azide as a preservative.
Enzyme Conjugate Reagent:
Contains propoxyphene derivative labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

Additional Material Required (sold separately):

REF	Kit Description
1664	DRI Negative Calibrator, 10 mL
1388	DRI Negative Calibrator, 25 mL
1588	DRI Multi-Drug Urine Calibrator 1, 10 mL
1589	DRI Multi-Drug Urine Calibrator 1, 25 mL
1591	DRI Multi-Drug Urine Calibrator 2, 10 mL
1592	DRI Multi-Drug Urine Calibrator 2, 25 mL
1594	DRI Multi-Drug Urine Calibrator 3, 10 mL
1595	DRI Multi-Drug Urine Calibrator 3, 25 mL
1597	DRI Multi-Drug Urine Calibrator 4, 10 mL
1598	DRI Multi-Drug Urine Calibrator 4, 25 mL
100200	MGC Primary DAU Control Set, 3 x 5 mL each (high and low)

⚠ Precautions and Warnings
This test is for in vitro diagnostic use only. The components are harmful if swallowed.

Reagents used in the assay components contain ≤ 0.09% sodium azide. Avoid contact with skin and mucous membranes. Refer to SDS for additional precautions, handling instructions, and accidental exposure treatment.

BSA ✖ The reagents contain ≤ 0.2% bovine serum albumin (BSA). Avoid contact with skin and mucous membranes. Avoid inhalation. May cause skin or inhaled allergic reaction. Refer to SDS for additional precautions, handling instructions, and accidental exposure treatment.

Do not use the reagents beyond their expiration dates.

Reagent Preparation and Storage
The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly at 2-8°C, are stable until the expiration date indicated on the label.

In the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, and state regulations.

In the case of damaged packaging on arrival, contact your technical support representative (refer to back page of this PI).

Specimen Collection and Handling
Collect urine specimens in clean glass or plastic containers. Testing fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs recommends that specimens that do not receive an initial test within 7 days of arrival at the laboratory should be placed into secure refrigeration units.

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

An effort should be made to keep pipetted samples free of gross debris. It is recommended that highly turbid specimens be centrifuged before analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure
Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Refer to the specific application instructions of each analyzer for chemistry parameters before performing the assay.

Quality Control and Calibration
Qualitative analysis
For qualitative analysis of samples, use the 300 ng/mL calibrator as a cutoff level. The DRI Multi-Drug Urine Calibrator 2, which contains 300 ng/mL propoxyphene, is used as a cutoff reference for distinguishing "positive" from "negative" samples.

Semiquantitative analysis
For semiquantitative analysis, use all calibrators.

Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Use controls near the cutoff calibrator to validate the calibration. Control results must fall within the established range. If results fall outside of the established range, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Results and Expected Values
Qualitative results
A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Semiquantitative results
A rough estimate of drug concentration in the samples can be obtained by running a standard curve with all calibrators and quantitating samples off the standard curve.

Limitations
1. A positive result for this assay indicates only the presence of propoxyphene and does not necessarily correlate with the extent of psychological effects.
2. A positive result by this assay should be confirmed by another nonimmunological method such as GC or GC/MS.
3. The test is designed for use with human urine only.
4. It is possible that other substances and or factors (e.g., technical or procedural) not listed in the specificity table may interfere with the test and cause false results.

Typical Performance Characteristics

Typical performance results obtained on the Indiko analyzer.[10] The results obtained in your laboratory may differ from these data.

Precision

Control samples were tested in qualitative and semiquantitative mode. The samples were tested in replicates of 2, twice per day for 20 days, total N = 80. The results are presented in the following tables:

Qualitative

Level	Low Control	Cutoff Cal	High Control
Mean (mA/min)	324.4	379.7	422.5
Within-run SD (mA/min)	2.3	2.6	1.9
Within-run CV%	0.7	0.7	0.4
Total-run SD (mA/min)	5.3	5.4	5.4
Total-run CV%	1.6	1.4	1.3

Semiquantitative

Level	Low Control	Cutoff Cal	High Control
Mean (ng/mL)	214.3	294.2	367.8
Within-run SD (ng/mL)	3.1	4.0	3.6
Within-run CV%	1.4	1.4	1.0
Total-run SD (ng/mL)	5.6	6.0	6.8
Total-run CV%	2.6	2.0	1.9

Typical performance results obtained on the Hitachi 717 analyzer.[10] The results obtained in your laboratory may differ from these data.

Sensitivity

Sensitivity, defined as the lowest propoxyphene concentration that can be differentiated from the negative sample with 95% confidence, is 15 ng/mL.

Accuracy

One hundred and twenty six urine samples were tested with a commercially available EIA assay and DRI Propoxyphene Assay. Fifty-nine samples were negative and fifty-seven were positive by both assays indicating a 92% concordance between the two assays. The fifty-seven positive samples were confirmed by a GC/MS technique to contain propoxyphene in excess of 300 ng/mL. Ten discrepant samples were all borderline samples.

Specificity

Various potentially interfering substances were tested for cross-reactivity in the assay. The following table summaraizes the results obtained at the concentrations tested for each potential cross-reactant.

Compound	Concentrations Tested (ng/mL)
Propoxyphene	300
Norpropoxyphene	500
Acetaminophen	1,000,000
Acetylsalicylic acid	1,000,000
Amitriptyline	50,000
d-Amphetamine	1,000,000
Benzoylecgonine	1,000,000
Caffeine	100,000
Carbamazepine	20,000
Chlorpromazine	10,000
Codeine	500,000
Dextromethorphan	200,000
Doxylamine	100,000
Imipramine	100,000
Methadone	100,000
Methaqualone	500,000
Morphine	200,000
Nortriptyline	50,000
Oxazepam	300,000
Phencyclidine	400,000

Table continued

Compound	Concentrations Tested (ng/mL)
Pheniramine	100,000
Phenobarbital	1,000,000
Phenytoin	40,000
Primidone	24,000
Secobarbital	1,000,000
Theophylline	40,000
Valproic Acid	150,000

References

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8. Rubenstein KE, Schneider RS, and EF Ullman: Homogeneous Enzyme Immunoassay: A New Immunochemical Technique. Biochem Biophys Res Commun 47:846-851, 1972.
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10. Data on file at Microgenics, a part of Thermo Fisher Scientific.

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