

DRI™ Propoxyphene Assay

IVD For In Vitro Diagnostic Use

Rx Only

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 immunoassay⁸ 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 mouse 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.

DANGER: 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.

The reagents contain ≤0.2% bovine serum albumin (BSA) and ≤0.5% Drug-specific antibody. 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.

H317 - May cause allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms; Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

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 plastic or glass containers.

Specimens kept at room temperature that do not receive initial test within 7 days⁹ of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8°C for up to 3 months.¹⁰ For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.^{10, 11}

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

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.¹²

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to 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 Hitachi 717 analyzer.⁵ The results obtained in your laboratory may differ from these data.

Precision

The within run and run to run precision were evaluated with negative, 300 ng/mL and 1000 ng/mL propoxyphene using a Hitachi 717 analyzer. The following results were obtained:

Sample	Within Run Precision		
	n	Mean	% CV
Negative	10	227	1.0%
300 ng/mL	10	325	0.9%
1000 ng/mL	10	400	1.0%

Sample	Run-to-Run Precision		
	n	Mean	% CV
Negative	10	226	1.4%
300 ng/mL	10	327	0.9%
1000 ng/mL	10	400	0.8%

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 summarizes the results obtained at the concentrations tested for each potential cross-reactant. The compounds listed in the table below produced a result approximately equivalent to the cutoff calibrator.

Table 1. Structurally related compounds that produce a positive result at the listed concentrations.

Compound	Concentrations Tested (ng/mL)
Propoxyphene	300
Norpropoxyphene	1400

Table 2. Structurally related and unrelated compounds that produce a negative result at the listed concentrations.

Compound	Concentrations Tested (ng/mL)
Acetaminophen	1,000,000
Acetylsalicylic acid	1,000,000
d-Amphetamine	1,000,000
Benzoylcegonine	1,000,000
Caffeine	100,000
Chlorpromazine	10,000
Codeine	500,000
Dextromethorphan	200,000
Doxylamine	100,000
Imipramine	100,000
Methadone	100,000
Methaqualone	500,000
Morphine	200,000
Oxazepam	300,000
Phencyclidine	400,000
Pheniramine	100,000
Phenobarbital	1,000,000
Secobarbital	1,000,000

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.
9. Data on file at Microgenics, a part of Thermo Fisher Scientific.
10. Gonzales E, Ng G, Pesce A, West C, West R, Mikel C, Latyshev S, Almazan P. Stability of painrelated medications, metabolites, and illicit substances in urine. *Clinical Chimica Acta* 416 (2013) 80-85.
11. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
12. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines; Federal Register, Substance Abuse and Mental Health Administration (SAMHSA)*, (1994) 110 (June 9):11983.

Glossary:

<http://www.thermofisher.com/symbols-glossary>



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