

Catalog No.: 0160 (100 mL Kit)
0161 (500 mL Kit)

Intended Use

The DRI® Phencyclidine Assay is intended for the qualitative and semiquantitative determination of phencyclidine 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

Phencyclidine (PCP) was originally made available as a surgical anesthetic agent, but it was removed from clinical use due to undesirable side effects both during surgery and in recovery.³ The illicit use of the drug produces clinical symptoms ranging from confusion, disorientation, stupor, coma and death in cases of overdose.^{4,5}

The DRI Phencyclidine Assay is a homogeneous enzyme immunoassay using ready-to-use liquid reagents.⁶ The assay is based on the competition of a drug labeled with enzyme, glucose-6-phosphate dehydrogenase (G6PDH), 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 with G6PDH and the enzyme activity is inhibited. This phenomenon creates a direct relationship between the drug concentration in urine and the enzyme activity. The G6PDH activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

Reagents

Antibody/Substrate Reagent. Contains monoclonal anti-phencyclidine antibodies, glucose-6-phosphate (G6P) and nicotinamide adenine nucleotide (NAD) in Tris buffer with sodium azide as a preservative.

Enzyme Conjugate Reagent. Contains phencyclidine labeled with glucose-6-phosphate dehydrogenase (G6PDH) in Tris buffer with sodium azide as a preservative.

Additional Materials Required (sold separately):

Catalog No. 1664 DRI Negative Calibrator, 10 mL
1388 DRI Negative Calibrator, 25 mL
1588 DRI MultiDrug Calibrator 1, 10 mL
1589 DRI MultiDrug Calibrator 1, 25 mL
1591 DRI MultiDrug Calibrator 2, 10 mL
1592 DRI MultiDrug Calibrator 2, 25 mL
1594 DRI MultiDrug Calibrator 3, 10 mL
1595 DRI MultiDrug Calibrator 3, 25 mL
1597 DRI MultiDrug Calibrator 4, 10 mL
1598 DRI MultiDrug Calibrator 4, 25 mL
1599 DRI MultiDrug Urine Control 1, 10 mL
1553 DRI MultiDrug Urine Control 1, 25 mL
1600 DRI MultiDrug Urine Control 2, 10 mL
1555 DRI MultiDrug Urine Control 2, 25 mL

Precautions and Warnings

1. This test is for in-vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagents used in the assay components contains sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with a large volume of water to prevent azide build-up.
3. 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 at 2-8°C, are stable until the expiration date indicated on the label.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested.

The Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines recommends that specimens that do not receive an initial test within 7 days of arrival in 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.

Before performing the assay, refer to the analyzer-specific protocol sheet, which contains parameters and/or additional instructions for use.

Quality Control and Calibration

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.

Qualitative analysis

For qualitative analysis of samples, use the 25 ng/mL calibrator as a cutoff level. The DRI® MultiDrug Urine Calibrator 2, which contains 25 ng/mL phencyclidine, is used as a cutoff reference for distinguishing “positive” from “negative” samples.

Semiquantitative analysis

For semiquantitative analysis, use all calibrators.

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

Specific Performance Characteristics

Typical performance data results obtained on the Hitachi 717 analyzer are shown below.⁷

Precision

The Negative, 20 ng/mL control, 25 ng/mL calibrator, 35 ng/mL control and 100 ng/mL calibrator were assayed, and the following results were obtained:

Calibrator or Control	Within-run (n=20)		Run-to-run (n=12)	
	Mean \pm SD (mA/min)	% CV	Mean \pm SD (mA/min)	% CV
Negative	315 \pm 2.5	0.8	316 \pm 1.9	0.6
20 ng/mL	378 \pm 2.3	0.6	380 \pm 3.4	0.9
25 ng/mL	400 \pm 2.0	0.5	400 \pm 2.4	0.6
35 ng/mL	426 \pm 1.3	0.3	425 \pm 4.3	1.0
100 ng/mL	502 \pm 2.0	0.4	501 \pm 4.5	0.9

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative urine with 95% confidence, is 5 ng/mL.

Accuracy

Two hundred and eight clinical urine specimens were tested with a commercially available EIA assay and DRI® Phencyclidine Assay. There was 100% agreement between the two methods. Ninety-five samples were positive and one hundred thirteen were negative by both assays. In addition, all ninety-five positive samples were confirmed positive by the GC/MS method.

Specificity

Various potentially interfering substances were tested for cross-reactivity in the assay. The compounds listed in the table below produced a negative result at the concentration tested.

Compound	Concentrations Tested (ng/mL)
Acetaminophen	1,000,000
Acetylsalicylic acid	1,000,000
Amobarbital	1,000,000
Amphetamine	1,000,000
Brompheniramine	50,000
Chlorpheniramine	50,000
Dextromethorphan	1,000,000
Diphenhydramine	100,000
EMDP	100,000
Imipramine	500,000
Ketamine	100,000
Meperidine	50,000
Methaqualone	100,000
Methadone	1,000,000
Metronidazole	1,000,000
Morphine	200,000
Naltrexone	10,000
Orphenadrine	200,000
Oxazepam	100,000
Phenobarbital	1,000,000
1-Phenylcyclohexylamine	50,000
1-Piperidinocyclohexane Carbonitrile (PCC)	100,000
Promethazine	100,000
Thioradazine	80,000
Triprolidine	10,000

References

1. *Urine Testing for Drug of Abuse*. National Institute on Drug Abuse (NIDA) Research Monograph 73 (1986).
2. *Mandatory Guidelines for Federal Workplace Drug Testing Programs*. National Institute on Drug Abuse. Federal Register **53**, No 69, pp 11970 (1988).
3. Ober RE, Gwynn GW, Chang T, McCarthy DA and AJ Glazko, *Metabolism of Sernyl*. Federation Proc **22**, 539 (1963).
4. Burns RS and SE Lerner. Perspectives: *Acute Phencyclidine Intoxication*. Clin Toxi **9**, 477 (1976).
5. Lundberg GC, Gupta RC and SH Montgomery. *Phencyclidine: Patterns Seen in Street Drug Analysis*. Clin Toxi **9**, 503 (1976).
6. Rubenstein KE, Schneider RS and EF Ullman. *Homogeneous Enzyme Immunoassay: A New Immunochemical Technique*. Biochem Biophys Res Commun **47**, 846 (1972).
7. Data on file at Microgenics Corporation.

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