DRI® Phencyclidine Assay

thermo scientific

IVD **For In Vitro Diagnostic Use**

Read Highlighted Changes: Revised August 2021

Rx Only

REF 10014673 (3 x 18 mL)
0160 (100 mL Kit)
0161 (500 mL Kit)

Intended Use
The DRI® Phencyclidine Assay is intended for the qualitative and semi-quantitative 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Phencyclidine (PCP) was originally made available as a surgical anesthetic agent, but it was removed from clinical use due to undesirable side effects both during surgery and in recovery.[3] The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 mouse 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):

REF	Kit Description
1664	DRI Negative Calibrator, 10 mL
1388	DRI Negative Calibrator, 25 mL
1588	DRI Multi-Drug Calibrator 1, 10 mL
1589	DRI Multi-Drug Calibrator 1, 25 mL
1591	DRI Multi-Drug Calibrator 2, 10 mL
1592	DRI Multi-Drug Calibrator 2, 25 mL
1594	DRI Multi-Drug Calibrator 3, 10 mL
1595	DRI Multi-Drug Calibrator 3, 25 mL
1597	DRI Multi-Drug Calibrator 4, 10 mL
1598	DRI Multi-Drug Calibrator 4, 25 mL
DOAT-2	MAS® DOA Total – Level 2, 6 x 18 mL
DOAT-3	MAS® DOA Total – Level 3, 6 x 18 mL
DOAT-4	MAS® DOA Total – Level 4, 6 x 18 mL
DOAT-5	MAS® DOA Total – Level 5, 6 x 18 mL

⚠ Precautions and Warnings
DANGER
1. This test is for in-vitro diagnostic use only. The reagents are harmful if swallowed.
2. Reagents used in the assay components contain ≤0.09% sodium azide, ≤0.2% bovine serum albumin (BSA) and ≤0.5% Drug-specific antibody (Mouse). Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.
3. Do not use the reagents beyond their expiration dates.

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.

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.

Specimens kept at room temperature that do not receive initial test within 7 days[7] of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8°C for up to six months.[7] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[8, 9]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[10]

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

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
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 ranges, as determined by laboratory procedures and guidelines. If results fall outside of the established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own calibration and control.

Qualitative analysis
For qualitative analysis of samples, use the 25 ng/mL calibrator as a cutoff level. The DRI Multi-Drug Urine Calibrator 2, which contains 25 ng/mL phencyclidine, is used as a cutoff reference for distinguishing "positive" from "negative" samples.

Semi-quantitative analysis
For semi-quantitative 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.

Semi-quantitative 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.

Typical Performance Characteristics

Performance data results obtained on the Hitachi 717 analyzer are shown below.[11] The results obtained in your laboratory may differ from these data.

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 ± SD (mA/min)	% CV	Mean ± SD (mA/min)	% CV
Negative	315 ± 2.5	0.8	316 ± 1.9	0.6
20 ng/mL	378 ± 2.3	0.6	380 ± 3.4	0.9
25 ng/mL	400 ± 2.0	0.5	400 ± 2.4	0.6
35 ng/mL	426 ± 1.3	0.3	425 ± 4.3	1.0
100 ng/mL	502 ± 2.0	0.4	501 ± 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	1,000,000
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 Drugs 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. Hughes R, Hughes A, Levin B, Smith ML. Stability of Phencyclidine and Amphetamines in Urine Specimens. *Clinical Chemistry,* Vol. 37, No. 12, 1991.
8. Gonzales E, Ng G, Pesce A, West C, West R, Mikel C, Latyshev, S, Almazan P. Stability of pain-related medications, metabolites and illicit substances in urine. *Clinica Chimca Acta* 416: (2013) 30-35.
9. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
10. *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.
11. Data on file at Microgenics, a part of Thermo Fisher Scientific.

Glossary:

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

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
US Customer and
Technical Support:
1-800-232-3342

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany

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