

REF 14244-4 4 x 18 mL/9 mL

PHENCYCLIDINE QUALITATIVE (PCP)

Wedges each contain usable volumes of 18 mL of R1 reagent and 9 mL of R2 reagent.

INTENDED USE

The EasyRA Phencyclidine (PCP) reagent is intended for the qualitative determination of Phencyclidine in human urine at a cutoff value of 25 ng/mL. The assay is designed for prescription use only on the EasyRA Clinical Chemistry Analyzer. For *in-vitro* diagnostic use only.

The assay provides a rapid screening procedure for determining the presence of phencyclidine in urine. The assay provides only a preliminary qualitative result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/mass spectrometry (GC/MS) or Liquid Chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. ^{1,2} Clinical consideration and professional judgment should be exercised to any drug of abuse test result, particularly when the preliminary test result is positive.

SUMMARY AND EXPLANATION

Phencyclidine (PCP), also known as angel dust, is a potent hallucinogen and surgical anesthetic. It is no longer in clinical use due to its undesirable side effects ³. PCP and its analogs, however, are frequently mixed with marijuana or tobacco and smoked. Adverse abuse of PCP results in conditions such as tachycardia, psychosis, paranoia, and mydriasis. It could also result in death in case of overdose ^{4,5}.

PRINCIPLE OF THE PROCEDURE

The phencyclidine assay is a homogeneous enzyme immunoassay¹⁰ which provides qualitative results relative to a single calibration cutoff value. The assay is based on competition between drug in the sample and drug labeled with the enzyme glucose-6-phosphate dehydrogenate (G6PDH) for a fixed amount of antibody in the reagent. Enzyme activity decreases upon binding to the antibody, and the drug concentration in the sample is measured in terms of enzyme activity.

In the absence of drug in the sample, phencyclidine -labeled G6PDH conjugate is bound to antibody, and the enzyme activity is inhibited. On the other hand, when free drug is present in the sample, antibody will bind to free drug, and the unbound phencyclidine -labeled G6PDH then exhibits its maximal enzyme activity.

Active enzyme converts nicotinamide adenine dinucleotide (NAD) to NADH, resulting in an absorbance increase that can be measured spectrophotometrically at 340 nm.

REAGENTS

Antibody/Substrate Reagent (R1): Contains monoclonal anti-phencyclidine antibody, glucose-6-phosphate (G6P), Nicotinamide adenine dinucleotide (NAD), stabilizers and sodium azide (0.09 %) as a preservative.

Enzyme-drug Conjugate Reagent (R2): Contains phencyclidine-labeled glucose-6-phosphate dehydrogenase (G6PDH), buffer and sodium azide (0.09 %) as a preservative.

Precautions

1. This test is for in-vitro diagnostic use only. Harmful if swallowed.
2. Good laboratory safety practices should be followed when handling any laboratory reagent. (CLSI, GP17-A2).
3. Reagent contains sodium azide as a preservative, which may form explosive compounds in metal drain lines. When disposing such reagents or wastes always flush with a large volume of water to prevent azide build-up. See National Institute for Occupational Safety and Health Bulletin: Explosive Azide Hazards (8/16/76).
4. As with any diagnostic test procedure, results should be interpreted considering all other test results and the clinical status of the patient.
5. Do not use washed cuvettes.

Instructions for Reagent Handling, Storage and Stability

The reagent is ready to use as supplied. Remove the cap and place the reagent in the Medica EasyRA Chemistry Analyzer reagent tray located in the reagent area. Unopened reagent is stable until the expiration date on the label if stored at 2-8 °C. The reagent is stable on-board in the refrigerated reagent area of the Medica EasyRA Chemistry Analyzer for the number of day programmed on the RFID chip on the reagent wedge.

SPECIMEN COLLECTION AND STORAGE / STABILITY

Urine sample may be collected in plastic or glass containers. Some plastics may absorb drugs. Use of plastics such as polyethylene is recommended⁸. Use fresh urine specimen for the test. If the sample cannot be analyzed immediately, it may be stored refrigerated at 2-8°C for up to 3 days⁹. For longer storage keep sample frozen at -20°C and thaw then before use. Studies have shown that phencyclidine analytes in urine are stable at -20°C up to 12 months¹⁰. Samples should be brought to a room temperature of 18-25 °C for testing. Samples with high turbidity should be centrifuged before analysis.

Adulteration may cause erroneous results. If sample adulteration is suspected, obtain a new sample and both samples should be forwarded to the laboratory for testing. Handle all urine specimens as if they are potentially infectious.

PROCEDURE

Materials Provided:

Medica PCP Reagent Wedge, REF 14244 (Qualitative)

Additional materials required:

Medica EasyCal Phencyclidine Cutoff Calibrator (Phencyclidine Cutoff, 25 ng/mL), REF 14668

Medica EasyQC Phencyclidine Negative Control (Phencyclidine, 18 ng/mL), REF 14798

Medica EasyQC Phencyclidine Positive Control (Phencyclidine, 32 ng/mL), REF 14797

Medica Precision Test Dye Wedge, REF 10764

Medica Cleaner Wedge – Chemistry & ISE, REF 10660 or

Medica Cleaner Wedge – Chemistry, REF 10661

Medica EasyRA Evaporation Caps, REF 10745

Instructions for Use

The reagent is ready to use as supplied. Remove the cap and place the reagent in the Medica EasyRA Chemistry Analyzer reagent tray in the reagent area. Dry the neck of the reagent wedge and check the inside of the necks of the wedge for foam after removing the caps and placing the wedge on the analyzer. If there is foam, remove it with a swab or a disposable pipette before performing the test. Use separate swabs or disposable pipettes for R1 and R2. Place Medica EasyRA Evaporation Caps, REF 10745 on both the R1 and R2 openings of the reagent wedge.

NOTE: Use of the Medica EasyRA Evaporation Cap is required to guarantee on-board calibration stability.

Calibration

Medica EasyCal Phencyclidine cutoff Calibrator, REF 14668 is required for the calibration of the qualitative assay. The calibration interval (20days maximum) with Evaporation Caps is programmed on the RFID chip on the reagent wedge. Recalibration is required whenever there is a change in reagent lot number or if a shift in quality control values occurs.

Quality Control

It is recommended that two levels of human urine-based controls (positive and negative) be run with the assay at least once every day and with each reagent lot change. Failure to obtain the proper values in the assay of control material may indicate reagent deterioration, instrument malfunction, or procedural errors. The laboratory should also follow local, state, and federal quality control guidelines when using quality control materials.

Results

The cutoff calibrator which contains 25 ng/mL of phencyclidine is used as a reference for distinguishing positive from negative samples. A sample with a change in absorbance (mA/min) equal to, or greater than, that obtained with the cutoff calibrator is considered positive. A sample with a change in absorbance value lower than that obtained with the cutoff calibrator is considered negative.

Procedural Limitations

1. The test is not intended for quantifying these single analytes in samples.
2. A positive result does not necessarily indicate drug abuse.
3. A negative result does not necessarily mean a person did not take phencyclidine.
4. Care should be taken when reporting results as numerous factors (e.g., fluid intake, endogenous or exogenous interferents) may influence the urine test result.
5. Positive results should be confirmed by other affirmative, analytical chemical methods (e.g., chromatography), preferably GC/MS or LC/MS.

The test is designed for use with human urine only.

PERFORMANCE CHARACTERISTICS

The results shown below were obtained with the EasyRA analyzer.

Inaccuracy/Correlation

One hundred and seven (107) clinical urine specimens were tested qualitatively and semi-quantitatively with the EIA method on the EasyRA. All results were confirmed with LC/MS* and are summarized in the tables below.

	(<12.5ng/mL) Negative LC/MS	Near Cutoff (12.5-25.0ng/mL) Negative LC/MS	Near Cutoff (25.0-37.50ng/mL) Positive LC/MS	(>37.5ng/ml) Positive LC/MS
EasyRA Positive(>25ng/mL)	0	0	6	40
EasyRA Negative(<25ng/mL)	50	9	2	0
% Agreement Negative	100%			
% Agreement Positive	95.80%			

Imprecision(CLSI, EP5-A2)

Qualitative analysis: Nine samples of Phencyclidine spread evenly throughout the range of 0-50 ng/mL were prepared in human urine and analyzed in duplicate twice a day for 20 days. The samples were tested in qualitative mode and the absorbance change versus time was also measured for each reading. Typical results (mA/min) are as follows:

Within Run Imprecision (EP5-A2) Qualitative Results (n=80)

Samples (ng/ml)	Mean (mA/Min)	SD (mA/Min)	%CV
0	165.0	0.87	0.53%
6.25	187.0	0.95	0.51%
12.5	203.0	0.95	0.47%
18.75	213.1	0.75	0.35%
25	221.3	1.51	0.68%
31.25	226.2	1.13	0.50%
37.5	231.6	1.54	0.66%
43.75	234.9	1.14	0.49%
50	236.6	1.20	0.51%

Total Imprecision (EP5-A2) Qualitative Results (n=80)

Samples (ng/ml)	Mean (mA/Min)	SD (mA/Min)	%CV
0	165.0	2.11	1.28%
6.25	187.0	1.97	1.05%
12.5	203.0	1.89	0.93%
18.75	213.1	2.09	0.98%
25	221.3	2.63	1.19%
31.25	226.2	2.13	0.94%
37.5	231.6	2.53	1.09%
43.75	234.9	2.32	0.99%
50	236.6	2.29	0.97%

% Agreement of Qualitative Precision Results with Target Values

Samples (ng/mL)	Number Positive	Number Negative	% Agreement
0	0	80	100%
6.25	0	80	100%
12.50	0	80	100%
18.75	0	80	100%
25.00	38	42	N/A
31.25	80	0	100%
37.50	80	0	100%
50.00	80	0	100%

Specificity

Various potentially interfering substances were tested for cross-reactivity with the assay on the Hitachi 717. Test compounds were spiked into the drug-free urine calibrator matrix to various concentrations and evaluated against the cutoff calibrator. The table listed the concentration of each test compound that gave a response approximately equivalent to that of the cutoff calibrator (as positive) or the concentration of the non-barbiturate compounds tested that gave a response below the response of the cutoff calibrator (as negative).

Cross-Reactant	Concentration (ng/mL)	Cross-Reactivity
Phencyclidine	25	
	Concentration (µg/mL)	
Acetaminophen	1000	Negative
Acetylsalicylic Acid	1000	Negative
Amitriptyline	1000	Negative
Amobarbital	1000	Negative
Amphetamine	1000	Negative
Benzoylcegonine	3000	Negative
Bupropion	100	Negative
Caffeine	100	Negative

Chlorpheniramine	50	Negative
Chlorpromazine	100	Negative
Codeine	100	Negative
Dextromethorphan	1000	Negative
Diphenhydramine	100	Negative
Ephedrine	1000	Negative
Ketamine	100	Negative
Meperidine	100	Negative
Methadone	1000	Negative
Methamphetamine	1000	Negative
Methaqualone	100	Negative
Morphine	500	Negative
Naloxone	1000	Negative
Naltrexone	25	Negative
Nicotine	1000	Negative
Norpropoxyphen	100	Negative
Nortriptyline	100	Negative
Oxazepam	1000	Negative
Phenobarbital	1000	Negative
Phenylpropanolamine	1000	Negative
Primidone	1000	Negative
Promethazine	100	Negative
Propranolol	100	Negative
Propoxyphene	1000	Negative
Pseudoephedrine	1000	Negative
Ranitidine	1000	Negative
Secobarbital	1000	Negative
Thioridazine	1000	Negative
Triprolidine	150	Negative
Tyramine	1000	Negative
Valproic Acid	1000	Negative

It is possible that other substances and/or factors not listed above may interfere with the test and cause false positive results.

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 Program, National Institute on Drug Abuse, Federal Register, vol. 53, No. 69, ppl 11970 (1988).
- 3 Ober, R.E., G.W. Gwynn, T. Chang, D.A. McCarthy, and A.J. Glazko, Metabolism of Semyl, Federation Proc. 22, 539 (1963).
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- 5 Bailey, K. et al., J. Pharm. Pharmacol. 28, 713 (1976).
- 6 Rubenstein, K.E., R.S. Schneider, and E.F. Ullman, Homogeneous Enzyme Immunoassay: A New Immunochemical Technique, Biochem Biophys Res Commun, 47, 846 (1972).
7. Schumann, G.B. and S.C. Schweitzer, 1989. Examinatin of Urine. In Clinical Chemistry: Theory, Analysis and Correlation, 2nd Ed, Kaplan, L.A. and A.J. Pesce (Editors), pp 820-849.
- 8 Yahya, A.M., McElnay, J.C., and D'Arcy, P.F. Drug absorption to glass and plastics, *Drug Metabol Drug Interact*, 6(1):1-45 (1988)
- 9 Gonzales, E., et al., Stability of pain-related medications, metabolites, and illicit substances in urine, *Clinica Chimica Acta*. 416:80-85 (2013)
- 10 Dugan, S., et al., Stability of drugs of abuse in urine samples stored at -20C, *J.Anal. Toxicol*, 18(7):391-396 (1994).

EasyRA Parameters:

	Qualitative
Primary Wavelength	340
Secondary Wavelength	N/A
Reaction Type	Qual. Kinetic
Reaction Direction	Increase
Calibration Curve	Increase
Reagent Blank	N/A
Sample Blank	N/A
Reaction Time	3 Minutes
On-Board Stability	30 Days
Cal Stability	20 Days*

* with anti-evap caps

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