Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep Phencyclidine Urine RapiDip™ InstaTest

REF 121080-1-21

IVD See external Label 2-30°C ∑=1 Test

Sensitivity	25 ng/ml

INTENDED USE

The Cortez Diagnostics Inc. OneStep PCP RapiDip™ InstaTest is an immunochromatography based one step in vitro test. 10It is designed for qualitative determination of Phencyclidine in human urine specimens above a cut-off level of 25 ng/ml. This assay may be used in the point of care setting.

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) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION

Phencyclidine, commonly known as PCP, is a hallucinogen which interacts with dopamine, cholinergic and adrenergic systems. It has dose dependent stimulant, depressant, hallucinogenic and psychological effects. PCP is mostly administered by oral or intravenously. Even moderate amount of PCP, from 5 to 100 ng/ml, can result in psychotic, violent and self-destruction. At high dose, from 100 to 500 ng/ml, PCP can cause convulsions, hypertion, and even death. PCP is metabolized via hydroxylation, oxidation, and conjugateion with glucuronic acid in the liver. About 10% of the dose is excreted in urine as unchanged drug. PCP can be detected in the urine for 7 to 8 days after drug administration. For chronic users, PCP may persist in urine for 2 to 4 weeks. However, the length of time following drug use for which a positive result may occur is dependent upon several factors, including the frequency and amount of drug, metabolic rate, excretion rate, drug half-life, and the drug user's age, weight, activity, and diet.

TEST PRINCIPLE

The Cortez OneStep PCP RapiDip™ InstaTest is based on the principle of specific immunochemical reaction between antibodies and antigens to analyze particular compounds in human urine specimen. The assay relies on the competition for binding antibody between drug conjugate and free drug which may be present in the urine specimen being tested. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, 100 ng/ml, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result.

A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

SPECIMEN COLLECTION AND PREPARATION

It is required that approximately 150 µl of sample for each test. Fresh urine specimens do not need any special handling or treatment. Specimens should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8°C or frozen up to 7 days. Specimens should be thawed and brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

STORAGE

The test device should be stored at 2 to 30°C and will be effective until the expiration date stated on the package. The product is humidity-sensitive and should be used immediately after being open. Any improperly sealed product should be discarded.

PRECAUTIONS

1. For in vitro diagnostic and forensic use only.
2. Do not use the product beyond the expiration date.
3. Handle all specimens as potentially infectious.
4. Humidity sensitive product, do not open foil pouch until it is ready to be tested.
5. Use a new urine specimen cup for each sample to avoid cross contamination.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Instructions for use.
2. Cortez PCP test device. The amount of each coated antigen and/or antibody on the strip is less than 1.0 mg for antigen conjugate and is less than 1.0 mg for goat anti-mouse IgG antibody.
   Test zone: contains PCP bovine protein antigen conjugates.
   Control zone: contains Goat anti-mouse IgG antibody.
   Conjugate pad: contains mice monoclonal anti-PCP antibody.

Materials required but not provided

1. Urine collection container.
2. Timer or clock.

ASSAY PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the sealed foil pouch.
3. Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample level should not be higher than the arrow pointed maximum line.
4. Hold the strip in the urine until a reddish color appears at the test area (approximately 20 seconds).
5. Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
6. Read the results at 5 minutes after adding the sample.
   Do not interpret the result after 10 minutes.

RESULTS

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- **Negative:** Two colored bands form. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative results. The negative result indicates that the Phencyclidine concentration in the specimen is either zero or less than cut-off level.
- **Positive:** One colored band forms. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication that the Phencyclidine level in the specimen is above the cut-off level.
- **Invalid:** If there are no colored bands in control line zone, the test result is invalid. Retest the sample with a new device.

Note: A b*orderline (+/-) in test line zone be considered negative result.*

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez PCP test was evaluated in comparison to GC/MS at a cut-off of 25 ng/ml of phencyclidine. Ninety-nine urine specimens with GC/MS confirmed phencyclidine concentration were evaluated in this study. The results are summarized and presented below:

	(-)		(+)		
Cortez PCP Test	GC/MS Negative (less than –25%)	Near cutoff negative (between –25% and c/o	Near cutoff positive (between c/o and +25%	GC/MS Positive (greater than +25%)	Percent agreement with GC/MS
Positive	1	0	5	36	87.2
Negative	45	6	2	4	98.1
Total	46	6	7	40	

Positive % agreement: 87.2, Negative % agreement: 98.1.
Seven specimens were found discrepant between the Cortez PCP and GC/MS method. When compared those data, 28.6% (2 out of 7) of the discrepancy specimens were found between –25% and +25% cut-off concentration (18.8 – 31.3 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of Cortez PCP test is determined to be 25ng/ml.

C. Precision

The precision study was performed by three individuals observing the test result to determine the random error of visual interpretation. The test results were found to have no significant differences between the three observers.

Device	Control Con. ng/ml	No. of Tested	No. of positive			No. of borderline #			No. of negative		
			1*	2*	3*	1*	2*	3*	1*	2*	3*
PCP	12.5	40							40	40	40
	18.8	40							40	40	40
	25	40				39	39	39	1	1	1
	31..3	40				40	40	40			
	37..5	40	10	10	10	30	30	30			

D. Specificity

The specificity for Cortez PCP test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. The test results were found to have no significant differences between the three observers.

1. Interference Testing

The Cortez OneStep PCP RapiDip™ InstaTest test performance at cut-off level is not affected when pH and Specific Gravity ranges of urine specimen are at 4.0 to 9.0 and 1.005 to 1.035.

The following substances were tested and confirmed not to interfere with Cortez PCP test at the listed concentrations.

Glucose	2000 mg/dl,
Human albumin	2000 mg/dl
Human hemoglobin	10 mg/dl,
Urea	4000 mg/dl
Uric acid	10 mg/dl

2. Specificity

The following table lists compounds that are detected by Cortez PCP test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Con. (ng/ml)
Phencyclidine	25

Each listed substance that commonly found in the urine was evaluated and indicated negative result at concentration of 100 µg/ml.

Acetaminophen	4-Acetamidophenol	Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital	Amphetamine	Arterenol
Aspartame	Ascorbic acid	Atropine	Caffeine
Camphor	Chloroquine	Chlorpheniramine	Cortisone
Deoxyephedrine	Dextromethorphan	Digitoxin	Digoxin
Diphenhydramine	Ecgonine	Ecgonine methylester	Ephedrine
Epinephrine	Gentisic	Guaiacol glycerester	Histamine
Hydrochloro-thiazide	Homatrophine	Imipramine	Ibuprofen
Isoproterenol	Ketamine	Lidocaine	Mepredine
Methadone	Methamphetamine	3,4±MDMA	Methaquolone
Methylphenidate	Neomycin	Niacinamide	Oxazepam
Perphenazine	Penicillin G	Phenylethylamine-α	Phenylpropanolamine
Promethazine	Psuedoephedrine	Quinine antidine	Salicylic acid Tetracycline
Tetrahydrozoline	Theophyline	11-nor-d8-THC-9-COOH (10 µg/ml)	
Tyramine	Thioridazine	Trifluoperazine	Tryptophan

QUALITY CONTROL

Good Laboratory Practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

The Cortez Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

LIMITATION OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer “SPECIFICITY” section for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is

found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

EXPECTED VALUES

The Cortez Diagnostics, Inc. OneStep PCP RapiDip™ InstaTest is a qualitative assay. It identifies Phencyclidine in human urine at a concentration of 25 ng/ml or higher. The concentration of Phencyclidine cannot be determined by this assay. The test is intended to distinguish negative result from presumptive positive result. All positive results must be confirmed using an alternate method, preferably GC/MS.

REFERENCE

1. Urine testing for drugs of abuse, NIDA Research Monograph 73 (1986).
2. Steven B. Karch, Drugs of abuse hand book, CRC Press, 1st Ed. (1998).
3. Ray H. Liu and Bruce A. Goldberger, Handbook of workplace drug testing, AACC Press, Washington DC (1995).

ISO 13485 ISO 9001 **Diagnostic Automation/ Cortez Diagnostics, Inc. 21250 Califa St, Suite 102 and 116, Woodland Hills, California 91367 USA**	
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