The Cortez Diagnostics Rapicard OneStep Phencyclidine Test is a rapid, qualitative, competitive binding immunoassay for determination of phencyclidine hydrochloride in urine at or above the cutoff level of 25 ng/ml. Cortez Diagnostic’s Rapicard OneStep Phencyclidine Test is not intended to monitor drug levels, but only to screen urines for the presence of phencyclidine and its metabolites.

**Note:** The test provides only preliminary data which should be confirmed by other methods, such as gas chromatography/mass spectrometry (GC/MS). Clinical considerations and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

**SUMMARY AND EXPLANATION OF THE TEST**

The Rapicard OneStep Phencyclidine Test is an easy, fast, and visually read screening method without the need for instrumentation to arrive at a determination. The test system employs unique monoclonal and polyclonal antibodies to selectively identify phencyclidine in urine samples with a high degree of sensitivity.

Phencyclidine hydrochloride, commonly known as PCP or “angel dust,” is used primarily as a recreational drug for its hallucinogenic effects. It is generally self-administered by intravenous injection or by inhalation and concentrates fastest in fatty tissues and the brain. Excretion patterns vary widely with the individual.

Methods historically used for detecting phencyclidine in biological fluids include thin-layer chromatography, gas chromatography, ultraviolet spectroscopy, enzyme immunoassay and radioimmunoassay. While confirmation techniques other than GC/MS may be adequate for some drugs of abuse, GC/MS is generally accepted as a vigorous confirmation technique for all drugs since it provides the best level of confidence in the result.

**PRINCIPLE OF THE TEST**

The Rapicard OneStep Phencyclidine Test consists of a chromatographic absorbent device in which the drug or drug metabolites in the sample compete with a drug conjugate immobilized on a porous membrane for limited antibody sites. As the test sample flows through the absorbent device, the free drug in the specimen competes with immobilized antigen conjugate in the test zone by binding to the antibody-dye conjugate forming an antibody-antigen complex and preventing the formation of a rose-pink color band when the drug is at or above the detection level of 25 ng/ml.

In the case where free drug in the sample is below the detection level of 25 ng/ml, antibody-dye conjugate is free to bind to the immobilized antigen in the test zone, producing a rose-pink color band. Furthermore, unbound dye conjugate binds to the reagent in the control zone, producing a rose-pink color band, demonstrating that the reagents and device are functioning correctly.

A NEGATIVE specimen produces two distinct color bands, one in the test zone and one in the control zone. A POSITIVE specimen produces one color band in the control zone only.

**REAGENTS AND MATERIALS PROVIDED**

1. Test Cassette.
2. Dropper.
3. Urine Cups (optional)
4. Test Instructions

**MATERIALS REQUIRED, BUT NOT PROVIDED**

1. Clock or timer.

**WARNINGS AND PRECAUTIONS**

1. For in vitro diagnostic and professional use only.
2. Do not use test device beyond the expiration date.
3. Use a new specimen container and dropper for each test to avoid cross contamination of urine samples.
4. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.
5. Visually inspect the foil package to insure it is intact. If the package is not intact, discard the device.

**SAMPLE COLLECTION AND PREPARATION**

The sample must be collected in a clean, dry container, either plastic or glass, without preservatives. If not analyzed immediately, urine specimens may be refrigerated (2°C - 8°C) and stored up to forty-eight hours, or frozen (-20°C or below) prior to assaying. If samples are refrigerated or frozen, they should be allowed to come to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged, or allowed to settle so that clear aliquots can be obtained for testing.

Urine samples within the normal urine pH range (4.5-8.0) do not require prior adjustment of pH. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample.

**TEST PROCEDURE**

1. Bring the test components and urine sample to room temperature (15°C to 28°C).
2. Open the foil pouch by tearing along the notch and remove the test device and dropper. Place the device on a clean, flat surface.
3. Holding the dropper vertically, dispense four drops of urine (~120 µl) without air bubbles to the sample well “S.”
4. Read the result at five minutes.

**IMPORTANT:** Do not interpret a test result after more than five minutes. Waiting longer than five minutes may cause inaccurate interpretation. To avoid confusion, discard the test device after reading the result at five minutes.

**INTERPRETATION OF RESULTS**

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**IMPORTANT:** Do not interpret a test result after more than five minutes. Waiting longer than five minutes may cause inaccurate interpretation. To avoid confusion, discard the test device after reading the result at five minutes.

**INTERPRETATION OF RESULTS**
1. **Positive.** A rose-pink color band appears in the Control Zone "C", but not in the Test Zone "T". This is a positive result and indicates that the phencyclidine level is at or above the detection sensitivity of 25 ng/ml.

2. **Negative.** Two rose-pink color bands appear, one in the Control Zone "C" and one in the Test Zone "T". This is a negative result and indicates that the phencyclidine level is below the detection sensitivity of 25 ng/ml.

3. **Invalid.** No rose-pink color bands appear, or a band appears in the Test Zone "T", but not in the Control Zone "C". An invalid result may be due to improper testing procedures or deterioration of the kit components.

**Note:** There is no meaning attributed to line color intensity or width.

**QUALITY CONTROL**

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability.

The use of an external control is recommended to verify proper kit performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

**PERFORMANCE CHARACTERISTICS**

1. **Sensitivity.** The Rapicard *OneStep* Phencyclidine Test detects phencyclidine and its metabolites in urine at concentrations equal to or greater than 25 ng/ml, which is suggested by the National Institute on Drug Abuse (NIDA) for the immunoassay method.

2. **Specificity.** A study was conducted to determine the cross-reactivity of phencyclidine-related compounds with the test. Substances listed in Table-I produced results approximately equivalent to the cut-off level for phencyclidine.

A separate study was conducted with the Rapicard *OneStep* Phencyclidine Test to determine the cross-reactivity of non-phencyclidine related compounds. with the test at concentrations much higher than normally found in the urine of people using or abusing them. No cross-reactivity was detected with the substances listed in Table-II.

**Table-I: Concentration of phencyclidine-related compounds showing a positive response approximately equivalent to the phencyclidine cut off set for the test.**

<table>
<thead>
<tr>
<th>Compound</th>
<th>Concentration (ng/ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phencyclidine</td>
<td>25</td>
</tr>
<tr>
<td>N-Acetylprocainamide</td>
<td>1000</td>
</tr>
<tr>
<td>Codeine</td>
<td>5000</td>
</tr>
<tr>
<td>p-Hydroxymethamphetamine</td>
<td>50,000</td>
</tr>
<tr>
<td>Thebaine</td>
<td>10,000</td>
</tr>
<tr>
<td>1-{1-phenylcyclohexyl}-morphine (PCMI)</td>
<td>600</td>
</tr>
<tr>
<td>N,N-Diethyl-1-phenyl-Cyclohexylamine (PCDE)</td>
<td>2.0</td>
</tr>
<tr>
<td>1{1-[2-thienyl(cyclohexyl)]-morphine (TCM)</td>
<td>200</td>
</tr>
</tbody>
</table>

**Table-II: Compounds tested and found not to cross-react with the test at a 1 mg/ml concentration in urine:**

- Aspartame
- Atropine Sulfate
- Benzoic Acid
- Benzoylcegonine HCl
- Caffeine
- Chlorpheniramine
- Chlorpropazine HCl
- Cimetidine
- Deoxyxylodrine
- Dextromorphan
- Diethylpropion
- Diphenylhydantoin
- Doxylamine
- Ecgonine HCl
- Ecgonine Methyl Ester
- Glucose
- Histamine
- Hydrocodone
- Hydromorphone
- Indomethacin
- Ketoprofen
- D-9-THC
- 11-nor-D-9-carboxy-THC-9-COOH
- Meperidine
- Methylphenidate
- Methadone
- Methaqualone
- Morp. Glucuronide
- Morphine Sulfate
- Oxycodone
- Penidimetazine
- Penicillln G
- Pentobarbital
- d-Prophoxyphene Hydrochlorothiazide
- Propanol
- Phenobarbital
- Phentermine
- Phenylpropanolamine
- L-Phenylephrine
- Quinine
- Ranitidine
- Sodium Salicylate
- Tryptophan
- Tetracycline
- Tetrahydronalene
- Theophylline
- Thioridazine
3. **Accuracy.** The accuracy of the Rapicard OneStep PCP Test was first tested through an in-house study by Cortez Diagnostic and subsequently in a clinical trial submitted to a NIDA certified laboratory. Each urine specimen was tested with the Rapicard OneStep Phencyclidine Test and a commercially available test (Syva EMIT II). Positive results were confirmed by GC/MS. The results are summarized as follows:

<table>
<thead>
<tr>
<th>EMIT II Positive</th>
<th>EMIT II Negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapicard +223</td>
<td>0</td>
</tr>
<tr>
<td>Rapicard -0</td>
<td>290</td>
</tr>
</tbody>
</table>

When compared to EMIT II the relative sensitivity was 100%. The relative specificity was 100%. The concordance of the combined data with respect to EMIT II was 100%. When compared to GC/MS both screening methods reported 2 false positives and no false negatives.

4. **Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. The resultant data indicated 100% precision for the duplicates within each lot and no appreciable interlot variation when testing both positive and negative spiked samples across three (3) different lots of devices.

**LIMITATIONS OF THE TEST**

1. This product is designed for use with human urine only.

2. Although the test is very accurate in detecting phencyclidine in urine, there is a possibility false results will occur due to the presence of interfering substances in the urine and/or factors beyond the control of the manufacturer, e.g., technical or procedural errors associated with the testing.

3. The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.

4. Adulterants such as bleach or other strong oxidizing agents, when added to urine specimens, may produce erroneous test results regardless of the analysis method used. If adulteration is suspected, obtain another urine specimen and retest.

**BIBLIOGRAPHY**