One Step
Phencyclidine Test Device (Urine)
Package Insert

(Catalog Number: 1189-C)

BIOMERICA

A rapid, one step test for the qualitative detection of Phencyclidine in human urine.

For professional in vitro diagnostic use only.

INTENDED USE

The One Step Phencyclidine Test Device (Urine) is a rapid chromatographic immunoassay for the detection of phencyclidine in human urine.

SUMMARY

Phencyclidine is an arylcyclohexylamine that is used as a veterinary anesthetic. It is used illegally as a hallucinogen, and is commonly referred to as PCP, angel dust, or crystal; PCP can produce lethargy, euphoria, ataxia, nystagmus and coma. Phencyclidine is readily absorbed when smoked or ingested, or even through skin contact. It is metabolized in the liver. About 10% of the dose is excreted in urine as the parent compound, phencyclidine.

The One Step Phencyclidine Test Device (Urine) is a rapid urine screening test that can be performed without the use of an instrument. The test utilizes a monoclonal antibody to selectively detect elevated levels of phencyclidine in urine. The One Step Phencyclidine Test Device (Urine) yields a positive result when the phencyclidine in urine reaches 25 ng/mL. This is the suggested screening cut-off for positive specimens set by the Substance Abuse and Mental Health Services Administration (SAMHSA, USA).

PRINCIPLE

The One Step Phencyclidine Test Device (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against the drug conjugate for binding sites on the antibody.
During testing, a urine specimen migrates upward by capillary action. Phencyclidine, if present in the urine specimen below 25 ng/mL, will not saturate the binding sites of antibody coated particles in the test device. The antibody coated particles will then be captured by immobilized phencyclidine conjugate and a visible colored line will show up in the test line region. The colored line will not form in the test line region if the phencyclidine level is at or above 25 ng/mL because it will saturate all the binding sites of antibodies.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition.

To serve as a procedural control, a colored line will always appear at the control line region if the test has been performed properly.

REAGENTS

The test device contains anti-phencyclidine particles and phencyclidine conjugate coated on the membrane.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The test device should be discarded in a proper biohazard container after testing.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at 4-30°C. The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear supernatant for testing.

Specimen Storage

Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed before testing.

PROCEDURE

Materials Provided

- Test devices
- Disposable droppers
- Package insert

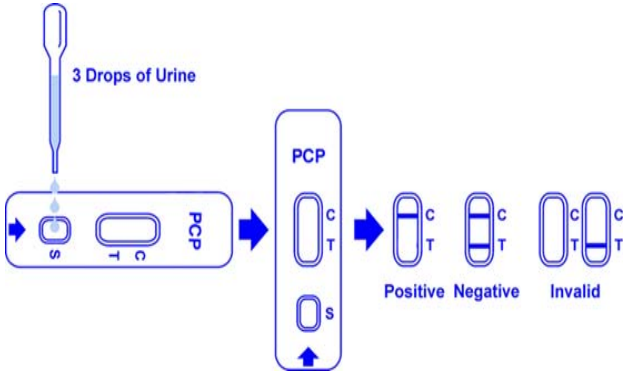
Materials Required But Not Provided

- Specimen collection container
- Timer

DIRECTIONS FOR USE

Allow the test device, urine specimen, and and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine (approx. 100µl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. Wait for the red line(s) to appear. The result should be read at 5 minutes. It is important that the background is clear before the result is read. Do not interpret the result after 10 minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

POSITIVE: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the phencyclidine concentration is at or above the detectable level (25 ng/mL).

NEGATIVE:* Two lines appear. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the phencyclidine concentration is below the detectable level (25 ng/mL).

INVALID: Control line fails to appear. Insufficient

specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

*** NOTE:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is required.

Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The One Step Phencyclidine Test Device (Urine) provides only a preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography and mass spectrometry (GC/MS) are the preferred confirmatory methods (3).
2. The One Step Phencyclidine Test Device (Urine) is a qualitative screening assay and can not determine either the drug concentration in the urine or the level of intoxication.
3. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
4. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
5. Certain medications containing phencyclidine may produce a positive result in any chemical or immunological assay.

PERFORMANCE CHARACTERISTICS

Sensitivity

The Substance Abuse and Mental Health Services Administration (SAMHSA) has set the screening cut-off for positive specimens at 25 ng/mL for phencyclidine. The One Step Phencyclidine Test Device (Urine) has been shown to detect 25 ng/mL of phencyclidine in urine at 5 minutes.

Specificity

The following table lists compounds that are positively detected in urine by the One Step Phencyclidine Test Device (Urine) at 5 minutes.

Table 1.

Compound	Concentration (ng/mL)
Phencyclidine	25
Thienylcyclohexylpiperidine (TCP)	1,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in urine not associated with phencyclidine. The following compounds show no cross-reactivity when tested with the One Step Phencyclidine Test Device (Urine) at a concentration of 10 µg/mL (Table 2).

Table 2. **Non Cross-Reacting Compounds**

Dextromethorphan	Thioridazine

BIBLIOGRAPHY

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 2nd Ed. Biomedical Publ., Davis, CA. 1982; 488
2. Hawwks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

	Storage Temperature	EC REP	Authorized Representative
LOT	Lot Code		Caution, See Instructions
	Expiration	IVD	For in vitro diagnostic use
	Manufacturer	REF	Catalog No.

Biomerica, Inc., 1533 Monrovia Avenue
Newport Beach, CA 92663 USA

EC REP

CE

according to IVDD 98/79/ EC
MDSS
Burckhardtstrasse 1
30163 Hannover, Germany