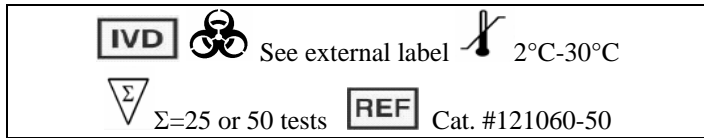




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OneStep Barbiturates InstaTest

Catalog No. 121060-50

INTENDED USE

The Cortez Diagnostics, Inc. OneStep Barbiturate InstaTest is a rapid qualitative, competitive binding immunoassay for the determination of barbiturates in urine.

Always justify preliminary positive and negative results with compelling clinical evidence and professional judgment. The test provides presumptive data which may need confirmation by other methods such as GC/MS.¹

INTRODUCTION

The OneStep Barbiturate InstaTest is an easy, fast, and visually read screening method without the need for instrumentation. The test system employs unique polyclonal antibodies to selectively identify barbiturates in urine samples with a high degree of sensitivity.

Barbiturates represent a class of commonly abused central nervous system depressants. They are usually administered orally but are sometimes injected intramuscularly and intravenously. Before the ultimate inactivation of the compound in the liver, 30-40% binds to plasma proteins, and the rest is distributed in various tissues.¹ Barbiturates range from short-acting (approximately 15 minutes, such as pentobarbital and secobarbital) to long-acting (24 hours or longer, such as phenobarbital). Short-acting barbiturates are extensively metabolized in the body, while the long-acting ones are secreted primarily unchanged.^{2,3} Standard reference methods of detection of barbiturates include gas chromatography, thin-layer chromatography, ultraviolet spectrophotometry, radioimmunoassay and enzyme immunoassay; GC/MS is usually preferred as the confirmation method.^{4,5}

The OneStep Barbiturate InstaTest allows detection of both short- and long-acting barbiturates in human urine, with high degree of specificity. The test is rapid, simple and does not require special instrumentation.

PRINCIPLE OF THE TEST

The OneStep Barbiturate InstaTest is an immunochromatographic device in which drug or drug

metabolites in a sample compete with drug conjugate immobilized on a porous membrane support for limited antibody sites.

Labeled antibody-dye conjugate mixes with sample specimen and binds to the free drug present forming an antibody-antigen complex. This complex competes with immobilized antigen conjugate in the test zone preventing the formation of a pink-rose color band when the drug is above the detection level of 300 ng/ml. Unbound dye conjugate binds to the reagent in the

* We supply 2000ng/ml cutoff levels too.

control zone and produces a pink-rose 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 only one color band in the control zone.

REAGENTS AND MATERIALS SUPPLIED

1. Test Cassette, 50 pcs. The test device contains membrane-immobilized reagents in a protein matrix containing sodium azide.
2. Dropper, 50 pcs. A transfer pipette is included with each test device inside the foil pouch.
3. Urine Cup (optional)
4. Test Instructions

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Sample collection and testing containers

WARNINGS AND PRECAUTIONS

1. For *in vitro* use only.
2. Do not use kit beyond the expiration date.
3. Urine specimens may be infectious; properly handle and dispose of all used reaction devices in a biohazard container.

STORAGE

Store the test kit below 28°C; do not freeze. Refer to the expiration date for stability.

SAMPLE COLLECTION AND PREPARATION

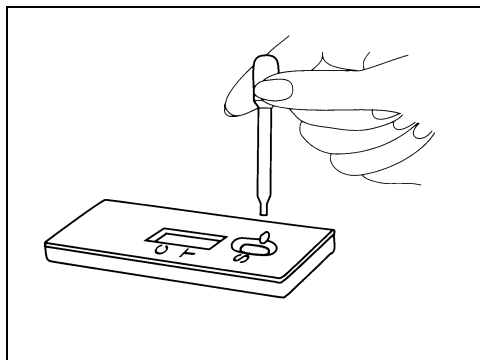
Collect a urine sample in clean, dry container, either plastic or glass, without any preservatives. Urine specimens may be refrigerated (2-8°C) and stored up to forty-eight hours. For longer storage, freeze the samples (-20°C or below).

Bring frozen or refrigerated samples to room temperature before testing. Urine samples exhibiting visible precipitates should be filtered, centrifuged or allowed to settle. Use only clear aliquots for testing.

ASSAY PROCEDURE

Procedure

1. Bring the test components and urine sample to room temperature (15-28°C) before testing.
2. Do not break the seal on the foil pouch until ready to perform the test.

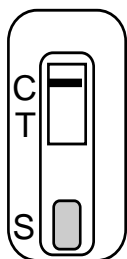


Testing

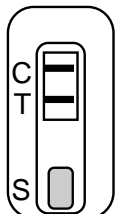
- Open the foil pouch at the notch and remove the test device and dropper. Place the test device on a clean, level surface.
- Holding the dropper vertically, dispense four full drops of urine without air bubbles into the sample well "S" of the test device.
- Read the test result at five minutes.

Important: The result must be interpreted at five minutes. Waiting more than five minutes may cause the reading to be inaccurate. To avoid confusion, discard the test device after interpreting the result.

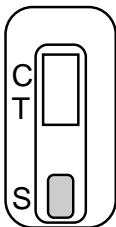
INTERPRETATION OF RESULTS



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 the barbiturates level is at or above the detection sensitivity of 300 ng/ml.



NEGATIVE Two horizontal 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 the barbiturates level is below the detection sensitivity of 300 ng/ml.



INVALID If no bands appear, or a test band appears without a control band, disregard the results. The presence of a control line is necessary to validate test performance.

QUALITY CONTROL

An internal procedure control has been incorporated into the test to ensure proper kit performance and reliability. Use of an external control is recommended to verify proper test performance. Quality control samples should be tested according to quality control requirements established by the testing laboratory.

LIMITATIONS OF THE TEST

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

- Although the test is very accurate, there is a possibility false results will occur due to the presence of interfering substances in the urine.
- The test is a qualitative screening assay and is not for determining quantitative concentration levels or the level of intoxication.
- 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.

PERFORMANCE CHARACTERISTICS

- Sensitivity.** The OneStep Barbiturate InstaTest detects barbiturates and their major metabolites in urine at concentrations equal to or greater than 300 ng/ml, which is much lower than the level normally found in the urine of regular users of barbiturates.
- Specificity.** A study was conducted with the OneStep Barbiturate InstaTest to determine the cross-reactivity of non-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 below.

Amphetamine	1000 µg/ml
Benzoylcegonine	1000 µg/ml
Morphine	1000 µg/ml
Oxazepam	250 µg/ml
Phencyclidine	1000 µg/ml
Propoxyphene	1000 µg/ml

- Accuracy.** An independent correlation study was performed using positive and negative urine specimens. Each urine specimen was tested with the OneStep Barbiturate InstaTest and a commercially available test (Syva EMIT® II). Positive results were confirmed by GC/MS. The results are summarized as follows:

	Syva EMIT II Positive	Syva EMIT II Negative
Positive	37	0
Negative	0	178

The relative sensitivity is 100%. The relative specificity is 100%.

The data demonstrates the OneStep Barbiturate InstaTest is substantially equivalent to the reference test. The clinical significance of the two tests is comparable.

- Precision.** The precision was determined by replicate assays of three different patient urine samples with kits from three different production lots. Ten parallel assays were run from each of the three different lots on each urine sample. The resultant data indicated 100% precision for the duplicates within each lot and 100% precision between different lots.

BIBLIOGRAPHY

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4. *Urine Testing for Drugs of Abuse*. NIDA Research Monograph 73, 1986.



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