

OneStep Barbiturates Urine RapiCard™ InstaTest

REF 121060-1-21

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

Sensitivity

300 ng/ml

INTENDED USE

The Cortez Diagnostics Inc. OneStep BAR RapiCard™ InstaTest is an immunochromatography based one step in vitro test.

SUMMARY AND EXPLANATION

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induces exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effects of short-acting barbiturates such as secobarbital last 3 to 6 hours. The effects of long-acting barbiturates such as phenobarbital last 10 to 20 hours. Short-acting barbiturates normally remain detectable in urine for 4 to 6 days, while long-acting barbiturates can be detected for up to 30 days. Barbiturates are excreted in the urine in unchanged forms, hydroxylated derivatives, carboxylated derivatives and glucuronide conjugates.

The Cortez OneStep BAR RapiCard™ InstaTest test 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, 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.

TEST PRINCIPLE

It is designed for qualitative determination of barbiturates and their metabolites in human urine specimens above a cut-off level of 300 ng/ml of secobarbital.

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.

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 or frozen. Specimens should be 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.

MATERIALS AND COMPONENTS

Materials provided with the test kits

1. Instructions for use.
2. OneStep BAR RapiCard™ InstaTest 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.

3. Test zone: contains barbiturate bovine protein antigen conjugates.
4. Control Zone: Contains Goat anti-mouse IgG antibody.
5. Conjugate pad: contains mouse anti-barbiturate monoclonal 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 card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card and deliver 3 drops (100-150 µl) of sample into the sample well.
5. Read the results at 5 minutes after adding the sample.

Do not interpret the result after 5 minute

RESULTS

- **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 barbiturate level 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 barbiturate 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 borderline (+/-) in test line zone be considered negative result.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The accuracy of the Cortez BAR test was evaluated in comparison to GC/MS at a cut-off of 300 ng/ml of secobarbital. One hundred and nineteen urine specimens with GC/MS confirmed barbiturate

concentration were evaluated in this study. The results are summarized and presented below:

Cortez BAR Test	(-)			(+) GC/MS		Percent agreement with GC/MS)
	GC/MS Negative (less than - 25% cut off)	Near cutoff negative (between - 25% and c/o)	Near cutoff positive (between c/o and +25%)	GC/MS Positive (greater than +25% cut off)		
Positive	0	0	8	36	93.6	
Negative	59	13	3	0	100.0	
Total	59	13	11	36		

Positive % agreement: 93.6, Negative % agreement: 100.

Three specimens were found discrepant between the Cortez BAR and GC/MS method. When compared those data, 100% (3 out of 3) of the discrepancy specimens were found between cut-off and +25% cut-off concentration (300 – 375 ng/ml).

B. Sensitivity

The cut-off concentration (sensitivity level) of Cortez BAR test is determined to be 300ng/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*
	150	40							40	40	40
	225	40				24			16	10	16
BAR	300	40	22	22	23	15	30	24			
	375	40	40	40	40	10	17				
	450	400	40	30	40						

D. Specificity

The specificity for Cortez BAR test was tested by adding various drugs, drug metabolites, and other compounds that are likely to be present in urine. All compounds were prepared in drug-free normal human urine.

1. Interference Testing

The Cortez BAR 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 BAR 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 BAR test which produced positive results when tested at levels equal or greater than the concentrations listed below:

Compounds	Cut-off (ng/ml)	Cross reactivity (%)
Secobarbital	300	100
Alphenal	100	300
Pentobarbital	150	200
Phenobarbital	150	200
Amobarbital	300	100
Barbital	150	200
Butalbital	5,000	5

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

Acetaminophen	4-Acetamidophenol	Acetylsalicylic Acid
Amitriptyline	Arterenol	Aspartame
Ascorbic acid	Atrophine	Caffeine
Chloroquine	Chlopheniramine	Cortisone
Dextromethorphan	Digitoxin	Digoxin
Ecgonine	Ecgonine methyl ester	Ephedrine
Gentisic		Histamine
Homatrophine	Guaiacol glycer ester	Ibuprofen
Ketamine	Imipramine	Meperidine
Methamphetamine	Lidocaine	Methylphenidate
Neomycin	Methaqualone	Perphenazine
Phenylethylamine-α	Niacinamide	Promethazine
Quinine antidine	Phenylpropanolamine	Tetracycline
Theophylline	Salicylic acid	
Thioridazine	11-nor-Δ ⁸ -THC-9-COOH(10 µg/ml)	
	Trifluoperazine	Tryptophan

Amikacin
D,L-Amphetamine
Cmpfor
Deoxyephedrin
Diphenhydramine
Epinephrine
Hydrochlorothiazide
Isoproterenol
Methadone
Morphine
Penicillin G
Pseudoephedrine
Tetrahydrozoline
11-nor-Δ⁸-THC-9-COOH(10 µg/ml)
Tyramine

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 established 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. This test has not been evaluated in a point of care setting.

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 OneStep BAR RapiCard™ InstaTest Test is a qualitative assay. It identifies barbiturates in human urine at a cut-off level or higher. The concentration of the barbiturates 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.

PRECAUTION

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.
6. 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.

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