RapidTech Drug Screen BAR

INTENDED USE

Genix RapidTech Drug Screen BAR test is an immunochromatography based one step test designed for the qualitative determination of barbiturate metabolite in human urine specimens at the cut-off concentration of 300 ng/ml. For in-vitro diagnostic use only.

SUMMARY AND EXPLANATION

Barbiturates are a group of prescription drugs that are frequently abused. They can depress the central nervous system. Acute higher dose induce exhilaration, sedation and respiratory depression. More acute responses produce respiratory collapse and coma. The effect 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.

PRINCIPLE

Each test strip is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. 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 coloured band on the test line zone, indicating a positive result, while the presence of a coloured band indicates a negative result.

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

REAGENT AND MATERIALS SUPPLIED

1. Test strips.
2. Instruction for use.

MATERIAL REQUIRED BUT NOT SUPPLIED

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

STORAGE AND STABILITY

The test strip should be stored refrigerated or at room temperature (2º to 30ºC) in the sealed pouch. The test strip is effective until the expiration date printed on the pouch.

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. 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.

SPECIMEN COLLECTION AND PREPARATION

Fresh urine does not require any special handling or pretreatment. If the assay is not performed immediately, urine specimen may be refrigerated at 2º to 8ºC up to 7 days or frozen. Specimens should be brought to room temperature (18º to 25ºC) before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing.

QUALITY CONTROL

1. The control band is an internal reagent and procedural control. It will appear if the test has been performed correctly and the reagents are reactive.
2. Control standards can be used to validate reagent performance and establish test reliability. Controls that are not provided with this test are commercially available.

TEST PROCEDURE

1. Bring all materials and specimens to room temperature (18º to 25ºC).
2. Open the sealed foil pouch and remove the test strip.
3. Label the strip with patient identification.
4. 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.
5. Hold the strip in the urine until a reddish colour appears at the test area (approximately 15 seconds).
6. Withdraw the strip and place it face up on a clean, non-absorbent surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
7. Read the result at 5 minutes.

Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

Negative:

Two coloured bands form. The appearance of two coloured bands, one in test (T) zone and the other in control (C) zone, indicates negative results. The negative result does not indicate the absence of drug in the specimen, it only indicates that the drug level in the specimen is less than cut-off level**.**

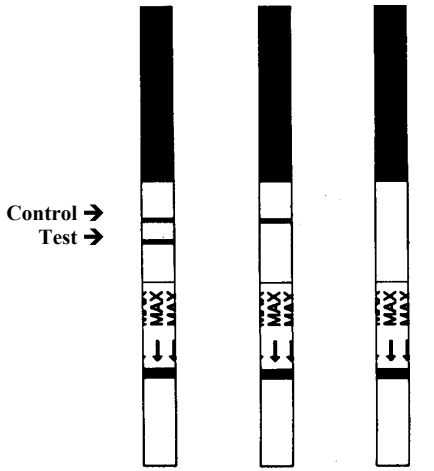
Positive:

One coloured band forms. One coloured band appears in control (C) zone. No coloured band is found in test (T) zone. This is an indication that the drug level in the specimen is above the cut-off level.

Invalid:

If there is no coloured band in control (C) zone, the test result is invalid. Repeat the test with a fresh test device.

Note: A very faint coloured band in test (T) zone indicates that the amount of drug in the sample is near the cut-off level. These specimens and any positive samples should be confirmed by and alternate method such as GC/MS.



EXPECTED RESULTS

The RapidTech Drug Screen BAR Test is a qualitative assay. It identifies barbiturate metabolite in human urine at its cut-off concentration or higher. The concentration of the drug 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.

PERFORMANCE CHARACTERISTICS

Sensitivity

The following compounds were tests at the cut-off concentrations indicated. The cross reaction (calculated in percentage) is indicated in the following table.

Compounds tested	Cut-off (ng/ml)	Cross Reactivity (%)
Secobarbital	300	100
Alphenal	100	300
Amobarbital	300	100
Barbital	150	200
Butalbital	5,000	6
Pentobarbital	150	200
Phenobarbital	150	200

Interference testing

The following substances did not interfere with RapidTech Drug Screen AMP Test at the concentrations tested.

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

Specificity

The following compounds show no cross-reactivity at concentration up to 100 μg/ml unless specified.

Acetaminophen	4-Acetamidophenol
Acetylsalicylic acid	Amikacin
Amitriptyline	Amobarbital
Arterenol	Aspartame
Ascorbic acid	Atrophine
Caffeine	Camphor
Chloroquine	Chlopheniramine
Cortisone	Deoxyephedrine
Dextromethorphan	Digitoxin
Digoxin	Diphenhydramine
Ecgonine	Ecgonine methyl ester
Ephedrine	Epinephrine
Gentisic	Guaiacol glycer ester
Histamine	Hydrochlorothiazide
Homatrophine	Imipramine
Ibuprofen	Isoproterenol
Ketamine	Lidocaine
Meperidine	Methadone
Methaqualone	Methylphenidate
Neomycin	Niacinamide
Perphenazine	Penicillin G
Phenylethylamine-α	Phenylpropanolamine
Promethazine	Pseudoephedrine
Quinine antidine	Salicylic acid
Tetracycline	Tetrahydrozoline
Theophyline	Thioridazine
Trifluoperazine	Tryptophan
Tyramine	

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Revision A: January 2000.