

# BZO Benzodiazepines cassette

CONTENTS			
REF	4420240	Benzodiazepines	40 tests
For professional <i>in vitro</i> diagnostic use only			

## Benzodiazepines

A rapid test for the qualitative detection of Benzodiazepines in human urine.

ONE STEP

### PRINCIPLE

The LINEAR BZO Benzodiazepines cassette (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. Benzodiazepines, if present in the urine specimen below the cut-off level, will not saturate the binding sites of the antibody in the test strip. The antibody coated particles will then be captured by immobilized Benzodiazepines-protein 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 Benzodiazepines level exceeds the cut-off level, because it will saturate all the binding sites of anti-Benzodiazepines antibody.

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 or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.


### REAGENT COMPOSITION

Benzodiazepines test devices, contains mouse monoclonal anti-Benzodiazepines antibody-coupled particles and Benzodiazepines - protein conjugate. A goat antibody is employed in the control line system.

### PACKAGING CONTENTS

REF 4420240 40 BZO Benzodiazepines test devices.  
Disposable specimen droppers.

### STORAGE AND STABILITY

 Store at 2-30°C.

The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

### SPECIMEN COLLECTION AND PREPARATION

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 particles should be centrifuged, filtered, or allowed to settle to obtain clear specimen for testing.

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

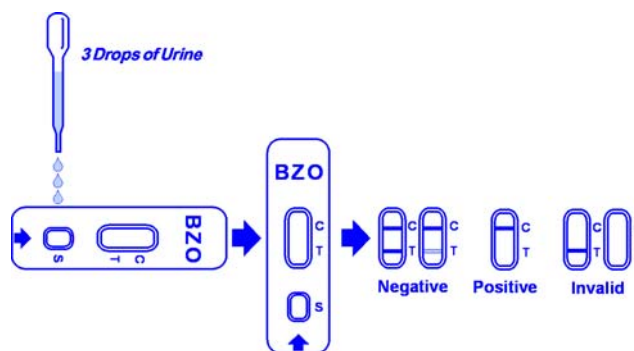
### MATERIAL REQUIRED

- Timer.
- Specimen collection container.

### PROCEDURE

**Allow the test cassette, urine or serum specimen 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 cassette from the sealed pouch and use it as soon as possible.
2. Place the test cassette 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 cassette, 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. Do not interpret the result after 15 minutes.



**NEGATIVE:**\* **Two lines appear.** One colored line should be in the control region (C), and another apparent colored line should be in the test region (T). This negative result indicates that the Benzodiazepines concentration is below the detectable cut-off level.

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

**POSITIVE:** **One colored line appears in the control region (C).** No line appears in the test region (T). This positive result indicates that the Benzodiazepines concentration exceeds the detectable cut-off level.

**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 using a new test strip. If the problem persists, discontinue using the lot immediately and contact your local distributor.

### QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

### CLINICAL SIGNIFICANCE

Benzodiazepines are medications that are frequently prescribed for the symptomatic treatment of anxiety and sleep disorders. They produce their effects via specific receptors involving a neurochemical called gamma aminobutyric acid (GABA). Because they are safer and more effective, Benzodiazepines have replaced Barbiturates in the treatment of both anxiety and insomnia. Benzodiazepines are also used as sedatives before some surgical and medical procedures, and for the treatment of seizure disorders and alcohol withdrawal. Risk of physical dependence increases if Benzodiazepines are taken regularly (e.g., daily) for more than a few months, especially at higher than normal doses. Stopping abruptly can bring on such symptoms as trouble sleeping, gastrointestinal upset, feeling unwell, loss of appetite, sweating, trembling, weakness, anxiety and changes in perception. Only trace amounts (less than 1%) of most Benzodiazepines are excreted unaltered in the urine; most of the concentration in urine is conjugated drug. The detection period for the Benzodiazepines in the urine is 3-7 days. The LINEAR BZO Benzodiazepines cassette is a rapid urine-screening test that can be performed without the use of an instrument. The test utilizes the antibody to selectively detect elevated levels of Benzodiazepines in urine. LINEAR BZO Benzodiazepines cassette yields a positive result when the Benzodiazepines in urine exceeds the cut-off level 300 ng/mL. Test to monitor therapeutic measures related to the study and control of detoxification treatments of drug of abuse and its effects in laboratory tests.

## ANALYTICAL PERFORMANCE

## A. Accuracy

The accuracy of the LINEAR BZO Benzodiazepines cassette was compared and checked against a commercially available test with a threshold value of 300 ng/mL. 120 urine samples taken from volunteer test persons who claimed to be non-consumers were examined with both tests. The results were 100% in agreement.

## B. Reproducibility

The reproducibility of the LINEAR BZO Benzodiazepines cassette was verified by blind tests performed at four different locations. All 60 utilized samples with an Oxazepam-concentration of 150 ng/mL yielded a negative result. All 60 samples with an Oxazepam-concentration of 600 ng/mL yielded a positive result. No significant differences were observed between test results of the different evaluation sites.

## C. Precision

Test precision was determined by blind tests with control solutions. Controls with an Oxazepam -concentration of 150 ng/mL yield negative results. Controls with an Oxazepam-concentration of 600 ng/mL provide positive results.

## D. Specificity

The specificity of the LINEAR BZO Benzodiazepines cassette was tested with the substances listed below, all of which can be found in a normal urine specimen. These substances were added to normal drug free urine.

The following compounds with a similar chemical structure yield a positive result at the specified concentration:

COMPOUND	CONCENTRATION (ng/mL)
Oxazepam	300
Alprazolam	125
Bromazepam	500
Chlordiazepoxide	6,250
Clobazam	150
Clonazepam	16,000
Clorazepate	4,000
Delorazepam	1,200
Diazepam	600
Estazolam	4,000
Fentanyl	>100,000
Flunitrazepam	600
Flurazepam	>10,000
$\alpha$ -Hydroxyalprazolam	100,000
Lorazepam	800
Lormetazepam	1,000
Medazepam	>100,000
Midazolam	6,250
Nitrazepam	50,000
Nordiazepam	300
Prazepam	12,500
Temazepam	2,500
Tetrazepam	1,000

All following listed compounds reacted negative up to a concentration of 100  $\mu$ g/mL.

Acetamidophene	Guaiacol Glyceryl Ether
Acetone	Hemoglobin
Albumin	Imipramine
Amitriptyline	(+/-)-Isoproterenol
Ampicillin	Lidocaine
Aspartame	(+)-Naproxen

Aspirin	Oxalic Acid
Atropine	Penicillin-G
Benzocaine	Pheniramine
Bilirubin	Phenothiazine
Caffeine	Phenylethylamine
Chloroquine	Procaine
(+/-)-Chlorpheniramine	Quinidine
Chlorpheniramine	Ranitidine
Creatine	Riboflavine
Dexbrompheniramine	Sodium Chloride
Dextromethorphan	Sulindac
4-Dimethylaminoantipyrine	Thioridazine
Dopamine	Trifluoperazine
Erythromycin	Trimethobenzamide
Ethanol	Tyramine
Furosemide	Vitamin C
Glucose	

## NOTES

- The LINEAR BZO Benzodiazepines cassette provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
- 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.
- A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
- A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
- Test does not distinguish between drugs of abuse and certain medications.

## REFERENCES

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