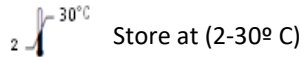


## Atlas One Step Benzodiazepines Test Strip (Urine)

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

**IVD** For *in vitro* diagnostic use only



### INTENDED USE

Atlas One Step Benzodiazepines Test Strip (Urine) is a lateral flow chromatographic immunoassay for the detection of Oxazepam (major metabolite) in urine at a cut-off concentration of 300 ng/mL. This test will detect other Benzodiazepines, please refer to Analytical Specificity table in this package insert.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

### INTRODUCTION

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.

Atlas One Step Benzodiazepines Test Strip (Urine) 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. Atlas One Step Benzodiazepines Test Strip (Urine) yields a positive result when the Benzodiazepines in urine exceeds the cut-off level.

### PRINCIPLE

Atlas One Step Benzodiazepines Test Strip (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.

### MATERIALS

#### Materials Provided

- Test strips (Contain mouse monoclonal anti-Benzodiazepines antibody coupled particles and Benzodiazepines-protein conjugate. A goat antibody is employed in the control line system).
- Package insert

#### Materials Required But Not Provided

- Specimen collection container
- Timer

### PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip 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 used test strip should be discarded according to federal, state and local regulations.

### STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30°C).
- The test Cassette is stable through the expiration date printed on the label on the sealed pouch.
- The test Cassette 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 particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

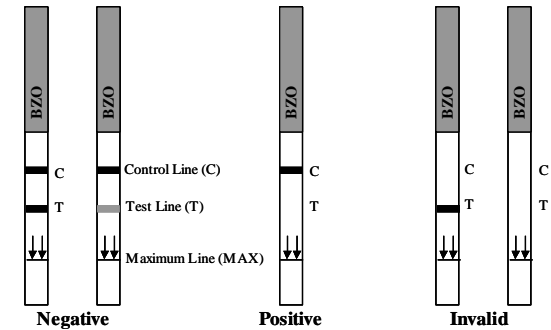
### Specimen Storage

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

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

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.
2. With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen until the specimen starts to migrate**. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the red line(s) to appear. The result should be **read at 5 minutes**. Do not interpret the result after 10 minutes.



**INTERPRETATION OF RESULTS** (Please refer to the illustration above)

**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 Benzodiazepines concentration is below the detectable cut-off level.

#### 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.

**POSITIVE:** **One red 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 with a new test strip. If the problem persists, discontinue using the test kit 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.

#### LIMITATIONS

- Atlas One Step Benzodiazepines Test Strip (Urine) 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. 12
- It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.

#### PERFORMANCE CHARACTERISTICS

##### Accuracy

A side-by-side comparison was conducted using Atlas One Step Benzodiazepines Test Strip (Urine) and a leading commercially available BZO rapid test. Testing was performed on specimens previously collected from subjects presenting for Drug Screen Testing Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

Method	Results	Other BZO Rapid Test		Total Results
		Positive	Negative	
Atlas One Step BZO Test Strip	Positive	131	4	135
	Negative	14	149	163
Total Results		145	153	298
% Agreement with this commercial kit		90%	97%	94%

When compared to GC/MS at the cut-off of 300 ng/mL, the following results were tabulated:

Method	GC/MS			Total Results
	Results	Positive	Negative	
Atlas One Step BZO Test Strip	Positive	131	8	139
	Negative	4	157	161
Total Results		135	165	300
% Agreement with GC/MS Analysis		97%	95%	96%

##### Analytical Sensitivity

A drug-free urine pool was spiked with Oxazepam at the following concentrations: 0 ng/mL, 150 ng/mL, 225 ng/mL, 300 ng/mL, 375 ng/mL and 450 ng/mL. The result demonstrates 100% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Oxazepam Concentration (ng/mL)	Percent of Cut-off	n	Visual Result	
			Negative	Positive
0	0	30	30	0
150	50%	30	30	0
225	75%	30	27	3
300	Cut-off	30	11	19
375	125%	30	5	25
450	150%	30	0	30

##### Analytical Specificity

The following table lists compounds that are positively detected in urine by Atlas One Step Benzodiazepines Test Strip (Urine) at 5 Minutes

















Compound	Concentration
Alprazolam	196
a-hydroxyalprazolam	1,262
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate dipotassium	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
(±) Lorazepam	1,562
RS-Lorazepam glucuronide	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Oxazepam	300

Temazepam	98
Triazolam	2,500

#### REFERENCES

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

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	Catalogue Number		Temperature limit
	In Vitro diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry