BZO Benzodiazepine MonlabTest®

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Product code:	
PRESENTATION	
REF	MO-806024 20 strips MonlabTest
Only for in vitro diagnostic use	

INTENDED USE

The BZO Benzodiazepine MonlabTest® is a simple, one-step immunochromatographic assay intended for professional use only in the qualitative detection of Oxazepam (major metabolite of Benzodiazepines) in human urine with a cutoff at 300ng/ml.

Note: This test provides only a preliminary analytical result which should be confirmed by a more specific method. Gas chromatography/mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the National Institute on Drug Abuse (NIDA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SUMMARY & EXPLANATION

Benzodiazepine is a central nervous system depressant which has anziolytic, hypnotic, anticonvulsant and muscle relaxant effects. It is usually taken orally or nasally. Benzodiazepines are absorbed into the stomach and small intestine and then metabolized (broken down) by the liver when taken orally. They are then metabolized in the liver with 90%-95% excreted through the urine. Only trace amounts (less than 1%) of most benzodiazepines are excreted unaltered in the urine. benzodiazepines are metabolized to desmethyldiazepam or oxazepam. Studies have shown that overdose and extended usage may lead to coma and possibly death. The effects of benzodiazepine generally last 4–8 hours following use.

The BZO Benzodiazepine MonlabTest® is a fast, qualitative, and visually read, immunoassay for screening without the use of an instrument. The method employs a unique monoclonal antibody to selectively identify Benzodiazepine in test urine at or above the concentration of 300ng/mL. This product is not intended to monitor drug levels, but only to screen urine for the presence of Benzodiazepine.

PRINCIPLE OF THE TEST

The BZO Benzodiazepine Monlabtest® is based on the principle of a competitive inhibition immunoassay, in which a chemically labeled drug (drug conjugate) competes with the drug which may be present in urine for the limited number of antibody binding sites. The test device consists of a membrane strip, which is pre-coated with benzodiazepine-BSA conjugate on the test band region, and a colored anti- benzodiazepine monoclonal antibody-colloid gold conjugate pad placed at the end of the membrane.

In the absence of the drug in the urine, the colored antibody-colloid gold conjugate moves with the sample fluid by capillary action along the membrane until it reaches the immobilized drug conjugate in the test band region. At this point, the antibody-colloid gold conjugate reacts with the pre-coated drug conjugate to produce a visible pink colored line as the antibodies form complexes with the drug conjugate. The formation of a **visible color line** on the test band region indicates the urine sample tested is **negative** for benzodiazepine.

When the drug is present in the urine, the drug/metabolite antigen will compete with the drug conjugate coated in the test band region for the limited antibody sites. When a sufficient concentration of drug is present, it will fill the limited antibody binding sites, and thus preventing the attachment of the colored antibody-colloid gold conjugate to drug conjugates pre-coated in the test band region. An absence of the color band on the test region indicates a **positive result**.

A control band with a different antigen/antibody reaction is also added to membrane strip to indicate that the test is performed properly. This control line should always be seen. A negative urine sample produces two distinct color bands. A positive sample produces only one color band in the control zone. If insufficient sample volume is used, there may not be a Control line, indicating the test is invalid.

MATERIALS PROVIDED

1) BZO Benzodiazepine Monlabtest®
2) Instructions for use

MATERIALS NEEDED BUT NOT PROVIDED

1) Clean glass or plastic container for specimens collection
2) Timer

REAGENTS

1) Coated Antibodies/Antigens:
   a. Control region (C): Goat anti-mouse (IgG) polyclonal antibody
   b. Test region (T): benzodiazepine-BSA conjugate
2) Labeled Antibodies:
   Colloidal gold conjugate of mouse monoclonal anti-benzodiazepine antibody

SPECIMEN COLLECTION

A fresh urine specimen should be used, no special pre-treatment is necessary. Specimens should be collected in a clean glass or plastic container. The specimen may be refrigerated (2-8°C) and stored up to 2 days. For longer storage, freeze samples at -20°C or below. Refrigerated samples should be allowed to come to room temperature and mixed thoroughly before assaying. Frozen samples should be thawed completely allowed to come to room temperature, and mixed thoroughly before assaying.

TEST PROCEDURE

1. When you are ready to begin testing, open the sealed pouch by tearing along the notch. Remove the test kit from the pouch and use it as soon as possible.

2. Immerse the strip into the urine sample with the arrow end pointing towards the urine. Do not immerse past the Mark line. Take the strip out after 10-15 seconds and lay the strip flat on a clean, dry, non-absorbent surface (e.g., mouth of the urine container).

3. Wait for colored bands to appear. Read results in 5 minutes. It is important that the background is clear before the result is read. Results obtained after more than 10 minutes are not considered valid.

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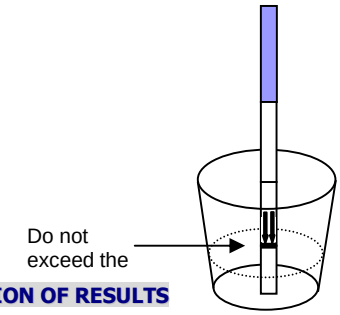


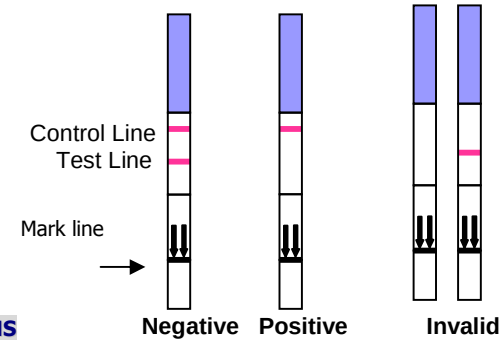
INTERPRETATION OF RESULTS

➢ **Negative:** In addition to one pink colored control (C) line in the control region, a distinct pink colored line will also appear in the test (T) region. The color intensity of the test line may be weaker or stronger than that of the control line.

➢ **Positive:** Only one pink colored line appears in the control (C) region. No apparent line in the test (T) region. This indicates the presence of benzodiazepine at a level of 300ng/mL or above.

➢ **Invalid:** No line appears in the control zone "C", the test should be voided since an improper test procedure may have been performed or deterioration of reagents may have occurred. This is due o the internal control built in which a distinct control region (C) line always appears. Repeat the test using a new device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

Note: A faint line on the test region indicates the benzodiazepine in sample is near the cut-off level for the test. These samples should be re-tested or confirmed with a more specific method before a clinical determination is made.



LIMITATIONS

1. This test is a qualitative, competitive screening assay. It is not designed to determine the quantitative concentration of drugs or the level of intoxication.
2. All positive samples must be confirmed by another method. Gas chromatography / mass spectrometry (GC/MS) is the method of choice to confirm the presence and concentration of the drug in urine.
3. The possibility exists that substances and factors not described in this directional insert may interfere with the test, causing false results (e.g., technical or procedural error).
4. This test has been developed for testing urine samples only. The performance of this test using other specimens has not been substantiated.
5. Adulterated urine samples may produce erroneous results. Strong oxidizing agents such as bleach (hypochlorite) can oxidize drug analytes. If a sample is suspected of being adulterated, obtain a new sample.
6. As the BZO Benzodiazepine Monlabtest® is a competitive assay, no prozone effect is present.
7. Samples containing target drug concentrations below the cutoff sensitivity for the test may produce a positive result occasionally.
8. Results read after 10 minutes may not be consistent with the original reading obtained within the result window of 5-10 minutes.

WARNINGS & PRECAUTION

1. For in vitro diagnostic use only.
2. For professional use only.
3. Do not use test kit beyond the expiry date.
4. The test device should not be reused.
5. Urine specimens may be infectious; insure proper handling and dispose of all used reaction devices into a biohazard container.

STORAGE AND STABILITY

The test kit can be stored at temperatures between 2 to 30°C in the sealed pouch to the date of expiration. The test kit should be kept away from direct sunlight, moisture and heat. The expiration dating was established under these storage conditions.

BIBLIOGRAPHY & SUGGESTED REFERENCE

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	Manufacturer	IVD	For i*n vitro* diagnostic use only
	Don't re-use		Consult instructions for use
Σ n	Contains sufficient for <n> tests		Keep dry
REF	Catalogue Code		Temperature limitation
LOT	Lot Number		Use by