

3 IN 1

Drink Spike Test

BZO&KET&GHB



Product Insert

For professional in vitro diagnostic use only.

INTENDED USE

The 3 in 1 Drink Spike Test BZO&KET&GHB is a rapid chromatographic immunoassay for the qualitative and simultaneous detection of the following drugs in drinks. The designed cutoff concentrations and direct calibrator for these drugs are as follows:

Test	Calibrator	Cut-off
Benzodiazepines (BZO)	Oxazepam	600 ng/mL
Ketamine (KET)	Ketamine	2000 ng/mL
γ-Hydroxybutyric acid (GHB)	γ-Hydroxybutyric acid	1 mg/mL

The test provides only preliminary test results. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method.

PRINCIPLE

The 3 in 1 Drink Spike Test BZO&KET&GHB is one-step immunoassay in which chemically labeled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in drinks. The test membrane strips are pre-coated with drug-protein conjugates on the test band(s). For each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the drinks, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test drinks is negative for the drug. When the drug is present in the drinks, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immune-chromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test strip should be discarded.

REAGENTS AND MATERIALS

Materials Provided

- Multi-drug Drink Spike Pens
- Product Insert

Materials Required but Not provided

- Specimen collection container
- Timer
- Positive and negative controls

PRECAUTIONS

- Read the entire package insert prior to performing test.
- For external use only.
- Do not use the test after expiration date printed on the package.
- Do not use the test if its foil pouch is torn or damaged.
- For single use. Discard after first use.
- The test device should remain in the sealed pouch until use.
- Contaminated or tainted sample may give false results.
- Keep out of reach of children.

STORAGE AND STABILITY

The 3 in 1 Drink Spike Test BZO&KET&GHB should be stored at normal humidity and room temperature or refrigerated (2-30°C; 36-86°F) until the expiration date stated on the pouch. The product is humidity-sensitive and should be used immediately after being opened. Any test in an improperly sealed pouch should be discarded. DO NOT FREEZE.

SPECIMEN COLLECTION AND STORAGE

Drink Assay

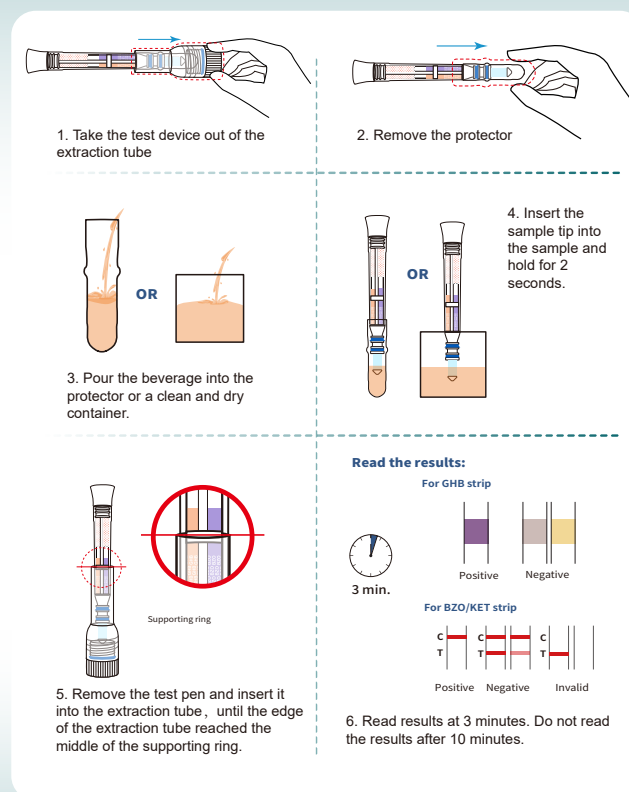
Drink specimen must be non-oily or non-dairy, that less than 25% alcoholic. pH ranges from 5 to 9. There was no odor or fungus in the drink specimen.

Specimen Storage

Drink may be stored according to different drink storage requirements.

PROCEDURE

IMPORTANT: Allow the test, drink specimen and/or controls to reach room temperature (15-30°C) prior to testing. Remove the test device from its packing. For the best results, the assay should be performed within two hours.



INTERPRETATION OF RESULTS



POSITIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).



NEGATIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).



INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE: 1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered negative. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen. 2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

The Result of GHB:



QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATIONS OF THE TEST

1. The 3 in 1 Drink Spike Test BZO&KET&GHB provides only a qualitative, preliminary result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. GC/MS or LC/MS is the preferred confirmatory method
2. Substances, such as bleach and/or alum, in specimens may produce incorrect results. If adulteration is suspected, the test should be repeated with another specimen.
3. A positive result indicates presence of the drug.
4. A negative result may not necessarily indicate drug-free specimen. Negative results can be obtained when drug is present but below the cut-off level of the test.

QUESTIONS AND ANSWERS

1. How do I know if the Test worked well?

When the control line (C) appears, it means that the test unit is working well.

2. How soon can I read my results?

For drugs BZO / KET / GHB, you can read your results after 3 minutes as long as a red line or pink colored line has appeared next to the control region (C), do not read results after 10 minutes.

3. How to read the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as negative whatever the color intensity of the test line (T) is.

4. What is a False Positive Test?

A false positive test result means the drug is not present but shows detected by the device. The most common causes of a false positive test are cross reactants.

5. What is a False Negative Test?

A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

GLOSSARY OF SYMBOLS

REF	Catalog number	Temperature limitation
	Consult instructions for use	Batch code
	Manufacturer	Use by
	Contains sufficient for <n> tests	Do not reuse

Assure Tech. (Hangzhou) Co., Ltd.

Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R. China
contact@diareagent.com