Rapid Response™

3-in-1 Spiked Drink Pen
(GHB, Ketamine, and Benzo)

REF D3.39-8DH,
D3.39-8DH1,
D3.39-8DH3,
D3.39-8DH5,
D3.39-8DH25

Product Insert

WARNING: THIS TEST DOES NOT EVALUATE BEVERAGE SAFETY OR PURITY

A rapid test for the qualitative and simultaneous detection of BZO/KET/GHB in beverages.

For Beverage Drug Testing use only.

Intended Use

The Rapid Response™ 3-in-1 Spiked Drink Pen detects multiple drugs in beverages. The designated cut-off 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 Rapid Response™ 3-in-1 Spiked Drink Pen 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 beverages. The test membrane strips are pre-coated with drug-protein conjugates on the test line(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 beverage, 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 line 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 beverage is negative for the drug. When the drug is present in the beverage, the drug/metabolite antigen competes with drug-protein conjugate on the test line 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 line region. Therefore, absence of the color line on the test region indicates a positive result.

A control line 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.

Summary

Benzodiazepines (BZO)

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 γ 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.

At higher doses, benzodiazepines can produce dissociation effects and anterograde amnesia during the effects. Benzodiazepines also have little to no taste or odor. Because of this, benzodiazepines can be unknowingly slipped into drinks and ingested. Due to the combination of properties, benzodiazepines are commonly associated with drug-facilitated sexual assault, known as a "date rape" drug.

Ketamine (KET)

Ketamine is a dissociative anesthetic developed in 1963 to replace PCP (Phencyclidine). While Ketamine is still used in human anesthesia and veterinary medicine, it is becoming increasingly abused as a street drug. Ketamine is molecularly similar to PCP and thus creates similar effects including numbness, loss of coordination, sense of invulnerability, muscle rigidity, aggressive / violent behavior, slurred or blocked speech, exaggerated sense of strength, and a blank stare. There is depression of respiratory function but not of the central nervous system, and cardiovascular function is maintained. The effects of Ketamine generally last 4-6 hours following use [1]. Ketamine is colorless and odorless. Due to this property, Ketamine can be unknowingly slipped into drinks and ingested. In combination with the dissociative effects, Ketamine is usually associated with drug-facilitated sexual assault.

γ-Hydroxybutyric acid (GHB)

γ-Hydroxybutyric acid (GHB) is an endogenous metabolite in the brain and peripheral organs. It has many characteristics of a neurotransmitter and has been studied for potential therapeutic use in the treatment of narcolepsy, drug addiction, and symptoms of withdrawal and to induce anesthesia. However, GHB also is widely abused. At higher doses, GHB produces sedation and a trance-like state with loss of memory. Because it has little smell or taste, it can be ingested un-knowingly.

This combination of properties has made GHB a drug used for drug-facilitated sexual assault, often administered to victims in beverages. [2,3]

Warnings and Precautions

- Read the entire product insert prior to performing the test.
- For external use only.
- Do not use the test after the 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 samples may give false results.
- Keep out of reach of children.
- **For beverage drug testing use only. Not an IVD.**
- **This test is NOT intended to determine the purity, composition, or if the liquid being examined is safe to use. A positive or negative test result is NOT a guarantee that the liquid being tested is safe or unsafe to use. <u>Any tested liquid is consumed or used at the consumer's own risk.</u>**
- **Rapid Response™ 3-in-1 Spiked Drink Pen provides information to consumers but does not eliminate risks. <u>Users of Rapid Response™ 3-in-1 Spiked Drink Pen accept responsibility for any consequences, including injury or death, that may occur after consuming a tested liquid.</u>**
- **Many factors come into play when testing a liquid, including but not limited to mixture of multiple substances, solubility, and pH of the sample.**
- **Technical or procedural errors, as well as other substances, and factors may affect the accuracy of the Rapid Response™ 3-in-1 Spiked Drink Pen and can cause false results.**
- **A positive result indicates the presence of GHB, Ketamine, and/or Benzodiazepine only and does not indicate quantity or concentration.**
- **A negative result does not rule out the presence of GHB, Ketamine, and/or Benzodiazepine, or any other potentially harmful substances.**

Reagents and Materials

Materials provided

- Test pens
- Quick reference guide (when applicable)
- Product insert

Materials required but not provided

- Specimen collection container
- Positive and negative controls
- Timer

Storage and Stability

The Rapid Response™ 3-in-1 Spiked Drink Pen should be stored at normal humidity and room temperature or refrigerated (36-86°F; 2-30°C) 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.**

Collection and Storage of Specimens

Beverage Assay

The beverage specimen must be non-oily or non-dairy, that less than 25% alcoholic. pH ranges from 5 to 9. No odor or fungus should be in the beverage specimen.

Specimen Storage

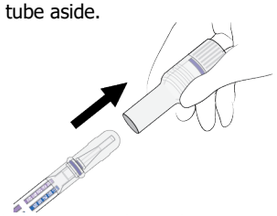
Beverage specimens may be stored according to different drink storage requirements.

Test Procedure

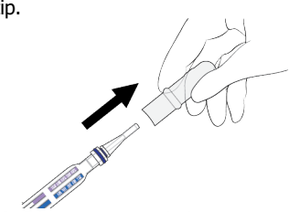
IMPORTANT: Allow the test pen, beverage specimen and /or controls to reach room temperature prior to testing.

1. Remove the test pen from the pouch. For the best results, the assay should be performed within two hours.

2. Take the test pen out of the extraction tube. Keep the extraction tube aside.

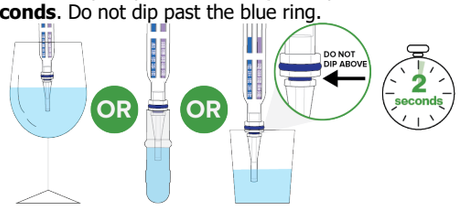


3. Remove the protector from the test pen to reveal the sample tip.

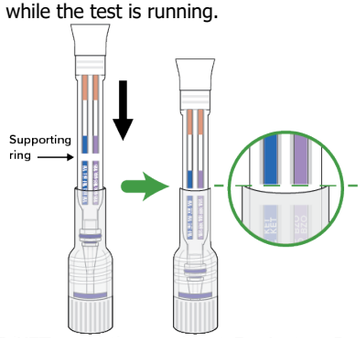


4. **<u>Option 1:</u>** Dip the sample tip into the beverage.
<u>Option 2:</u> Add the beverage into the protector cap OR pour the beverage into a clean, dry container and then dip the swab tip into the collected sample.

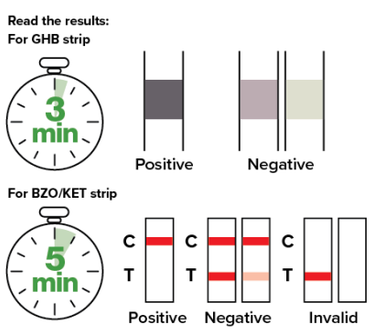
Hold the sample tip in the beverage sample for **2 seconds**. Do not dip past the blue ring.



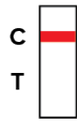
5. Remove the test pen from the sample. Insert it into the extraction tube until the middle of the test pen, supporting ring, aligns with the top edge of the tube. Ensure the test pen is secured in place. Place the test upright on a flat surface while the test is running.



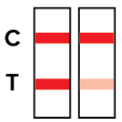
6. For BZO/KET, read the results at 5 minutes. Do not read the results after 10 minutes. For GHB, read the results at 3 minutes.



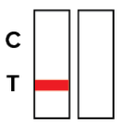
Results Interpretation



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



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



INVALID: Control line fails to appear. Results from any test which has not produced a control line 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 line failure.

The Result of GHB:

Quality Control

BZO/KET: 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

1. The Rapid Response™ 3-in-1 Spiked Drink Pen 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. Dark condensed juice or syrup may affect the background color of the GHB pad and the performance of BZO and KET product, thus affecting the interpretation of the results. If the concentration of grenadine juice is less than or equal to 10%, it has no effect on the product.
4. It is possible that technical or procedural errors, as well as other interfering substances in the beverages specimen may cause erroneous results.
5. A positive result does not indicate level or intoxication, administration route or concentration in beverage.
6. A negative result may not necessarily indicate drug-free beverage. Negative results can be obtained when the drug is present but below the cut-off level of the test.
7. This test does not distinguish between drugs of abuse and certain medications.

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 and KET, you can read the results after 5 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.
   For GHB, you can read the results at 3 minutes by comparing the test area with the Results Interpretation for GHB.
3. **How to read the test if the color and the intensity of the lines are different?**
   The color and intensity of the lines do not affect the result interpretation. The test should be considered negative regardless of the color intensity of the test line (T).
4. **What is a False Positive Test?**
   A false positive test results 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.

Bibliography

1. Baselt RC. Disposition of Toxic Drugs and Chemicals in Man. 6th Ed. Biomedical Publ., Foster City, CA 2002.
2. Bravo D T, Harris D O, Parsons S M. Reliable, Sensitive, Rapid and Quantitative Enzyme-Based Assay for Gamma-Hydroxybutyric Acid(GHB)[J].Journal of Forensic Sciences, 2004, 49(2):379-387.
3. Ureda N, Ruan W, French D, et al. Lack of gamma-hydroxybutyrate prevalence among an urban emergency department population[J]. Journal of Analytical Toxicology, 2010, 34(2):110-111.

Glossary of Symbols

Consult instructions for use	Tests per Kit	Do Not Reuse	
Store between 36°F to 86°F (2°C to 30°C)		Use by	Catalogue #
Lot Number		Manufacturer	

BTNX Inc.
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