

Rapid Response™

GHB (Gamma-Hydroxybutyric Acid) Test Strip (Urine)

REF GHB-1S154 -50

Product Insert

For forensic use only

Intended Use

The Rapid Response™ GHB Test Strip (Urine) can detect the presence of GHB in human urine or beverage at concentrations from 10 µg/mL to 50 µg/mL. The range of detection compares favorably with the manufacturer's specified working range shown on device label.

Parameter	Calibrator	Cut-off (µg/mL)
GHB	Gamma-hydroxybutyric acid	10

This assay provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain a confirmed analytical result, a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the preferred confirmation method.

Summary

Gamma-hydroxybutyric acid (GHB) is a colorless, odorless chemical and has become one of the most dangerous illicit drugs of abuse today. It has become known as one of the "date rape" drugs and there is an increasing trend that GHB is being used as a recreational drug.

Principle

GHB-DH catalyses the reaction of GHB and NAD to produce NADH, and a diaphorase-coupled tetrazolium dye reaction results in the production of a purple dye complex. The reagents were stabilized and used to produce the dip test to screen for low levels of GHB in urine samples.

Materials

Materials provided

- GHB Test Strips
- Product insert

Materials required but not provided

- Specimen collection cup (for dip test)
- Timer
- External positive and negative controls (Optional)

Warnings and Precautions

- For forensic use only.
- Specimens may be potentially infectious. Proper handling and disposal methods should be established.
- Avoid cross-contamination of samples by using a new specimen collection container for each sample.
- Test strip should remain sealed until ready for use.
- Do not use the test kit after the expiration date.
- A positive test result does not always mean an individual has taken the drug illegally as the drug can be administered legally.

Storage and Stability

- The Rapid Response™ GHB Test Strip (Urine) should be stored at 36-86°F (2-30°C) in the original sealed pouch.
- Do not store and or expose reagent kits at temperature greater than 86°F (30°C).
- Do not freeze.**
- Care should be taken to protect the components of the kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Collection and Storage of Specimens

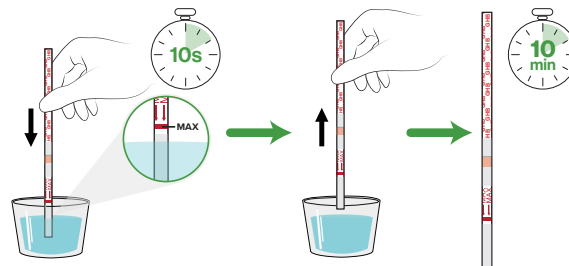
- The Rapid Response™ GHB Test Strip (Urine) is intended for use with human urine specimens only.
- Fresh urine does not require any special handling or pretreatment.
- Urine collected at any time of the day may be used.
- Urine specimens must be collected in clean, dry containers.
- Turbid specimens should be centrifuged, filtered, or allowed to settle and only the clear supernatant should be used for testing.
- Perform testing immediately after specimen collection. Do not leave specimens at room temperature for prolonged periods. Urine specimens may be stored at 35.6-46.4°F (2-8°C) for up to 2 days. For long term storage, specimens should be kept below -4°F (-20°C).
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Avoid repeated freezing and thawing of specimens.
- If specimens are to be shipped, pack them in compliance with all applicable regulations for transportation of etiological agents.

Note: Urine specimens and all materials coming in contact with them should be handled and disposed as potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire.

Test Procedure

Bring tests, specimens, buffer and/or controls to room temperature (15-30°C) before use if the specimens are refrigerated.

- Collect the specimen into the collection cup.
- Remove the test strip from its sealed pouch, and use it as soon as possible. For best results, the assay should be performed within one hour.
- Hold the strip by the end where the product name is printed. To avoid contamination, do not touch the strip membrane.
- Immerse sampling tip into the specimen for about 10 seconds and then place the test on a flat surface.
- Read the results at 10 minutes. Results after 15 minutes are considered invalid.



Results Interpretation

Use the color chart on the Rapid Response™ GHB Test Strip (Urine) pouch to interpret GHB levels at the three indicated semi-quantitative GHB

concentrations. The 0 µg/mL level indicates that no significant GHB is present, the 10 µg/mL level and the 50 µg/mL level indicates a presumptive positive.

Sample Interference

The following list of compounds were added to urine pre-spiked with 100µg/mL of GHB. The device signal intensities were compared directly to those obtained with matched urine samples without interferants added. Increased color signal was noted with L-Ascorbic acid spiked urine. Highly colored urine test samples such as those containing high concentrations of (-) Riboflavin and Hemoglobin made signal interpretation difficult or impossible. A slight diminishment in signal intensity was observed with EDTA potassium tetra oxalate and low pH urine.

Interferants	Interferants (mg/dl) Unless otherwise indicated	Average Observed Signal Intensity
GHB	-	5.5
Ethanol	2000	5.5
Urea	6000	5.5
Sodium Chloride	6000	5.5
Human Serum Albumin	500	5.5
Creatinine	500	5.5
Glucose	3000	5.5
L-Ascorbic acid	500	10
(-) Riboflavin	10	Too Yellow
Bilirubin, mixedisomers	30	5.5
Bile Salts	5 mg/mL	5.5
Hemoglobin	800	Too Red
Urine pH	pH 5.0	45
Urine pH	pH 10.0	5.5
Disodium EDTA	25mM	4.5
Sodium Citrate	40 mM	6
Heparin	100 USP/4mL	5.5
Potassium Oxalate	2 mg/mL	4.5
Sodium Fluoride	1.25 mg/mL	5.5

Limitations Of The Test

- The Rapid Response™ GHB Test Strip (Urine) is used to obtain a visual, qualitative result and is intended for forensic use only.
- A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication.
- There is a possibility that technical or procedural error as well other substances as factors not listed may interfere with the test and cause false results. See SPECIFICITY for lists of substances that will produce positive results, or that do not interfere with test performance.
- If adulteration is suspected, the test should be repeated with new sample.

Specificity

Cross-Reactivity:

The following structurally similar compounds were checked for cross reaction. None of the tested compounds produced a color change at 500 µg/mL greater than that observed for 10 µg/mL of GHB. The calculated cross reaction is predicted to be less than 2%.

Compound	Percent Cross Reactivity
GHB	100%
1,4-Butanediol	< 2%
Gamma-Butyrolactone	< 2%
Succinic Semialdehyde	< 2%
Gabapentin	< 2%
Alpha-Hydroxy-Gamma-Butyrolactone	< 2%

Bibliography

- Bravo, D.T, D.O. Harris and S.M. Parsons. 2004 Reliable, Sensitive, Rapid and Quantitative Enzyme based assay for gamma HydroxybutyricAcid (GHB). H. Forensic Sci. 49; 1-9
- Parsons, S.M. D.O. Harris, and D.T. Bravo. 2004. Methods, Compositions, and Apparatuses for Detection of gamma-HydroxybutyricAcid (GHB). US Patent 6,703,216, filed Mar. 14th 2002, and issued Mar.2004
- Ureda, N. W. Ruan, D. French and A.H.B. Wu 2010. Letter to the Editor; Lack of gamma-Hydroxybutyrate Prevalence Among and Urban Emergency Department Population. J. Anal. Toxicol. 34:110-11
- Bengtsrom. L. 2010. Detection and Determination of Gamma-hydroxybutyrate(GHB) in Urine and Blood.UppsalaUniversitet.

Glossary of Symbols

Consult instructions for use Test per Kit Do Not Reuse

Store between 36°F to 86°F Use by Catalogue #

Lot Number Manufacturer

BTNX Inc.
722 Rosebank Road,
Pickering, ON L1W 4B2
Canada
Technical Support: 1-888-339-9964

