GHB Rapid Test Cassette (Urine)
Package Insert

REF DGHB-102	English

A rapid test for the qualitative detection of GHB in human urine. For medical and professional in vitro diagnostic use only.

【INTENDED USE】

The GHB Rapid Test Cassette is a rapid biochemical-based assay to detect the presence of GHB in human urine and provide a presumptive result for presence of GHB in human urine at concentrations between 10 µg/mL to 50 µg/mL.

This test provides a preliminary result only. A more specific alternate chemical method is recommended. Gas chromatography/mass spectroscopy (GC/MS) is the preferred confirmation method. Clinical consideration and professional judgment should be applied to any test result, particularly when preliminary positive screens are indicated.

【SUMMARY】

γ-Hydroxybutyric acid (GHB), also known as 4-hydroxybutanoic acid, is a naturally occurring neurotransmitter and a psychoactive drug. It has been used in a medical setting as a general anesthetic and as a treatment for cataplexy, narcolepsy, and alcoholism.[1,2] It is also used illegally as an intoxicant, to try to increase athletic performance, and as a date rape drug.[3] It is commonly used in the form of a salt, such as sodium γ-hydroxybutyrate (Na.GHB, sodium oxybate) or potassium γ-hydroxybutyrate (K.GHB, potassium oxybate).

Urine is often the preferred specimen for routine drug abuse monitoring purposes. Both γ-butyrolactone (GBL) and 1,4-butanediol are converted to GHB in the body.[4,5,6] Other liquids such as suspected spiked drinks can also be tested. However, cross-reactivity with Ascorbic Acid and Alcohol need to be taken into account, while interpreting the test results.

【PRINCIPLE】

GHB-DH catalyses the reaction of GHB and NAD to produce NADH, and a diaphorase couple tetrazoliym dye reaction results in the production of a purple dye complex. The reagents were stabilized and used to produce the test to screen for GHB in urine at 10 µg/mL.

【REAGENTS】

GHB-DH
NAD
Diaphorase
Tetrazoliym Dye
Other additives

【PRECAUTIONS】

- The GHB Rapid Test Cassette is a visually read test system, where color change due to enzymatic catabolism is used to provide a visual result for presence of GHB in human urine at a concentration between 10 µg/mL to 50 µg/mL.
- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test should remain in the sealed pouch and store in 2-30°C until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.

【STORAGE AND STABILITY】

The GHB Rapid Test Cassette should be stored as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). **However enzyme-based tests work best when stored at 2-8°C. Therefore, even though the kit is stable up to 30°C, storage at 2-8°C range is advised for enhanced performances.**

The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Specimen Assay

The specimen must be collected in a clean and dry container. The specimen collected at any time of the day may be used. The specimens exhibiting visible particles should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

Specimen Storage

The 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.

【MATERIALS】

Materials Provided

- Test Cassettes
- Droppers
- Package Insert

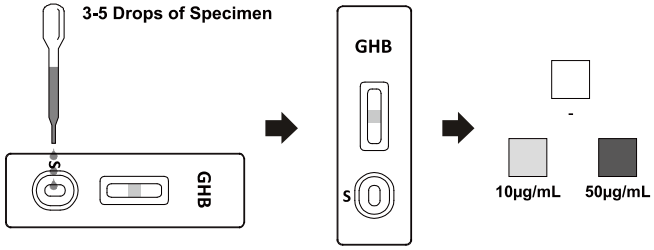
Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

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

1. Remove the test cassette from the sealed pouch and use it within 30 minutes. Observe the reactive pad on the central window of the strip. **If the reaction pad has a purple color before use, it indicates that the product is invalid, do not use.**
2. Place the test cassette on a clean and level surface. Add **3-5 drops of specimen (About 120-200 µL)** to the specimen well (S) and start the timer.
3. **Read the results after 10 minutes** by comparing the color in the Test area with the color card on the foil pouch to determine the relative GHB concentration**.** Testing may take 15 minutes when testing a concentration of 10 µg/mL. **Do not interpret the results after 15 minutes.**



【INTERPRETATION OF RESULTS】

POSITIVE: The GHB Rapid Test Cassette will produce a color change in the presence of GHB. The color will range from light purple color at 10 µg/mL of GHB to a dark purple color greater than or equal 50 µg/mL of GHB.

NEGATIVE: When the GHB Rapid Test Cassette shows no color change or a color less intense than the color specifying 10 µg/mL of GHB, it should be interpreted as a negative result indicating that GHB concentration in the sample is below the detectable level (10 µg/mL).

INVALID: If the color pad has a purple color before applying urine sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with specimen.

The test is not reusable.

【LIMITATIONS】

1. Highly colored samples such as those urines containing high amounts of blood or riboflavin can interfere with interpretation of the color signal. Grossly hemolyzed samples will require clean-up or possibly re-sampling.
2. The GHB Rapid Test Cassette reaction zone is sensitive to moisture. Handle with care in areas with potential high moisture exposure.
3. Storage of the devices in the original packaging materials is critical for stability.

【ASSAY SPECIFICITY】

Detect whether the following compounds with similar structures cross-react. None of the compounds tested produced a GHB depth of 10 µg/mL at a concentration of 500 µg/mL, and the calculated cross reactivity was expected:

Compounds	Cross reaction percentage
GHB	100%
1,4-butanediol	<2%
γ butyrolactone	<2%
Succinate semialdehyde	<2%
Gabapentin	<2%
α-Hydroxy-gamma-butyrolactone	<2%

【INTERFERING SUBSTANCES】

The following substances may interfere with the GHB Rapid Test Cassette when using samples other than urine. Substances listed below do not normally appear in sufficient quantity in urine to interfere with the test.

A. Agents which will enhance color development
- Alcohol
- Ascorbic acid>100mg/dL

B. Agents which will inhibit color development
- Disodium EDTA
- Potassium Oxalate

【BIBLIOGRAPHY】

1. "Sodium Oxybate: MedlinePlus Drug Information". Nlm.nih.gov. 28 July 2010. Retrieved 2010-08-01.
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5. "Erowid GHB Valut: Basics". Erowid. 2012-03-27. Retrieved 2014-01-22. GHB; G; Liquid X; Liquid E
6. Galloway GP, Frederick-Osborne SL, Seymour R, Contini SE, Smith DE (2000). "Abuse and therapeutic potential of gamma-hydroxybutyric acid". Alcohol. 20 (3): 263–9. PMID 10869868. Doi: 10.1016/S0741-8329(99)00090-7.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use	Σ	Contains sufficient for <n> tests	2°C 30°C	Temperature limit
IVD	*In vitro* diagnostic medical device	LOT	Batch code	REF	Catalogue number
EC REP	Authorized representative in the European Community/European Union		Use-by date		Do not re-use
	Do not use if package is damaged and consult instructions for use		Manufacturer		Caution

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