

A rapid test for the qualitative detection of GHB in human urine. For forensic use only.

【INTENDED USE】

The GHB Rapid Test Cassette is a rapid biochemical-based assay to detect the presence of GHB in urine at concentrations above 10 µg/mL.

This assay provides only a qualitative, preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SUMMARY】

γ-Hydroxybutyric acid (GHB) is an en-dogenous metabolite in 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 “date rape” drug that often is administered to victims in beverages^[1,2].

GHB has an half-life from 20 to 60 min, is extensively metabolized, and less than 5% of an oral dose is eliminated unchanged in urine. Exogenous GHB usually becomes undetectable in, more or less, 12 h in urine and 6 h in blood or plasma^[3].

【PRINCIPLE】

A qualitative assay for GHB requires the dehydrogenase reaction to be pulled to completion by coupling to another reaction. GHB-DH catalyses the reaction of GHB and NAD to produce NADH, and a diaphorase couple tetrazolium dye reaction results in the production of a purple dye complex.

【REAGENTS】

The test contains GHB-DH, NAD, Diaphorase, Tetrazolium Dye and Other additives.

【PRECAUTIONS】

- For medical and other professional in vitro diagnostic use only. Do not use after the expiration date.
- For individually packed test, the test should remain in the sealed pouch 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.
- If any serious incident that has occurred in relation to this test shall be reported to us and the competent authority of the Member State in which the user and/or the patient is established.
- Please read all the information in this package insert before performing the test.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch 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. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

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

Specimen Storage

Urine 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.

【QUALITY CONTROL】

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【MATERIALS】

Materials Provided

- GHB Test Cassettes
- Package insert
- Droppers
- Color card

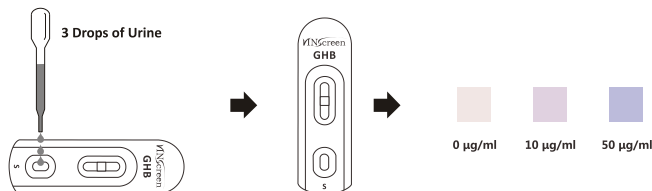
Materials Required but Not Provided

- Specimen collection container
- Timer

【DIRECTIONS FOR USE】

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

- Bring the pouch to room temperature before opening it. Remove the test cassette from the sealed pouch and use it within one hour. **If the reaction pad has a purple color before applying urine sample, do not use the test.**
- Place the test cassette on a clean and level surface. Hold the dropper vertically and **transfer 3 drops of urine (approx. 120µL)** to the specimen well (S) of the test cassette, and then start the timer. Avoid trapping air bubbles in the specimen well (S).
- Read results at 10 minutes by observing any color change on the reaction pad.** compare the color of reaction pad with GHB color card to determine the urine GHB level. Do not interpret the result after 15 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

Negative: No color change appears or the color is lighter than 10 µg/mL color pad, it should be interpreted as a negative result indicating that GHB concentration in the urine is below 10 µg/mL.

Positive: The GHB test produces a color change based on the presence of GHB. The color will range from light purple color (10µg/mL) to a dark purple color (50µg/mL or more). It should be interpreted as a positive result indicating that GHB concentration in the urine exceeds 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 produce 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.

【LIMITATION OF PROCEDURE】

- The GHB rapid test (urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography mass spectrometry (GC/MS) is the preferred confirmatory method^[4].
- Highly colored samples such as the urine containing high amount of blood or riboflavin will interfere the interpretation of the color signal. Grossly hemolyzed samples will require clean-up or possibly re-sampling.
- It is possible that technical or procedural errors, as well as other interfering substances in the urine

specimen may cause erroneous results.

【EXPECTED RESULTS】

This negative result indicates that the GHB concentration is below the detectable level. Positive result means the concentration of GHB is above the level.

【PERFORMANCE CHARACTERISTICS】

Analytical Sensitivity

A drug-free urine pool was spiked with GHB at the following concentrations. The results are summarized below.

GHB Concentration	n	GHB	
		Negative	Positive
0% cutoff	30	30	0
-50% cutoff	30	30	0
-25% cutoff	30	25	5
Cut-off	30	0	30
+25% cutoff	30	0	30
+50% cutoff	30	0	30
3X cutoff	30	0	30

Precision

A study was conducted at three labs by untrained operators using three different lots of products to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens containing, no GHB, 25% GHB above and below the cut-off and 50% GHB above and below the cut-off standard was provided to each site. The following results were tabulated:

GHB Concentration	n per Site	Site A		Site B		Site C	
		-	+	-	+	-	+
0% cutoff	10	10	0	10	0	10	0
-50% cutoff	10	10	0	10	0	10	0
-25% cutoff	10	8	2	9	1	9	1
+25% cutoff	10	0	10	0	10	0	10
+50% cutoff	10	0	10	0	10	0	10

Analytical Specificity

The following table lists compounds that are positively detected in urine by the GHB rapid test (urine) at 10 minutes.

Compound	Concentration (µg/mL)	Compound	Concentration (µg/mL)
γ -Hydroxybutyric acid	10	Gabapentin	>500
4-Aminobutanoic acid	>1,000	2-Hydroxybutanoic acid	>1,000
3-Hydroxybutyric acid	>1,000	Alcohol	2%
Ascorbic acid	200		

Interference

A study was conducted to determine the cross-reactivity of the test with compounds in drug-free urine. The following compounds showed no cross-reactivity when tested with the GHB rapid test (urine) at the corresponding concentration.

Compound	Concentration (mg/dL)	Compound	Concentration (mg/dL)
Urea	6,000	Sodium chloride	6,000
Glucose	3,000	Human Serum Albumin	500
Creatinine	500	Bilirubin	30

【BIBLIOGRAPHY】

- [1] 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.
- [2] 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.
- [3] Castro, André L,Dias, Mário,Reis, Flávio,et al.Gamma-hydroxybutyric acid endogenous production and post-mortem behaviour – The importance of different biological matrices, cut-off reference values, sample collection and storage conditions[J].Journal of Forensic & Legal Medicine, 2014, 27:17-24.
- [4] Parsons S M, Harris D O, Bravo D T. Methods, compositions and apparatuses for detection of gamma-hydroxybutyric acid (GHB):US10098811[P]. US06703216 B2 [2023-11-03].

Index of Symbols

	Consult Instruction for use		Tests per kit		Do not reuse
	Store between 2-30°C		Use by		Catalog #
	Do not use if package is damaged		Lot Number		

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