CLEARTEST® DIAGNOSTIK

CLEARTEST® Drug test Liquid Ecstasy

A rapid test for the qualitative detection of GHB in urine.

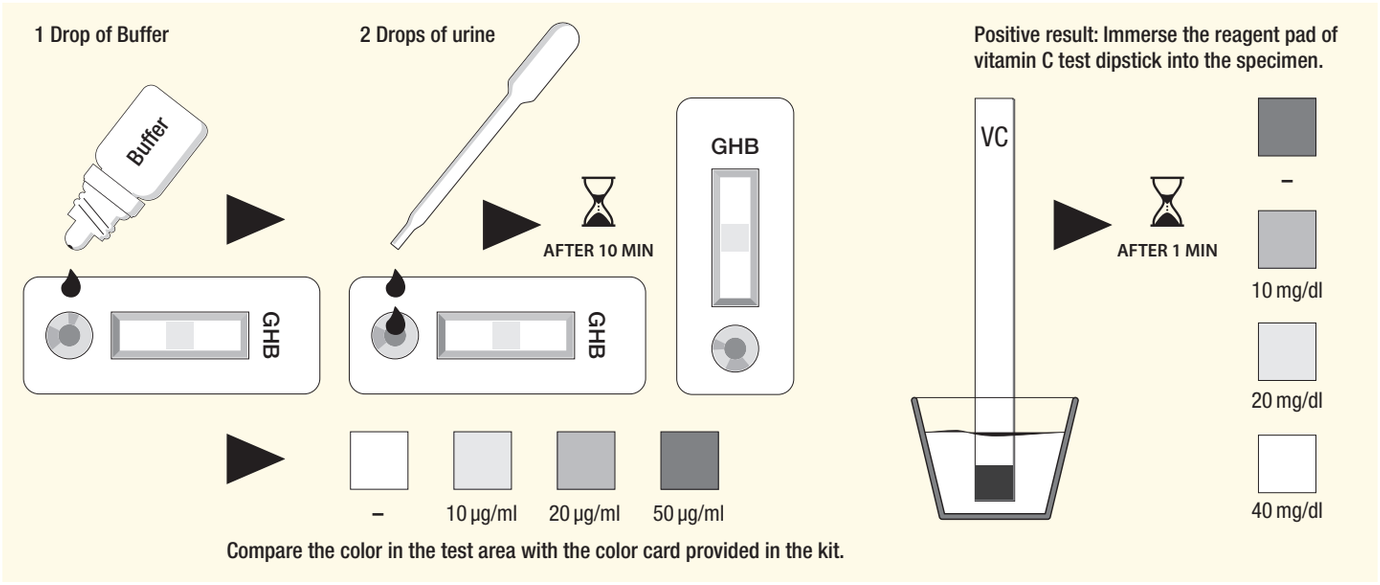
For medical and professional in vitro diagnostic use only.

INSTRUCTIONS FOR USE

IVD

INTENDED USE

The CLEARTEST® Drug test Liquid Ecstasy is a rapid biochemical-based assay to detect the presence of GHB in urine and provide a presumptive result for presence of GHB in urine at concentrations above 10 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 CLEARTEST® Drug test Liquid Ecstasy 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 CLEARTEST® Drug test Liquid Ecstasy should be stored as packaged in the sealed pouch either at room temperature or refrigerated (2 - 30 °C). **However enzymebased 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

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.

MATERIALS

Materials Provided

- GHB Test Cassettes
- Droppers
- Instrutions for use
- Vitamin C Test Dipsticks
- Color Card
- Buffer

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 cassette.

   If the reaction pad has a purple color before applying urine sample, do not use.
2. Place the test cassette on a clean and level surface. Add **1 drop of GHB Buffer** and then add **2 drops of specimen** to the specimen well and start the timer.
3. Initial Results may start showing up at 5 minutes for higher concentrations. However, **read test results at 10 minutes** to detect lower concentrations of GHB near the cut off of 10µg/ml. Read the results by comparing the color in Test area (Reagent area) with color card provided in the kit. Do not interpret the results after 15 minutes.
4. If the result is positive for GHB, immerse the the reagent pad of vitamin C test dipstick (provided) into the specimen and immediately remove the dipstick to avoid dissolving the reagents. Read result at 1 minute to rule out cross reaction with vitamin C. Read the results by comparing the color in Test area (Reagent area) with color card provided in the kit.

INTERPRETATION OF RESULTS

Positive: The CLEARTEST® Drug test Liquid Ecstasy will produce a color change in the presence of GHB. The color will range from light purple color at 10µg/mL of GHB to a dark purple color greater than or equal 50µg/mL of GHB.

***If the vitamin C rapid dipstick shows negative result, the positive result of GHB rapid test is reliable.**

If the vitamin C dipstick shows positive result, the positive result of GHB rapid test is maybe a cross reaction result with vitamin C in the specimen.

Negative: When the CLEARTEST® Drug test Liquid Ecstasy 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. The CLEARTEST® Drug test Liquid Ecstasy appears to be relatively resistant to common interferants but a strong false positive signal can be produced with extreme concentrations of L-Ascorbic acid. The impact of this interference is expected to be low in human urine as concentrations are expected to be much less. Further titration is required to ascertain at what concentration this effect is observed. L-ascorbic acid may be more problematic for beverage testing applications.
2. 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.
3. The CLEARTEST® Drug test Liquid Ecstasy reaction zone is sensitive to moisture. Handle with care in areas with potential high moisture exposure.
4. Storage of the devices in the original packaging materials is critical for stability.

ASSAY SPECIFICITY

The CLEARTEST® Drug test Liquid Ecstasy is relatively resistant to common interferants but a strong false positive signal can be produced with extreme concentrations of Ascorbic acid and Alcohol. The impact of this interference is expected to be low in human urine as concentrations are expected to be much less.

Ascorbic acid and Alcohol may be more problematic for beverage testing applications.

INTERFERING SUBSTANCES

The following substances may interfere with the CLEARTEST® Drug test Liquid Ecstasy 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*
   *Rule out False Positive result with Vitamin C test dipsticks provided.
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.
2. Benzer, Theodore I (8 January 2007). „Toxicity, Gamma Hydroxybutyrate“.Medicine.
3. US Drug Enforcement Administration. „GHB, GBL and 1,4BD as Date Rape Drugs“. Archived from the original on 10 May 2012. Retrieved 2012-05-10
4. Schep LJ, Knudsen K, Slaughter RJ, Vale JA, Mégarbane B (July 2012). „The clinical toxicology of gamma-hydroxybutyrate, gamma-butyrolactone and 1, 4-butanediol“. Clin Toxicol (Phila). 50 (6): 458–70. PMID 22746383. Doi:10.3109/15563650.2012.702218.
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.

Symbolerläuterung			
REF	Item number		Temperature limitation
	Operating instructions	LOT	Batch code
IVD	In-vitro-Diagnostic		Use by date
	Manufacturer		Counting
	Harmful/corrosive substances		Do not re-use
	Keep away from sunlight		Caution
	Keep dry		
	Do not use if package is damaged		
CE	CE mark		

ORDERING INFORMATION

CLEARTEST® Drug test Liquid Ecstasy
5 test cassettes REF **C3 19095**
PZN 14057009

CLEARTEST® Drug test Liquid Ecstasy
Single test REF **C3 19095-1**
PZN 14057015

DRUG TESTS

Available drug tests:

Drug type	Abbr.	Cut-off level	PZN	Cont.	REF
Amphetamine	AMP	1000 ng/ml	09746066	1 test	**C3 11130-1**
			01714380	20 tests	**C3 11130**
Benzodiazepines	BZD	300 ng/ml	09746072	1 test	**C3 18030-1**
			01714411	20 tests	**C3 18030**
Buprenorphine	BUP	10 ng/ml	09746089	1 test	**C3 19093-1**
			01714463	20 tests	**C3 19093**
Ecstasy	MDMA	500 ng/ml	10628998	1 test	**C3 19070-1**
			01714500	20 tests	**C3 19070**
GHB	GHB		14057015	1 test	**C3 19095-1**
			14057009	5 tests	**C3 19095**
Cocaine	COC	300 ng/ml	09746095	1 test	**C3 12020-1**
			01714517	20 tests	**C3 12020**
Lysergic Acid Diethylamide	LSD	20 ng/ml	14057073	1 test	**C3 19094-1**
			14057067	20 tests	**C3 19094**
Methadone	MTD	300 ng/ml	09746103	1 test	**C3 19030-1**
			01714552	20 tests	**C3 19030**
Methamphetamine	MET	1000 ng/ml	09746126	1 test	**C3 11330-1**
			01714569	20 tests	**C3 11330**
Morphine	MOR/MOP	300 ng/ml	09746132	1 test	**C3 11230-1**
			01714606	20 tests	**C3 11230**
Spice-Synth. Cannabinoide	SYN CAN	50 ng/ml	10629029	1 test	**C3 14090-1**
			10629012	20 tests	**C3 14090**
Tetrahydrocannabinol	THC	50 ng/ml	09746250	1 test	**C3 13030-1**
			01714687	20 tests	**C3 13030**

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