

Braccialetto Self Test Rilevamento BEVANDA ALTERATA

GHB TEST / REF:HDGHB-D06B Usare solo come indicato





Registration File of

Drink Check Test

HDGHB-D06B

Version: 01



CATALOGUE

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1 General description

1.1 Intended Use

The Drink Check Test is an assay for qualitative detection of GHB in drink and at concentration 1.0g/250mL.

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.

1.2 Summary

Gamma-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. It is also used illegally as an intoxicant, to try to increase athletic performance, and as a date rape drug. This is a depressant that has many nicknames: easy lay, Georgia home boy, liquid X, liquid ecstasy, liquid E, grievous bodily harm, Gib, G-riffic, scoop, soap, salty water, organic Quaalude, or fantasy. Doctors sometimes prescribe it to treat a sleep disorder called narcolepsy.

The Drink Check Test is a rapid drink screening test that can be performed without the use of an instrument. The Drink Check Test yields a positive result when GHB exceeding 1.0g/250mL.

1.3 Principle

The Drink Check Test is a color test based on the principle of colorimetry. When the drug to be tested in the drink, the color of the spot will change to blue.

1.4 Precautions

The Drink Check Test is a for personal only, For external use only, please read the entire user instructions prior to performing test, do not use the test after expiration date.do not use the test if the test wristband is wet or damaged. Each spot can only reactonce. Keep out of reach of children.

1.5 Storage and Stability

The Drink Check Test is to be stored at 2-30°C (36-86°F) up to date expiration. Keep away from direct sunlight, moisture and heat. DO NOT FREEZE.

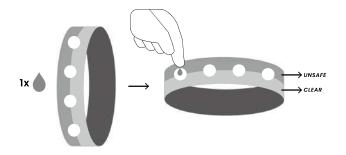
1.6 Controls

The Drink Check Test may be qualitatively verified by using a drop of drink. This test should produce a color change on the paper wristband. The color change is proportional to the concentration of the drug in the drink. The higher the concentration, the darker the color.

1.7 Standard testing procedure

Remove the test from the package

- 1:Apply a drop of drink to any one test spot
- 2: Gently smear spot, wait until dry(10s).
- 3.If spot turns to a blue, DO NOT DRINK!
- 4. This tests for GHB based drugs on





1.8 Interpretation of results

Positive: If the spot turns to a blue of the Drink Check Test.

NOTE: The Drink Check Test is very sensitive to the presence of drug. A blue color that is lighter than the GHB concentration at in 1.0g/250ml color spot should be interpreted as being positive to the presence of GHB in drink.

Negative: When The Drink Check Test shows no color change this should be interpreted as a negative result indicating that drug has not been detected.

Invalid: Do not use this test if the spot is blue or wet or damaged before applying the drink.

1.9 Limitations

- 1. The results of this test are for personal use and reference only.
- 2. Make sure the test spot is dry before use.
- 3.Blue colored beverage or liquor mayshow a false reading(false positive).
- 4. Discard any suspect beverages immediately.
- 5. This product should not be used with milk products or beverages containing milk products, cream or oily liquids.
- 6.A positive results reading on this product should never be used as the sole basis for determining the presence of illegal drugs.
- 7. This test is designed to detect GHB at realistic concentration 1.0g/250mL respectively.

1.10 Performance Characteristics

The detection limit on The Drink Check Testis from- 50% cut-off, cut-off and +50% cut off level. The cutoff level of The Drink Check Test can vary based on local regulations and laws. Test results can be compared to reference levels with color chart on the test.

1.11 Composition of Product

A) Organic or inorganic chemicals

B) Paper

C) Outside package

1.12 Reagents

Bromocresol green

Other organic or inorganic chemicals

1.13 Manufacturing Procedure

- 1. Prepare solutions containing chemicals needed.
- 2. Soaking filter paper with the solutions and dried.
- 3. Test the product according to Final-product QC procedure and release the finished Product.

1.14 User

For personal use



2 Technical Report for Drink Check Test

2.1 Specimen Collection

A side-by-side comparison was conducted using the Drink Check Test and a commercially available Drink test. Testing was performed on 200 clinical specimens previously collected from the volunteers of drinking different kind of drink. Compare the spot areas to the corresponding color blocks at the specified times. The test results are shown in table below.

GHB:

Table: Specimen Correlation

| Method | | | | | | |
|----------------|----------|----------|----------|-------|--|--|
| GHB Rapid Test | Results | Positive | Negative | t | | |
| | Positive | 48 | 8 | 56 | | |
| GHB24110001-T | Negative | 2 | 142 | 144 | | |
| Total Result | - | 50 | 150 | 200 | | |
| Total Agreeme | ent | 96.0% | 94.7% | 95.0% | | |

Relative Sensitivity = 47/50×100% = 96.0% Relative Specificity = 141/150×100%=94.7%

Total Agreement = $(47+141) / (50+150) \times 100\% = 95.0\%$

Clinical test has been conducted on altogether 200 specimens. Drink Drug Rapid Test(GHB) were parallel comparison studied with comparison device, the total conformity rate of the test result of Drink Check Test and of other product for comparison is 95.0%, and this indicate that the two has got high conformity.

2.2 Analytical Sensitivity

Study to validate the sensitivity of the test spot on the Drink Check Test was conducted. The analytical sensitivity was determined by spiking with drug standard at -50%, cut off,+50%. The drug standards were randomized and coded. The results were confirmed by commercial Drink test. A total of 30 replicates for each standard were tested. The specimens were visual compare the color of the test spot with at 10s after specimen application. Results are presented in table below:

Sensitivity Claim for each Analyte

The minimum sensitivity level for each analyte of the Drink Check Test is defined as the lowest level at which over 90% of the test results are positive when the diluted positive samples for an analyte of known concentrations were tested.

Results:

Test results are listed in the following tables. Gray blocks identify the low range (sensitivity) of each analyte.

Table: Analytical Sensitivity



GHB:

GHB24110001-T

| GHB Conc. | n | Negative | Positive | % Positive |
|-----------|----|----------|----------|------------|
| 0 | 30 | 30 | 0 | 0% |
| 2mg/ml | 30 | 30 | 0 | 0% |
| 3mg/ml | 30 | 26 | 4 | 15.4% |
| *4mg/ml | 30 | 2 | 28 | 93.3% |
| 5mg/ml | 30 | 0 | 30 | 100% |
| 6mg/ml | 30 | 0 | 30 | 100% |

* Lowest Positive Concentration

GHB24011002-T

| GHB Conc. | n | Negative | Positive | % Positive |
|-----------|----|----------|----------|------------|
| 0 | 30 | 30 | 0 | 0% |
| 2mg/ml | 30 | 30 | 0 | 0% |
| 3mg/ml | 30 | 24 | 6 | 20% |
| *4mg/ml | 30 | 3 | 27 | 90.0% |
| 5mg/ml | 30 | 0 | 30 | 100% |
| 6mg/ml | 30 | 0 | 30 | 100% |

* Lowest Positive Concentration GHB24110003-T

| GHB Conc. | n | Negative | Positive | % Positive | | |
|-----------|----|----------|----------|------------|--|--|
| 0 | 30 | 30 | 0 | 0% | | |
| 2mg/ml | 30 | 30 | 0 | 0% | | |
| 3mg/ml | 30 | 25 | 5 | 16.7% | | |
| *4mg/ml | 30 | 2 | 28 | 93.3% | | |
| 5mg/ml | 30 | 0 | 30 | 100% | | |
| 6mg/ml | 30 | 0 | 30 | 100% | | |

^{*} Lowest Positive Concentration

Conclusions:

From data listed in the above tables, the sensitivity level of GHB was 4 mg/ml respectively.

2.3 Variability (Inter/Intra/Day to assay)

Drop the sample onto the spot and tested according to the package inset. Five replicates of 0,-50% cutoff and +50% cutoff were tested each day for 3 consecutive days using all the 3 lots. Compare the spot areas to the corresponding color blocks on the test at the specified times. Results were presented in Table below

| | 0 | GHB24110001-T | N* | N | N | N | N |
|-------|-------|---------------|----|---|---|---|---|
| | | GHB24011002-T | N | N | N | N | N |
| | | GHB24110003-T | N | N | N | N | N |
| | -50% | GHB24110001-T | N | N | N | N | N |
| Day 1 | | GHB24011002-T | N | N | Ν | N | N |
| | | GHB24110003-T | N | N | N | N | N |
| | +50% | GHB24110001-T | P* | Р | Р | Р | Р |
| | | GHB24011002-T | Р | Р | Р | Р | Р |
| | | GHB24110003-T | Р | Р | Р | Р | Р |
| Day | Conc. | Lot#: | 1 | 2 | 3 | 4 | 5 |
| | 0 | GHB24110001-T | N | N | N | N | N |
| | | GHB24011002-T | N | N | N | N | N |
| | | GHB24110003-T | N | N | N | N | N |
| | -50% | GHB24110001-T | N | N | N | N | N |
| Day 2 | | GHB24011002-T | N | N | N | N | N |
| | | GHB24110003-T | N | N | Ν | N | N |
| | +50% | GHB24110001-T | Р | Р | Р | Р | Р |
| | | GHB24011002-T | Р | Р | Р | Р | Р |
| | | GHB24110003-T | Р | Р | Р | Р | Р |
| | 0 | GHB24110001-T | N | N | N | N | N |
| | | GHB24011002-T | N | N | Ν | N | N |
| | | GHB24110003-T | N | N | N | N | N |
| | -50% | GHB24110001-T | N | N | N | N | N |
| Day 3 | | GHB24011002-T | N | N | N | N | N |
| | | GHB24110003-T | N | N | N | N | N |
| | +50% | GHB24110001-T | Р | Р | Р | Р | Р |
| | | GHB24011002-T | Р | Р | Р | Р | Р |
| | | GHB24110003-T | Р | Р | Р | Р | Р |

Note: "N*" mean Negative, "P*" mean Positive.

Conclusion: Test results were consistent between the 3 lots of Drink Check Test.

2.4 Cross-reactivity Study

A study was conducted to determine the cross-reactivity of the test with different drink.

No-cross reactivity Drink

| Water | N | Wine | N |
|------------|---|--------|---|
| Beer | N | Brandy | N |
| Caffeine | N | Gin | N |
| Coala | N | Vodka | N |
| Sucrose | N | Rum | N |
| Tea | N | Whisky | N |
| Soda water | N | Sake | N |
| Vitamin C | N | Spirit | N |

Note: "N*" mean Negative

Conclusion: There was no cross-reaction with the different drinks in the test form.

2.5 Assay Specificity

The following table lists compounds that are positively detected in drinks by the Drink Check Test at 10s. Results were read by comparing control color according to the Instructions on the package insert.

GHB

| Sodium carbonate | Blue(P) | Milk | Blue(P) |
|------------------|---------|---------|----------|
| 000.00.00.00 | 2.00(.) | 1711110 | 2.0.0(.) |

Note: "P*" mean Positive

Conclusion: The Drink Check Test interferes with milk and sodium carbonate.

2.6 Accelerate Stability

Accelerated Stability of The Drink Check Test was evaluated using samples from three different batches. These were placed with the temperature calibrated at 55°C. Relative humidity (RH) calibrated at about 60%. A series of stability tests were performed at 0, 7, 14, 17,21, 23,28,31,35 and 42days for 55°C according to Arrhenius Plot. See Table in below. The Drink Check Test were assayed using each test concentration at negative drink, -50% and +50% cutoff specimens. Testing at each specific time interval consisted of quintuplicate for each specimen and read the result at 1-3 minutes according to control color. Results are presented in tables below.

Following table illustrate the designated time points when the stability test will be performed. Results are presented in tables below.

Arrhenius Formula:

In K=-Ea/RT + In A

"K" mean Rate constant

"A" mean Arrhenius constant

"Ea" mean Activation energy

"R" mean Gas constant

"T" mean Temperature in Kelvin

Table: Timeline for Accelerate Stability Study

| Day | 0 | 7 | 14 | 17 | 21 | 23 | 28 | 31 | 35 | 42 |
|-------|-----|------|------|------|------|------|------|------|------|------|
| Temp. | day | days |
| 55℃ | * | * | * | * | * | * | * | * | * | * |

Acceptance Criteria:

The Drink Check Test must be exceed 90% given same as control color results when with test all the samples.

Remark:

N=Negatie

P=Positive

F= Fail

I=Invalid

Results:

Store at 55℃

GHB

| Dave | Specimen | Lot No. | | | | | | | | | | | | | | |
|------|----------------|---------|-------|-------|-------|------|-----|-------|-------|-------|------|-----|-------|----------------|-------|------|
| Days | | Lot | 1: GI | HB24: | 11000 |)1-T | Lot | 1: GI | 1B240 | 01100 |)2-T | Lot | 1: GH | 1B 2 4: | 11000 |)3-T |
| | Negative Drink | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| 0 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N |
| 7 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |

| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
|----|----------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 14 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 17 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 21 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 28 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 31 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 35 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | Negative Drink | N | N | Ν | N | N | N | N | N | N | N | N | N | N | N | N |
| 42 | -50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |
| | +50% cutoff | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р | Р |

Conclusion: Drink Rapid Testis stable at 55° C for 42 days. These data were plotted on an Arrhenius Plot and the shelf life of this product was determined to beat least 24 months from the data of manufacture.

Document History Summary

| Version No. | Date | Description | Remark |
|-------------|-----------|-----------------|--------|
| 01 | 2025.01.2 | Initial Release | N/A |
| | | | |
| | | | |



Clinical Study Report of Drink Check Test

HDGHB-D06B

Test company: Hangzhou AllTest Biotech Co., Ltd

Contact person: Roger Xiong

Phone: 0571-56267857

Test company: Hangzhou AllTest Biotech Co., Ltd



Clinical Study Report of Drink Check Test

1. Purpose of the test

Through test on certain quantity of representative clinical specimens, and scientific and rational statistical analysis on the test result, evaluate the consistency of the result of Drink Check Test produced by Hangzhou Alltest Biotech, and evaluate its clinical application capacity.

2. Overall design of the test

The test of parallel contrast is adopted. The Drink Check Test produced by our company and the comparison device will parallel test on the same specimens, and the result will be recorded respectively. The enumeration data will be false i. Nspected by 2x2 list table, for evaluating the consistency of Alltest test and the confirmed result.

3. Study method

Perform the clinical study by Alltest Drink Check Test and compare with Commercially Drink Check Test.

3.1 Specimens size and its confirmation basis

To investigate the function of product, A side-by-side comparison was conducted using the Drink Check Test and a commercially available Drink test. Testing was performed on 200 clinical specimens previously collected from the volunteers of drinking different kind of drink. Compare the spot areas to the corresponding color blocks at the specified times. The test results are shown in table below.

Allow the test, specimen to reach room temperature (15-30°C) prior to testing.

3.2 Selection of specimen

The samples were selected from volunteer who probably drink.

To protect the privacy of the specimen suppliers, the providers' name shouldn't appear in the test record.

3.3 Confirmation method

| Product | Alltest GHB Product | Commercially Drink Check Test | | |
|--------------------------|---------------------|-------------------------------|--|--|
| Cutoff Test Wristbands | | Test Wristbands | | |
| 1.0g/250ml GHB24110001-T | | / | | |

4. Statistic analysis method of test result

This test will adopt statistical analysis on pair enumeration data, and will record analysis in the form of fourfold table, see below:

Table: fourfold table for evaluating diagnostic test

| | <u> </u> | |
|-------------------|----------|-------|
| Comparison device | | Total |
| positive | negative | |



| Test device | Test device positive | | b | r1 | |
|-------------|----------------------|----|----|----|--|
| | negative | c | d | r2 | |
| total | | C1 | C2 | N | |

Positive conformity rate= $[a/(a+c)]\times 100\%$

Negative conformity rate= $[d/(b+d)] \times 100\%$

Total conformity rate= $[(a+d)/(a+b+c+d)] \times 100\%$

We'll do Kappa consistency test on the result, and when the Kappa value is between 0-1, it means better consistency between the test results of the two devices. It is normally considered consistent when the Kappa value bigger than 0.75.

Kappa=
$$\frac{N(a+d) - (\gamma_1 C_1 + \gamma_2 C_2)}{N^2 - (\gamma_1 C_1 + \gamma_2 C_2)}$$

5. Clinical test result

5.1 Result of all the specimens

Among all 200, Alltest tests get 48 positive results, and 142negative results, see below table.

Table: fourfold table of Drink Check Test Dipstick result

| Method | | Commercially Drin | Agreemen | |
|--------------------------------|----------|-------------------|----------|-------|
| CUD D : 1T | Results | Positive | Negative | t |
| GHB Rapid Test GHB24110001- | Positive | 48 | 8 | 56 |
| T | Negative | 2 | 142 | 144 |
| Total Result Total Agreement | | 50 | 150 | 200 |
| | | 96.0% | 94.7% | 95.0% |

Relative Sensitivity = $48/50 \times 100\% = 96.0\%$

Relative Specificity = 142/150×100%=94.7%

Total Agreement = $(48+142) / (50+150) \times 100\% = 95.0\%$

Clinical test has been conducted on altogether 200 specimens. Drink Drug Rapid Test(GHB) were parallel comparison studied with comparison device, the total conformity rate of the test result of Drink Check Test and of other product for comparison is 95.0%, and this indicate that the two has got high conformity.

5.2 Discussion and conclusion

Clinical test has been conducted on altogether 200 specimens. Alltest tests were parallel comparison studied with comparison device, the total conformity rate of the test result of Alltest test and Commercially Drink Check Test for comparison is 95.0%, and this indicate that the two has got high conformity in the respect of Drink Check Test.



Confirming of the test company:

Hangzhou AllTest Biotech Co., Ltd #550, Yinhai Street, Hangzhou Economic & Technological Development Area, Hangzhou -310018, P.R. China

Roger Xiong

R&D Project Manager

Date: 2024.11.12

| 杭州奥泰生物技术股份有限公司 Hangzhou AllTest Biotech Co.,Ltd | 文件号 Document No.: ZTC-QC-005-R-002 |
|--|---------------------------------------|
| 毒品类 COA The DOA COA | 生效日期 Effective Date: 2018 年 07 月 02 日 |

Certificate of Analysis

| Product Name: | t Name: Drink Check Test-GHB | | | Catalog No.: | HDGHB-D06B | | |
|----------------------|------------------------------|-------------------|------------|----------------|------------|--|--|
| Batch No.: | GHB25090008 | Date of Sampling: | 2025.09.28 | Quantity: | 2000PCS | | |
| Expiry Date: | 2027-08 | Date of Analysis: | 2025.09.29 | Specification: | / | | |
| Other informati | | | | | | | |

Other information:/

| | QC Item | QC Criterion | QC Result | Conclusion | |
|---------------------|--------------------|--------------|-----------|------------|--|
| Physical Appearance | | Good | Good | Pass | |
| GHB | GHB Purified water | | Clear | Pass | |

| Others: |
|---------|
|---------|

| Final QC | This batch of meduat mot the OC Critaria |
|-------------|--|
| Conclusion: | This batch of product met the QC Criteria. |

QC supervisor:

Date:2025.09.29



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L'Ufficio PARAFARMACO è a Vs disposizione dal lunedì al venerdì (8:30 -18:30) per: attribuzione codici paraf, aggiornamento anagrafica prodotti e prezzi e consulenza e informazioni.

Nella Tabella sono riportati i codici base 10 e base 32 attribuiti ai prodotti per l'elaborazione del Barcode tipo 39 in base 32.

N.B. nel codice base 32 non sono utilizzabili le lettere: A,E,I,O. I codici paraf elencati nel presente modulo sono univoci e validi per tutto il territorio nazionale. La variazione della grammatura o della descrizione del prodotto, comporta l'attribuzione di un nuovo paraf.

| Codice base 10 | Codice base 32 | Codice a barre | Codice EAN | Descrizione prodotto | Ditta | Codice articolo (ditta) | lva | Prezzo al pubblico indicativo | Data prezzo al pubblico | Data inizio commercio |
|--|----------------|----------------|--------------------------------|----------------------|-----------|-------------------------|-------|-------------------------------------|----------------------------|--------------------------|
| 951864154 WCSLUU IIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIIII | | 6942598200087 | VERIFY BRACC SELFTEST BEV ALTE | VERIFY Srls | HDGB-D06B | 22 | 14,90 | 16/10/2025 | 28/02/2025 | |