

ALL TEST™ Drink Drug Check Rapid Test

Package Insert

**Instruction Sheet for testing of any combination of the following drugs:
BAR/BZO/MET/PCP/SCOP/TML/ZOL/FYL/GHB**

A rapid test for the qualitative detection of multi-drug in drink.

【INTENDED USE】

The Drink Drug Check Rapid Test offers a variety of solutions for fast, accurate and reliable drug testing.

This Drink Drug Check Rapid Test can detect the possible use of following Drugs in your drink:

Drug Name (Abbreviation)	Calibrator	Detectable Level/ Cut-off (ng/mL)
Barbiturates (BAR)	Secobarbital	600
Benzodiazepines (BZO)	Oxazepam	300/600
Methamphetamine (MET)	d-Methamphetamine	500/2,000
Phencyclidine (PCP)	Phencyclidine	50
Scopolamine (SCOP)	Scopolamine	2,000
Tramadol (TML)	Cis-Tramadol	600
Zolpidem (ZOL)	Zolpidem	50/100
Fentanyl (FYL)	Fentanyl	200
γ-Hydroxybutyric acid (GHB)	γ-Hydroxybutyric acid	10,000

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.

【SUMMARY】

The Drink Drug Check Rapid Test is a rapid screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in drink.

【WARNINGS AND PRECAUTIONS】

- Read the entire package insert prior to performing test.
- For external use only.
- Do not use the test after expiration date printed on the package.
- Do not use the test if its foil pouch is torn or damaged.
- For single use. Discard after first use
- The test device should remain in the sealed pouch until use.
- Contaminated or tainted sample may give false results.
- Keep out of reach of children.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at 2-30°C up to the date of expiration. Keep away from direct sunlight, moisture and heat. **DO NOT FREEZE.**

【SPECIMEN COLLECTION AND PREPARATION】

Drink Assay

Drink specimen must be non-oily or non-dairy, that less than 25% alcoholic. pH ranges from 5 to 9. There was no odor or fungus in the drink specimen.

Specimen Storage

Drink may be stored according to different drink storage requirements.

【MATERIALS】

Materials Provided

- Test Panels
- Package Insert

Materials Required But Not Provided

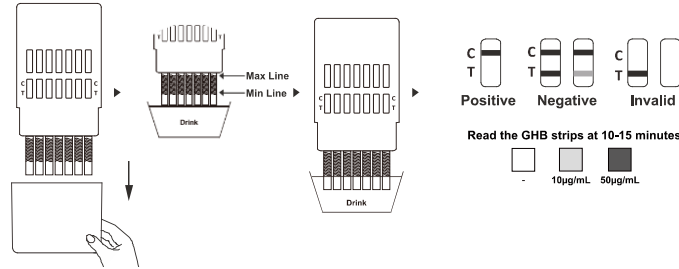
- Specimen Collection Container
- Timer

【DIRECTIONS FOR USE】

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

1. Collect drink specimen in a clean and dry container.
2. Remove the test panel from the sealed pouch and use it within one hour.
3. Remove the cap.
4. With arrows pointing toward the drink specimen, immerse the test panel vertically in the specimen for at least 10-15 seconds. **Immerse the dipstick to at least the level of the wavy lines, but not above the arrow on the test panel.**
5. Replace the cap and place the test panel on a non-absorbent flat surface.

6. Start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.
7. **For GHB Test, if applicable, read the results at 10 minutes by comparing the color in test area with color card on the foil pouch.** Do not interpret the results after 15 minutes.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

Each strip only contain 1 drug test, drug name was shown on the top of the strip.

Results for Drug strips other than GHB:

NEGATIVE: Two colored lines appear on the test strip. One line appears next to the letter 'C' and the other line appears next to the letter 'T', meaning a NEGATIVE RESULT for that drug.

POSITIVE: Only one colored line appears next to the letter 'C'. No colored line appears next to the letter 'T', meaning a preliminary POSITIVE RESULT for that drug.

INVALID: Control line fails to appear.

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.

Note: Each test strip and test area should be looked at individually. Do not compare lines between test strips or different areas. Also, do not compare the color or darkness of the lines, or the rate at which the lines appear.

Test results for GHB strip:

POSITIVE: The GHB Test 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 to 50 µg/mL of GHB.

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

INVALID: If the color pad has a purple color before applying 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.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

【LIMITATIONS】

1. The Drink Drug Check Rapid Test provides only a qualitative, preliminary result. 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
2. Substances, such as bleach and/or alum, in specimens may produce incorrect results. If adulteration is suspected, the test should be repeated with another specimen.
3. A positive result indicates presence of the drug.
4. A negative result may not necessarily indicate drug-free specimen. Negative results can be obtained when drug is present but below the cut-off level of the test.

【Q&A】

1. How do I know if the Test worked well?

When the control line(C) appears, it means that the test unit is working well.

2. How soon can I read my results?

For drugs other than GHB, You can read your results after 5 minutes as long as a red line or pink colored line has appeared next to the control region(C), do not read results after 10 minutes.

For GHB strip, you can read the results at 10 minutes by comparing the test area with the color card on the foil pouch, do not read results after 15 minutes.

3. How to read the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The test should be considered as negative whatever the color intensity of the test line (T) is.

4. What is a False Positive Test?

A false positive test result means the drug is not present but shows detected by the device. The most common causes of a false positive test are cross reactants.

5. What is a False Negative Test?

A false negative test means the drug is present but is not detected by the device. If the sample is diluted, or the sample is contaminated that may cause a false negative result.

Index of Symbols

	Consult instructions for use or consult electronic instructions for use		Contains sufficient for <n> tests		Temperature limit
	Manufacturer		Batch code		Catalogue number
	Do not use if package is damaged and consult instructions for use		Use-by date		Do not re-use



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Number: 14601817700
Revision date: 2023-10-12