

## PRINCIPLE AND INTENDED USE

The *CLIAwaived, Inc.* Rapid Breath Alcohol Test is intended to measure alcohol in the human breath. Results are used in the diagnosis of alcohol intoxication. The *CLIAwaived, Inc.* Rapid Breath Alcohol Test is a semi-quantitative, rapid screening test. It indicates relative Blood Alcohol Concentration (BAC) at 0.02% or 0.08% cut-off levels. Each test contains crystals that detect a specific cut-off level of BAC. The test is based on a chemical reaction. Alcohol reacts with the crystals in the test to produce a color change. The color change depends on the amount of alcohol in the breath. If the test is positive, the amount of alcohol in the breath is greater than or equal to the cut-off level of the test.

## REAGENTS

The test contains Silica Gel, Inorganic Acid, Oxidative Indicator and other additives.

## PRECAUTIONS

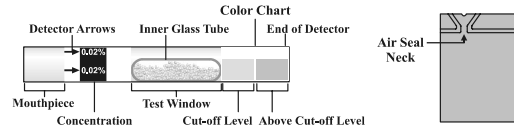
- For *in vitro* diagnostic use only.
- Do not use if the Inner Glass Tube has been broken.
- For diagnosing intoxication.
- Do not use if the crystals are not yellow.
- Do not use after the expiration date printed on the sealed pouch.
- Results are affected by color perception and the lighting conditions when the test is read.
- Keep out of reach of children.
- Do not immerse in liquid.
- Do not swallow or eat the crystals.
- Dispose of properly.
- Do not reuse the test.

## STORAGE AND HANDLING

Store as packaged. Keep test in the sealed pouch until use. Store at room temperature or refrigerated (2-30°C or 36-86°F). **DO NOT FREEZE.** Do not leave the test in direct sunlight or near heat sources.

## PRODUCT FEATURES

- Accurate and reliable
- Easy to use
- Individually packaged
- Results in 2 minutes



## MATERIALS PROVIDED

- Tests
- Blow bags (REF CLIA-C031-031 only)
- Package insert

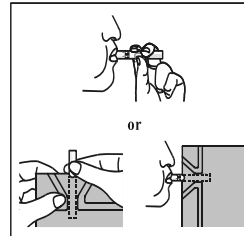
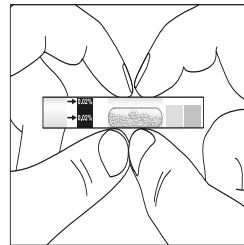
## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

## INSTRUCTIONS FOR USE

**Wait 15 minutes after last alcohol intake or drink a glass of water before testing.**

1. Bring the pouch to room temperature (15-30°C or 59-86°F) before opening. Remove the test from the sealed pouch. Do not touch the Mouthpiece to avoid contamination.
2. Hold the middle of the test. Firmly squeeze the test to break the Inner Glass Tube. Perform the test as soon as possible to avoid the affects of humidity. **Do not crush or bend the test.** Refer to the picture on the right.
3. Breathe into the test.



### • For breath alcohol testing without blow bag:

- Hold the middle of the test horizontally. Take a deep breath. Blow hard into the Mouthpiece, in the same direction as the Test Arrows. Blow

hard into the test for **12 seconds**.

Note: Failure to blow hard, or for 12 seconds, may cause false results. Do not inhale while blowing into the test. Refer to the picture on the right.

- Shake the test slightly to distribute the crystals evenly in the Test Window.

### • For breath alcohol testing with blow bag:

- Insert the test into the Air Seal Neck of the blow bag in the same direction as the test Arrows. Roll the test into the blow bag until the Test Window is completely covered. Ensure the end of the test is past the Air Seal Neck of the blow bag. Refer to the picture on the right.

- Hold the middle of the test horizontally. Take a deep breath. Blow hard into the Mouthpiece of the

test until the blow bag is completely inflated.

Note: Failure to blow hard, or to inflate the blow bag completely, may cause false results. Do not inhale while blowing into the test.

- Remove the test from the blow bag. Shake the test slightly to distribute the crystals evenly in the Test Window.
4. Read results at **2 minutes** by comparing the color of the majority of crystals to the Color Chart on the test label. Do not read results after 5 minutes.

## INTERPRETATION OF RESULTS

Compare the color of the majority of crystals in the test to the Color Chart on the detector label.

**NEGATIVE:** Majority of the crystals are more yellow than the Color Chart on the test label. The relative BAC is below the cut-off level of the test. The crystals may be lighter than the crystals from an unused test.

**POSITIVE:** Majority of the crystals are the same color as the Color Chart, or more green-blue than the Color Chart on the test label. The relative BAC is at or above the cut-off level of the test.










## LIMITATIONS

1. Alcohol impairs judgment. The test should be performed by someone who is not under the influence of alcohol.
2. The *CLIAwaived, Inc.* Rapid Breath Alcohol Test is screening test. It cannot detect exact BAC. Confirm results with an approved alcohol test before taking legal action. The test should not be used to determine if the user is capable of operating machinery or driving. Actions of any person, based on the outcome of the test, are at the person's own risk.
3. Failure to wait 15 minutes after the last alcohol intake, or to drink a glass of water, before testing may cause false results.
4. Wait 15 minutes after using over-the-counter products, eating, smoking, or chewing gum before testing. Such items may cause false positive results.
5. People who are color-blind or visually impaired should not read results.
6. Read the test under incandescent, fluorescent, or indirect sunlight. Do not read under streetlights. Sodium vapor from streetlights can cause colors to appear differently. Use a flashlight to read the results. Shine the light on the side of the test and not directly on it.
7. Sex, age, physical condition, and the amount of food or drugs consumed may affect the test. A person under the influence of alcohol may test negative.
8. The test is highly sensitive to alcohol and alcohol vapors in the air. Perform the test in an area free of vapors.

## PERFORMANCE CHARACTERISTICS

The *CLIAwaived, Inc.* Rapid Breath Alcohol Test will react with ethyl alcohol and other volatile alcohols. Some substances such as volatile alcohols, volatile aldehydes, and volatile alkenes do not normally interfere with the Breath Alcohol Detector in sufficient quantity.

### Index of Symbols

	Consult instructions for use		Authorized Representative		Manufacturer
	For <i>in vitro</i> diagnostic use only		Use by		Do not reuse
	Store between 2-30°C (36-86°F)		Lot Number		Catalog #

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