



Breath Alcohol Detector

Package Insert

REF C031-011	English
REF C031-031	

PRINCIPLE

The Breath Alcohol Detector is for the semi-quantitative, rapid detection of alcohol in the exhaled breath. It indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels. The test is based on a chemical reaction. Alcohol reacts with the crystals in the detector to produce a color change. The color change depends on the amount of alcohol in the breath.

REAGENTS

The test contains Acids, Oxidants, and other non-reactive additives.

PRECAUTIONS

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

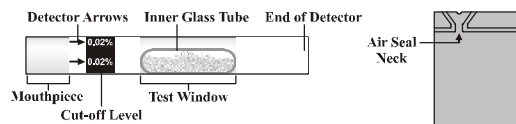
STORAGE AND HANDLING

Store as packaged. Keep detector 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 AND INTENDED FOR USE

The Breath Alcohol Detector is a screening test. It can be used to diagnose intoxication or to help prevent drunk driving.

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



MATERIALS PROVIDED

- Detectors
- Blow bags (REF 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 detector from the sealed pouch. Do not touch the Mouthpiece to avoid contamination.

2. Hold the middle of the detector. Firmly squeeze the detector 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 detector. Refer to the picture at right.

3. Breathe into the detector.

- **For Breath Alcohol Detector without blow bag:**

- Hold the middle of the detector horizontally. Take a deep breath. Blow hard into the Mouthpiece, in the same direction as the Detector Arrows. Blow hard in **one continuous breath for 12 seconds.**

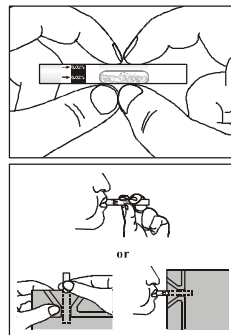
Note: Failure to blow hard, or in one continuous breath for 12 seconds, may cause false results. Do not inhale while blowing into the detector. Refer to the picture at right. Shake the detector slightly to distribute the crystals evenly in the Test Window.

- **For Breath Alcohol Detector with blow bag:**

- Insert the detector into the Air Seal Neck of the blow bag in the same direction as the Detector Arrows. Roll the detector into the blow bag until the Test Window is completely covered. Ensure the End of the Detector is past the Air Seal Neck of the blow bag. Refer to the illustration at right.

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



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

INTERPRETATION OF RESULTS

For best results, compare the crystals from the used detector to the crystals from an unused detector of same cut-off level.

NEGATIVE: Majority of the crystals remain yellow-orange. The relative BAC is below the cut-off level of the detector. The crystals may be lighter than the crystals from an unused detector.

POSITIVE: Majority of the crystals are green-blue. The relative BAC is at or above the cut-off level of the detector.

LIMITATIONS

1. Alcohol impairs judgment. The test should be performed by someone who is not under the influence of alcohol.
2. The Breath Alcohol Detector is screening test. It cannot detect exact BAC. Confirm results with an approved alcohol test before taking legal action. 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 detector 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 Breath Alcohol Detector will react with certain reductive substances, such as ethyl alcohol in human breath. Other reductive substances do not normally interfere with Breath Alcohol Detector in sufficient quantity.

Index of Symbols

	Attention, see instructions for use		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Tests per kit		Authorized Representative		Manufacturer



CONFIRM
BIOSCIENCES