

Breath Alcohol Detector

Package Insert

PRINCIPLE AND INTENDED USE

The Breath Alcohol Detector is intended to measure alcohol in the human breath. Results are used in the diagnosis of alcohol intoxication. The Breath Alcohol Detector is a semi-quantitative, rapid screening test. It indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.04%, 0.05%, 0.06%, 0.08% or 0.10% cut-off levels. Each detector 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 detector 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 detector.

REAGENTS

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

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

MATERIALS PROVIDED

- Detectors
- Blow bags (optional)

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

INSTRUCTIONS FOR USE

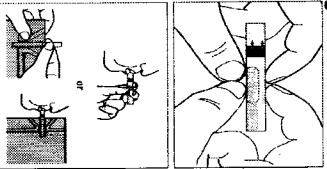
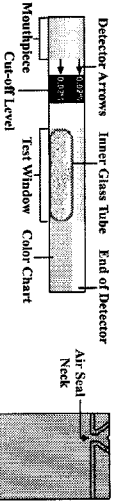
Wait 15 minutes after last alcohol intake or drink a glass of water before testing.

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 on the 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 into the detector for 12 seconds.

- Note: Failure to blow hard, or for 12 seconds, may cause false results. Do not inhale while blowing into the detector. Refer to the picture on the 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 picture on the 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 comparing the color of the majority of crystals to the Color Chart on the detector label. Do not read results after 5 minutes.

INTERPRETATION OF RESULTS

Compare the color of the majority of crystals in the detector to the Color Chart on the detector label. **NEGATIVE: Majority of the crystals are more yellow than the Color Chart on the detector label.** 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 the same color as the Color Chart, or more green-blue than the Color Chart on the detector label. 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. 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 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 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.