

## Breath Alcohol Detector



**IVD** For In-Vitro diagnostic and professional use only

2  30°C  
Store at 2-30 °C

### INTENDED USE

For rapid detection of the presence of alcohol in the exhaled breath and indicates relative Blood Alcohol Concentration (BAC).

### INTRODUCTION

A screening test which provides a reliable method and warning to help prevent drunk driving due to an impairment of judgment.

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

### PRINCIPLE

Atlas Breath Alcohol Detector is for rapid detection of the presence of alcohol in the exhaled breath and indicates relative Blood Alcohol Concentration (BAC) at 0.02%, 0.05%, or 0.08% cut-off levels. The test is based on a chemically chromogenic reaction. Alcohol, if present in the exhaled breath, reacts with the chemically coated crystals and produces a color change. This color change is proportional to the concentration of alcohol in the breath, which is an approximation of relative Blood Alcohol Concentration (BAC).

### MATERIALS

#### MATERIALS PROVIDED

- Detectors (contain Silica Gel, Inorganic Acid, Dichromates and other additives).
- Package Insert

#### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

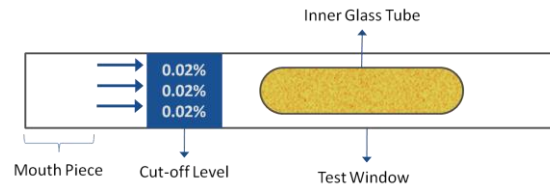
### PRECAUTIONS

- For *in vitro* diagnostic use only. Do not use after the expiration date.

- Keep out of reach of children.
- Do not swallow or eat the crystals. The test contains Dichromates which are a hazardous chemical.
- Do not reuse the test.
- Do not immerse in liquid.
- Do not use the detector if the inner glass tube has been broken or the crystals are not yellow.
- Interpretation of visual results is dependent on variability of color perception and the lighting conditions when the test is read.
- Follow proper precautions and local regulations when disposing of the test.

### STORAGE AND HANDLING

- Store as packaged in the sealed pouch either at room temperature or refrigerated ranging from 2-30°C (36-86°F).
- The test is stable through the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Do not use beyond the expiration date.
- Do not leave the test in direct sunlight or near heat sources.

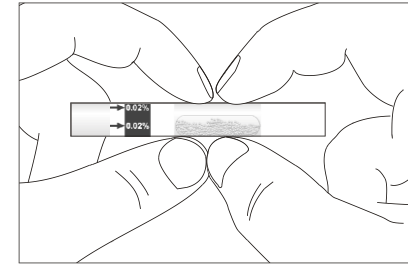


### PROCEDURE

**Allow the test to reach room temperature at 15-30°C (59-86°F) prior to testing. Wait 15 minutes after last alcohol consumption or drink a glass of water before taking the test.**

1. Bring the pouch to room temperature before opening and use it as soon as possible.
2. Remove the detector from the sealed pouch by tearing the sealed pouch at the pre-cut mark to avoid touching the Mouthpiece. Do not touch the Mouthpiece to avoid any contamination.
3. Hold the middle of the detector using left and right index finger and thumb, and then firmly squeeze the detector to break the Inner Glass Tube containing the yellow or orange crystals. **Do not crush or bend the detector.** Perform the test as soon as possible after breaking the Inner Glass

Tube. Refer to illustration (1)

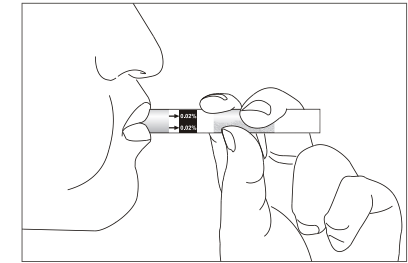


(1)

4. Hold the middle of the detector horizontally, then take a deep breath and blow hard into the Mouthpiece of the detector in **one continuous breath for 12 seconds**. Then shake the detector slightly to distribute the crystals evenly in the Test Window.

### NOTE

Failure to blow hard or to blow in one continuous breath for 12 seconds into the detector may cause erroneous results. Do not inhale while blowing into the detector. Refer to the illustration (2)



(2)

5. **Read results at 2 minutes** by identifying the color of the crystals to determine the relative BAC. Do not read results after 5 minutes.

### INTERPRETATION OF RESULTS

The results should be read by the majority of the crystals due to the sensitivity of the detector to the presence of alcohol. The result may be difficult to determine when it is very close to the cut-off level printed on the detector due to limitations of the test. For best interpretation of results, compare the majority of the crystals in the tested detector to the crystals from an unused detector with the same cut-off level. Read results according to cut-off levels listed below:

**0.02%**

**NEGATIVE:**

**Majority of the crystals remains light yellow in the Test Window.** It indicates the relative BAC is less than 0.02% cut-off level printed on the detector. The crystals may be a lighter color than the crystals from an unused detector.

**POSITIVE:**

**Majority of the crystals changes from light yellow to white, light gray, light green or light blue in the Test Window.** It indicates the relative BAC is equivalent or above 0.02% cut-off level printed on the detector.

**0.05% and 0.08%****NEGATIVE:**

**Majority of the crystals remains yellow or orange in the Test Window.** It indicates the relative BAC is less than the cut-off level printed on the detector. The crystals may be a lighter color than the crystals from an unused detector.

**POSITIVE:**

**Majority of the crystals change from yellow or orange to light green or light blue in the Test Window.** It indicates the relative BAC is equivalent or above the cut-off level printed on the detector.

**LIMITATIONS**

- Alcohol impairs judgment. The test should be performed and the results should be read by someone who has not been drinking to ensure accurate results.
- The Breath Alcohol Detector is a screening test which can provide a preliminary result but may be difficult to determine when it is very close to the cut-off level printed on the detector due to limitations of the test. A secondary analytical method using an evidentiary alcohol test must be used to obtain a confirmed result and before taking any legal or workplace actions.
- The result of the Breath Alcohol Detector may represent relative BAC, but it cannot detect the exact alcohol concentration in blood.
- The test can produce erroneous results due to possible contamination of the breath by interfering substances. Wait at least 15 minutes after last alcohol consumption or drink a glass of water before taking the test to remove alcohol vapors from mouth because it may cause false positive results.
- Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce false positive results. Wait at least 15 minutes after ingesting such products before taking

the test.

- Results should not be interpreted by users who are color-blind or visually impaired. Interpretation of visual results is dependent on variability of color perception and the lighting conditions when the test is read. For best results, read under incandescent, fluorescent, or indirect sunlight. Results read under street lights such as sodium vapor may cause light green to look gray-green and light blue to look amber-green, use a flashlight to read the results under these lighting conditions. When using a flashlight, ensure that the light falls on the side and does not fall directly on the detector.
- A person who may have tested negative from the test may display signs of intoxication or impaired judgment later due to certain factors including sex, age, physical condition, and amount of food or drugs consumed.
- The test is highly sensitive to the presence of alcohol. Alcohol vapors in the air can be detected by the test. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners, and is present in homes and many institutions. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors for accurate reading.

















**PERFORMANCE CHARACTERISTICS**

Atlas Breath Alcohol Detector will react with ethyl alcohol and other volatile alcohols. Some substances such as volatile alcohols, volatile aldehydes, volatile alkenes, and other reductive volatile substances do not normally interfere with the Breath Alcohol Detector in sufficient quantity.

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**Rev A (02.09.2019)**

	Catalogue Number		Temperature limit
	<i>In Vitro</i> diagnostic medical device		Caution
	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry