

FREQUENTLY ASKED QUESTIONS

Using the Detector:

Q - Do I have to break the inner glass tube using two hands?

A - Yes. The use of two hands (as shown in Step 1) creates a more uniform break of the glass tube, which allows the crystals to be more consistently exposed to the breath.

Q - How do I know if enough breath was blown into the Detector?

A - The plastic bag will fully inflate (see Step 2) when enough breath has been blown into the Detector.

Q - What if I don't shake the Detector after use?

A - Not following the directions may cause incorrect results. Shaking the Detector ensures that all crystals are exposed to the breath. This will give a more accurate result.

Using the Analyzer:

Q - Do I have to do anything to the Analyzer to use it?

A - No. The Analyzer is factory calibrated (to each Detector lot number) and will sense the presence of that Detector and immediately read the crystals and indicate a result. DO NOT use, if expired.

Q - What if I do not 'flick' the plastic tube to allow the powder to settle to the bottom?

A - Not following the directions may cause incorrect results. The powder must settle to the bottom to allow proper reading of the crystals and provide accurate results.

Q - Why do I have to twist the Detector while inserting into the sample port?

A - Twisting ensures proper insertion, accurate results, and makes insertions easier. There is a small ledge on the inside that conforms to the tube and the direction it is inserted into the sample port.

Q - Why aren't either of the lights working on the Analyzer?

A - The Detector must be pushed down completely to 'read' the crystals. Be sure that the labeled end is facing up.

Interpreting Results:

Q - How long can I wait to read the results of a test?

A - For best performance, results should be read within 30 minutes of using the Detector. Do not read before 2 minutes. Results will remain the same for up to 4 hours after completing the test.

Breath Alcohol  is a registered trademark of Akers Biosciences, Inc.

Manufactured by:



Akers Biosciences

Accelerating Diagnostic Science To Deliver Real-Time Results

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Read All Instructions Before Beginning the Test


Intended Use:

The Breath Alcohol  .02 Detection System is an *in vitro* medical device that qualitatively detects the presence of alcohol in the human breath. The test system detects breath alcohol at 0.02 BAC and above. The system is used only as a screening device and is only an indication of the possible presence of alcohol in the blood of the test subject.

Test System:


The key elements of the Breath Alcohol  .02 Detection System are the self-contained analyzer and single use breath alcohol detectors. The analyzer is a re-usable device designed for use with a specific lot of Breath Alcohol  Detectors. The detectors are disposable screening devices designed for one time use. The Breath Alcohol  .02 Electronic Analyzer enable the users to read or interpret their Breath Alcohol  Detectors charged by human breath.

The Breath Alcohol  .02 Detector is a plastic tube which contains an inner glass tube and crystals that change color in the presence of alcohol vapors. The results are interpreted by the Breath Alcohol  .02 Electronic Analyzer. The bags are attached to the Detector and used to make sure that enough air is blown into the Detector.

The Breath Alcohol  .02 Electronic Analyzer provides an automatic visual result of the tested Detector. The Analyzer is pre-calibrated for the specific Detector lot and is ready to use when a Detector is fully inserted by twisting into the sample port. **Do not use the Analyzer with another lot of Detectors.**



For *In Vitro* Diagnostic Use

Preparation and Storage:


The Detectors and Breath Alcohol  .02 Electronic Analyzer are ready to use. Store at ambient temperature. Do not Freeze. Do not store at temperatures above 50°C (122°F).

Materials Needed


but not Provided: Timing device

Kit Contents: (1) Breath Alcohol  .02 Electronic Analyzer
(25) Breath Alcohol  .02 Detectors
(3) Plastic Bags (3 per 8 Detectors)
(1) Package Insert

Interpretation of Results:

Once the Detector has been used, the results can be read after waiting two (2) minutes. The Breath Alcohol  .02 Electronic Analyzer will continually flash a red light if the sample is positive or a green light if the sample is negative.

Warnings, Precautions, and Limitations

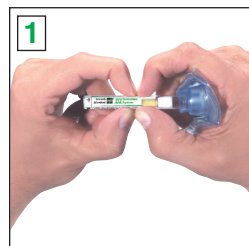
- **Alcohol impairs judgment. Do not test yourself OR drive if you have been drinking alcohol. Someone who has not been drinking should perform the test and read the results.**
- The lot number and expiration date are printed on the Analyzer and Detector. Do not use the Analyzer and Detectors after the expiration date.
- Do not use the Detector in an area with open containers of alcohol.
- *Keep out of reach of children.*
- Do not immerse in liquid.
- **DO NOT INGEST.** Detectors contain potassium dichromate, a hazardous chemical. *If ingested, induce vomiting and contact your physician.*
- Analyzer and Detectors have no special disposal requirements and can be discarded with ordinary trash.
- The Breath Alcohol  .02 Detection System provides a reliable indication of the alcohol in the breath of the test subject when these directions are *completely* followed.
- The system is intended to be a screening device for breath alcohol. The exact level of alcohol in the blood cannot be accurately determined by using this device. Positive results should be confirmed by an evidentiary alcohol test method.

Important Pre-Test Information

Verify the Analyzer is calibrated to the Detector lot being used and have not expired (on the label). Use the Detector immediately after breaking the tubes. Inspect the Detector before beginning the Test Procedure.

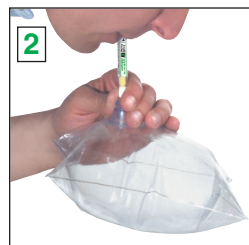
Do not use Detector if: Inner glass tube containing crystals is broken.
Crystals are not yellow.

INSTRUCTIONS FOR USE



For DOT testing, a qualified BAT (Breath Alcohol Technician) or STT (Screening Test Technician) must administer the test. Wait 15 minutes after the test subject's last alcoholic drink. Attach one of the plastic bags provided with the kit to the Detector at the end opposite the blowing end. (The blowing end is marked with arrows.)

Squeeze middle of the outer plastic tube of the Detector between thumbs and forefingers to break the inner glass tube containing yellow crystals. **SQUEEZE ONLY ONCE.** **DO NOT BEND** the Detector. Use the Detector right away.




Hold the Detector vertically.

Instruct testee to take a deep breath and blow very hard into the Detector. Do this in **one continuous blow**. Do not inhale. The bag will be full when they have blown enough. This may take up to 12 seconds. Stop blowing when the bag is fully inflated and remove the bag.



Shake the Detector **vigorously** from end-to-end for 2-3 seconds. Allow the Detector to incubate for 2 minutes.

NOTE: The bag can be returned to the box for additional uses.



Read the result after 2 minutes using the Breath Alcohol  .02 Electronic Analyzer:


Hold the Detector in a vertical position with the label at the top and "flick" the side of the Detector with your finger several times to settle the powder to the bottom and the glass to the top of the contents.

- A. Place the Breath Alcohol  .02 Electronic Analyzer on a flat surface with the device label facing you and the LED lights and sample port facing up.
- B. Insert the Detector, unlabeled end first, all the way into the sample port. Twist while pushing until it comes to a complete stop.
- C. The Breath Alcohol  .02 Electronic Analyzer automatically turns on and the lights will flash instantaneously once when the Detector is inserted properly.

Positive – A continuously flashing red light, the result is above a 0.02 BAC.

Negative – A continuously flashing green light, the result is below a 0.02 BAC.

D. After recording the result, remove the Detector and discard.

The Breath Alcohol  .02 Electronic Analyzer will automatically power off and can be stored until the next use.

Dispose of Analyzer when Detectors are depleted.