



Frequently Asked Questions: BioCheck™ Powder Screening Test Kit February 2003

Q. Why is this product useful?

A. The BioCheck™ Kit provides a fast, simple inexpensive test for first responders to rapidly screen suspicious powder samples for the possible presence of a bioterror agent. This reduces the need for more time-consuming, expensive specific agent field and laboratory testing for the majority of ordinary substances (e.g., sugar, drywall dust, cornstarch) that frequently lead citizens to call 911. Use of the product greatly reduces the fear, cost and inconvenience associated with 'false alarms'. A positive result with the kit indicates the need for further testing for specific bioterror agents.

Q. How does the kit work?

A. The kit measures the presence or absence of protein in a sample. Protein is found in all living materials including biohazardous bacteria and in many toxins. The presence of protein (shown by a change to a purple color in the Protein Solution) indicates the possibility that a biological agent may be present: all biological materials and many toxins contain protein. A pH test is included to provide further information about the sample. Samples are collected using special chemically treated swabs provided with the kit.

Q. Has the product been field tested?

A. The BioCheck Kit was extensively field tested. It was used more than 50 times in response to actual 911 calls. In more than 80% of calls, the suspicious material (e.g. powdered sugar, dry wall dust) could be ruled out immediately as a possible bioterror agent. Common safe substances that would give a positive result with the product (such as whole wheat flour and yeast) rarely caused citizens to call 911.

Q. Has the product been tested by independent laboratories?

A. Yes. The product has been evaluated by a nationally recognized testing company and performed well within specifications. In addition the Metropolitan Health Research Center in Tokyo, Japan, has completed preliminary testing of the product-- in 10 of 10 tests, anthrax was detected.

Q. How do experts from the Federal Government view such tests?

A. A recent EPA report prepared by leading experts from the U.S. Army concludes that "the basic recommended approach is to screen with a generic detector" to detect the presence of DNA, protein or ATP and determine if a material is of biological origin, "then use an immunoassay device in tandem with a nucleic acid analysis technique for identification." *Bio-Detector Assessment* ERT Technical Bulletin 2001-4, March 6, 2002.

Q. What is the intended use of the product?

A. The BioCheck Kit is for the use of first responders to perform an initial assessment of powders suspected of possibly containing bioterrorism agents. A positive with this product indicates that protein is present: further testing must be done to determine which if any biohazardous materials might be in the sample. As a rapid screen, it can therefore save time and cost compared to more expensive agent detection by labs or HAZMAT teams.



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Q. What is the sensitivity of the kit?

A. The product is designed for detection of *visible* amounts of toxins or pathogens. It will detect as little as 100 micrograms of protein or 100,000 anthrax spores. The anthrax letter mailed to Senator Daschle's office last year contained gram amounts of material: many thousands of times as much as this. The product has been used successfully to detect Anthrax. Testing to determine the detection threshold for ricin toxin is underway. It is intended for the screening of suspected weapons of mass destruction (WMDs) where quantities of the active agent will be visible in large (visible) quantities. It is not designed for environmental sampling or testing for individual poisons.

Q. How does this product differ from other field tests?

A. Most other field tests are designed to test for one specific agent. With these products, a negative result for anthrax (for example) says nothing about the possible presence of ricin or other toxins. The BioCheck product allows the user to screen in minutes for multiple pathogens. It is important to note that the product will only detect biohazardous agents if they are present in visible quantities in the sample: a trace amount of a biohazard not visible by the naked eye mixed with a non-toxic powder may not be detected by the kit.

Q. If the kit shows the presence of protein, does this mean that the sample is a biohazard?

A. No. A positive result for protein indicates the need for further testing. Some safe substances (e.g., yeast, whole wheat flour) will test positive for protein. These substances have not normally caused citizens to call 911.

Q. What is the incidence of "false positives" with the kit?

A. The kit will give a positive result with materials that contain protein. Many ordinary substances (e.g., cornmeal, whole wheat flour) contain protein and will give a positive result. Field test results to date show the presence of protein in less than 20% of samples tested. These field samples are 'positive' for protein; whether they are 'positive' for anthrax or other bioterrorism agent can only be determined by different tests.

Q. What is the incidence of 'false negatives' with the kit?

A. The incidence of false negatives is virtually zero (i.e., no color change even if a WMD is present) IF the kit is used correctly. This involves two things:

- I.** Use of the Control and **II.** the timing of reading the result. **I.** The Control (a positive control for protein) is the most important: In the event of a test that is negative for the presence of protein, the Control Swab should be added to the Protein Test Solution (NOTE: it is important that the Protein Test Swab is already in the tube). In most instances, the Protein Test Solution will turn purple within 5 minutes after addition of the Control Swab. Failure of the solution to change color indicates that the kit is not working. The sample should be tested using a new kit and/or other testing methods. **II.** It is important to take the reading within 30 minutes of the test: after longer intervals, even materials that don't contain protein may start to show a faint purple color. It is important to note that potentially fatal quantities of some agents can be dispersed in quantities that could not be detected by this product. However, these quantities are unlikely to constitute a WMD where relatively large (visible) amounts of material are dispersed.



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Q. How often will the kit give a positive result for protein?

A. In field tests from more than 50 incidents, the BioCheck™ ruled out as bioterror threats more than 80% of substances that caused citizens to call 911.

Q. What is the shelf life of the kit?

A. The product is stable for 1 year. Testing is underway to confirm it is stable for at least 2 years.

Q. What does the pH test do?

A. The pH test indicates whether the material being tested is acidic (pH Solution turns **reddish pink**), basic (pH Solution turns **blue**) or of neutral (physiological) pH (pH solution does not change color: it remains a **pale yellow**).

Q. What is the purpose of the pH test?

A. The pH test provides additional information about the sample. Specifically, materials that may contain dangerous bioterrorism agents are likely to be of neutral pH. (A neutral pH does NOT mean a bioterrorism agent is necessarily present, only that further testing may be needed if the protein test is positive). A neutral pH will not cause a color change in the pH Solution. In addition, a change in color to reddish pink indicates the presence of an acidic material. Acidic materials may cause the protein test to fail so the pH test can assist in explaining the performance of the protein test. In actual field tests, the vast majority of substances tested had a neutral pH.

Q. What is the effect of temperature on kit performance?

A. The color change in the presence of protein will happen more quickly in warm temperatures and more slowly in cool temperatures. Store the kit at room temperature.

Q. How should the kit be disposed of after use?

A. The kit should be discarded according to your department's guidelines. The BioCheck Kit contains no hazardous reagents however the materials tested with the kit are unknowns and should be handled accordingly.

Q. If anthrax or other pathogen is present, what will the tube solution colors be?

A. The presence of protein will cause the solution in the protein test tube to turn purple. The solution in the pH tube should not change color, remaining a pale yellow. It is important to note that these results indicate only the possibility of a pathogen or other bioterrorist agent: **further testing is required.**

Q. If the protein test changes color indicating the presence of protein, how long will this color remain?

A. The purple color will remain indefinitely. However, it is important to take the reading within 15 minutes of the test: after longer intervals, even materials that don't contain protein may start to show a faint purple color.