BioCheck™ Powder Screening Kit

FAQ's

Why is this product useful?

The BioCheck Kit is a fast & simple test allowing first responders to rapidly screen suspicious powder samples for the possible presence of a bioterror agent. This reduces the need for more time-consuming, agent-specific field testing for the majority of ordinary substances (e.g., sugar, drywall dust, cornstarch) that frequently lead citizens to call 9-1-1. Use of this product can greatly reduce 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.

How does the kit work?

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

Has the product been field-tested?

The BioCheck Kit was extensively field-tested. In more than 80% of calls, the suspicious material 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 - will also yield positive results and require further evaluation.

Has the product been tested by independent laboratories?

Yes. The product has been evaluated by a nationally recognized testing company (please see the report) 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.

How do experts from the Federal Government view such tests?

A recent EPA report prepared by leading experts from the U.S. Army concluded that "the basic recommended approach is to screen with a generic detector" to detect the presence of DNA, protein or ATP. If the material is determined to be 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.*

What is the intended use of the product?

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 result with this product indicates that protein is present: further testing must be done to determine which, if any, biohazardous materials might be present in the sample. As a rapid screen, it can therefore save time and cost by terminating non-credible responses in a timely fashion.

What is the sensitivity of the kit?

The product is designed for the 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 necessary for detection. 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 present in large (visible) quantities. It is not designed for environmental sampling or testing for individual poisons.

How does this product differ from other field tests?

Most other field tests are designed to test for one specific agent. With these products, a negative result on anthrax (for example) says nothing about the possible presence of ricin or other toxins. The BioCheck product allows the user to screen for possible 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 eye, mixed with a non-toxic powder, may not be detected by the kit.

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FAQ's...continued.

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

No. A positive result for protein indicated the need for further testing. Some safe substances (e.g. - yeast, whole wheat flour) will test positive for protein.

What is the incidence of "false positives" and "false negatives" with the kit?

The kit will give a positive result with materials that contain protein. Many ordinary substances (e.g. - cornstarch, 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 agents can only determined by using the Guardian Reader System. The incidence of false negatives (i.e. - no color change when a WMD is present) is virtually zero IF the kit is used correctly. This involves **two** key components: Control Use and Timing of Reading the Result.

1. Use of the Control

The positive control is the most important factor. In the event of a test that is negative for the presence of protein, the Control Swab should be added to the 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 sample contains interferrant materials. The sample should be tested using a new kit & other agent-specific testing methods.

2. Timing & Reading Results

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.

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

In limited field testing, the BioCheck ruled out as bioterror threats more than 80% of the substances that caused citizens to call 9-1-1.

What is the purpose of the pH test and what does it do?

The pH test indicates whether the material being tested is acidic (pH solution turns reddish pink), basic (pH solution turns blue) or of neutral pH (pH solution does not change color; remains a pale yellow). The pH helps to provides additional information about the sample. Specifically, materials that may contain dangerous bioterrorism agents are likely to be of a neutral pH. (A neutral pH does NOT mean a bioterrorism agent is necessarily present, only that further testing may be need 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.

What is the shelf-life of the kit and what effect does temperature have on kit performance?

The product is stable for one year. Testing is ongoing to determine if we can extend the shelf life. The color change will happen more quickly in warm temperatures and more slowly in cool temperatures. Store the kit at room temperature.

How should the kit be disposed of after use?

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.

If anthrax (or other toxins) is present, what will the tube solution colors be?

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.

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

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.