

Ahead of the Curve?

Tetracore Says Its Anthrax Test Was Unfairly Lumped With Rivals'

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When the fear of mail-borne anthrax struck 17 months ago, firefighters and hazardous-materials teams snatched up Tetracore Inc.'s domino-size anthrax detectors at a record pace. A niche market suddenly went national.

Today, sales are down 60 percent, six months after federal regulators called the commercial devices unreliable and urged federal, state and local health officials to cease using them.

For Tetracore, the rebuff has a frustrating twist: The government warning was based on a study that, though it found problems, ranked Tetracore's product far above its competition.

Worse, Tetracore can't get the message out. Neither the FBI nor the Centers for Disease Control and Prevention, which conducted the study, will publicly identify the four anthrax detectors in the test. They instead released a summary, promising to disclose the full report in a scientific journal later this year.

"We were told our product performed the best and we're now being lumped in with other tests that didn't do as well," said Thomas W. O'Brien, vice president and senior scientist at Gaithersburg-based Tetracore.

At the center of the company's troubles is a highly technical debate about the quality of an anthrax test that now sits inside the tool kits of dozens of hazardous-materials teams across the country. The device, called a handheld assay, is designed to rapidly screen large samples of suspected anthrax using a technology similar to a home pregnancy test. A yes or no verdict arrives on the spot, typically in less than 30 minutes.

But the test has serious drawbacks that make its use one of many tough calls in this new world of high terror alerts. Because it is designed for large samples of anthrax, it misses small but deadly doses. Even with larger samples, the tests can detect anthrax when none is present, spreading unnecessary panic. As a result, the Office of Science and Technology Policy -- which advises the Executive Office of the President of the United States -- and the Department of Health and Human Services have advised federal and local health officials to instead rely on highly sensitive laboratory analysis that can take up to 24 hours to report.

Hazardous-materials teams from Arlington to Seattle have ignored the warning. They contend that any rapid field test for anthrax -- even a limited one -- is better than none. Without it, these officials say, they lose critical time to seal off exposed spaces, treat potential infections and launch a criminal investigation.

"When we've got people in a building, we need to give them some kind of assessment of what an

unknown substance is. Otherwise there is just panic," said Gene Ryan, a deputy chief in the Chicago Fire Department who directs the city's hazardous-materials team. The city continues to use handheld anthrax detectors, including Tetracore's.

There are no known cases in which commercial handheld assays detected anthrax in the field, if only because anthrax attacks are extremely rare. Federal authorities, who have identified anthrax in the field, use a similar, but noncommercial, version.

The rift over the tests has also highlighted a little-known hole in the nation's regulatory system. When it comes to commercial bioterrorism tools, no single federal authority grants approval or even issues product standards. The absence of such a clearinghouse has left local fire departments and hazardous-materials teams unsure of how to pick through the torrent of commercial detection kits that have flooded the market since the Sept. 11, 2001, terrorist attacks. The new Department of Homeland Security has said it will draft product standards, but officials there say the task could take months.

"There is no regulation right now, no established standards for any of these kinds of commercial products," said David Cullin, a Defense Department director for chemical and biological defense.

With no blueprint for disclosure in place, the FBI and the CDC notified each manufacturer of its product's performance in their study and released a summary of their data. An FBI spokesman said the agency withholds the names of commercial products under its review to avoid the appearance of endorsing or rejecting them. A CDC spokesman declined to comment on the report, referring calls to the FBI.

According to company representatives and federal and local health officials familiar with the study, Tetracore's BioThreat Alert system accurately distinguished between anthrax and other bacteria in 97 percent of tests, at least 30 percentage points higher than the three other detectors in the report.

The remaining tests recorded a score of 17 to 67 percent. The rest of the time, they detected anthrax when none was present, what scientists call a "false positive" reading. When it came to finding anthrax disguised in other powders and liquids, three of the tests, including Tetracore's, achieved 85 percent accuracy. Data for the fourth detection system was not available because, the study notes, testing required "too much total time."

All of the companies whose products were tested object to the test's structure, to the degree that they know it.

"We thought we were going to be involved in the study's design and were not," said Lawrence Loomis, president of New Horizons Diagnostics Corp. in Columbia, who says the company's handheld anthrax test was included in the FBI-CDC study. He believes government scientists did not follow company instructions for its use.

The third detector belongs to Response Biomedical Corp. of Vancouver, B.C., said chief executive Bill Radvak. Osborn Scientific Group in Lakeside, Ariz., makes the fourth test in the report, said the company's director of business strategy, Greg Emery. The testmakers said they learned of their product's inclusion in the federal study from government scientists. Those who

have seen the report confirm that the four products were included but would not comment on their individual performance.

Support for the full report's speedy disclosure is coming from unexpected quarters. Jerome M. Hauer, an acting assistant secretary in the Department of Health and Human Services, opposes the use of handheld screeners. But he wants the federal study released so local health officials and the companies "can evaluate how the testing was done and how the devices measured against that testing." A senior official at the Department of Homeland Security agreed, calling the release of the data and standards for the handheld tests a "top priority."

Privately held Tetracore, founded by four former Navy scientists, developed its BioThreat Alert system two years ago to detect anthrax, ricin, bubonic plague and other pathogens. It fashioned a modest market in government contracts. Then the 2001 anthrax attacks began, eventually claiming five lives up and down the East Coast. As reports of white powder bred fear in the nation's biggest cities, Tetracore's sales surged.

Soon the market was flooded with detection kits, overwhelming local health officials who wanted a quick and accurate field test to dispense with anthrax hoaxes. The FBI-CDC study attempted to sort through the thicket.

The scientists conducting the study narrowed their search to antibody-based tests like Tetracore's, so called because they exploit the natural interaction between antibodies and foreign objects. A strip of absorbent paper is filled with anthrax antibodies, proteins specifically structured to attach to the bacteria. When anthrax is diluted in a liquid and applied to the strip, the antibodies attack, sliding across the strip and triggering a color change visible to the naked eye. (Tetracore's BioThreat Alert system includes an optional computer that analyzes test strips to avoid human error.)

But even the most accurate of these antibody-based anthrax detectors are severely limited. Inhalation anthrax infections require fewer than 100 spores, said Mary S. Bogucki, a professor of emergency medicine at Yale University who works closely with hazardous-materials teams. Of the tests studied by the FBI and CDC, the most sensitive can detect only 100,000 spores or more.

Just as worrisome, the tests often produce positive readings when no toxins are present. In the federal study, for example, Tetracore's detector recorded "false positive" readings 3 percent of the time. Such results can prompt massive evacuations and unnecessary medical treatment, health officials say.

Critics of handheld anthrax tests also seize on an oft-repeated admission from companies such as Tetracore: The devices do not offer definitive results. Rather, they accelerate the process of sorting out potential bioterror threats from cases of mistaken identity.

"If the results of the handheld assay do not allow you to make a definitive decision one way or the other, why use it?" said Kathryn Harrington, a spokeswoman at the Office of Science and Technology Policy.

The local hazardous-materials teams that have stuck by the tests, including those in large cities such as Chicago and Seattle, use Tetracore's detector in combination with two or three other field

tests and work with certified laboratories.

"We don't make medical decisions based on it," said A.D. Vickery, deputy chief in the Seattle Fire Department and head of its hazardous-materials team. "But we decide how to contain the situation in a timely manner."

That is the approach endorsed by the Defense Department, which continues to use antibody-based handheld anthrax detectors despite the federal advisory. The department manufactures its own detectors, which it says outperform commercial versions. One of them was used to positively identify anthrax in a letter to Sen. Thomas A. Daschle (D-S.D.).

The tests, the department noted in a July memo, "are effective when employed as part of a systematic, layered detection" strategy. Why does the Defense Department use a device the government has advised local hazardous-materials teams against using?

"We think it has a place," said a Defense Department official who works with the technology. "It is not the be-all, end-all test, but if I get a positive reading on a handheld assay, you better start planning some reaction."

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