Summary of FBI/CDC Study on Hand-Held Anthrax and Plague Tests

Background:

Federal memoranda released on July 21, 2002 advised First Responders not to use hand-held anthrax and plague tests for field evaluation of suspected biological threats. This followed a Department of Health and Human Services' (DHHS) internal review of test data produced from an FBI/CDC study of commercially available hand held tests for anthrax and plague.

Although the recommendations cited unfavorable test results for all commercially-available anthrax tests, Federal authorities declined to make the test results, the protocols, or the evaluation standards publicly available. A redacted version of the test results was obtained recently that clearly indicates that all of the products did not perform below acceptable standards.

Test Results:

The Tetracore anthrax and plague tests outperformed other commercial tests. In the interest of full disclosure and to allow review by current and potential users of these technologies, the test data are summarized below:

Table 1 - Commercial Anthrax Tests

Ranking of Commercial Supplier	*Sensitivity (CFU/ml)*	*Specificity[1] (false positives)*	*Reproducibility*	*Robustness[2]*	
				Without Target	*With Target*
1-Tetracore BioThreat Alert[3]	10^6	3 %	98 %	100%	85 %
2	10^5	37 %	90 %	90 %	85 %
3	10^5	83 %	94 %	85 %	85 %
4	10^6	41 %	78 %	n.d.	n.d.

[1] As determined across 30 different non-anthrax bacterial species.

[2] Performance of each test in the presence of additives (interferrants); with or without anthrax (target).

[3] Tetracore BioThreat Alert tests were read visually; the Guardian Reader was not used in this study.

The full test protocols were not included in the redacted test summary nor were the identities of the other commercial tests disclosed. It was confirmed through at least 5 separate and independent sources that the Tetracore anthrax test was ranked as the best performing test. Sensitivity levels were determined by the lowest concentration that produced ten out of ten positives. (Note: Tetracore production lots perform at concentration ranging from 1.25-2.5 x 10^5 CFU/ml in the QC laboratory).

When compared across 30 near-neighbor bacteria, the false-positive rate for the Tetracore anthrax test (3%) was well within acceptable standards for field tests. In marked contrast, the competitors all produced unacceptably high false positive rates (37 % to 83 %). Within-run reproducibility and robustness against potential interferrants were equally favorable for the Tetracore tests.

In the case of the plague test evaluations, only two commercial products were tested. Again the Tetracore test outperformed the competitor as evidenced below:

Table 2 - Commercial Plague Tests

Ranking of Commercial Supplier	*Sensitivity (CFU)*	*Specificity[1] (false positives)*	*Reproducibility*	*Robustness[2]*	
				Without Target	*With Target*
1 - Tetracore BioThreat Alert[3]	10^5	7 %	100 %	100%	100 %
2	10^4	7 %	99 %	80 %	85 %

[1] As determined across 15 different non-plague bacterial species.

[2] Performance of each test in the presence of additives (interferrants); with or without plague (target).

[3] Tetracore BioThreat Alert tests were read visually; the Guardian Reader was not used in this study.

Although Tetracore offers BioThreat Alert tests for botulinum, SEB, tularemia and ricin, no other biological tests were evaluated by the CDC since no competitive products were commercially available for comparison.

Discussion:

As no tests were performed at concentrations between 1.0 x 10^5 and 1.0 x 10^6 CFU/ml in the CDC test, precise sensitivity between these concentrations was not determined. Notably, these sensitivity levels are in the microgram-per-ml range. The mailed letters sent to the Senate last Fall contained gram quantities of anthrax, an amount equivalent to roughly one million times more than that necessary to cause a positive in the Tetracore test. If the threat is visible, sensitivity is therefore not an issue for on-site testing. However, specificity, i.e. false positive rate, is a critical criterion for First Responders. The false-positive rate for the Tetracore anthrax test (3 %) exceeds acceptable standards for field tests, in marked contrast to all the competitors (37 % to 83 %).

In addition to CDC laboratory test results, user surveys of Alexeter customers demonstrate less than 0.2 % false positive tests in actual field use (2 false positives out of 1027 test reports).

Summary:

Alexeter's Guardian Reader System and Tetracore's BioThreat Alert tests remain the industry standard and the tools of choice for First Responders and safety organizations. Results from the CDC study demonstrate the BioThreat Alert tests perform at or above manufacturer's specifications and outperform all other competitors. Review of the available data supports continued use of the Tetracore BioThreat Alert tests by first responders for field analysis.