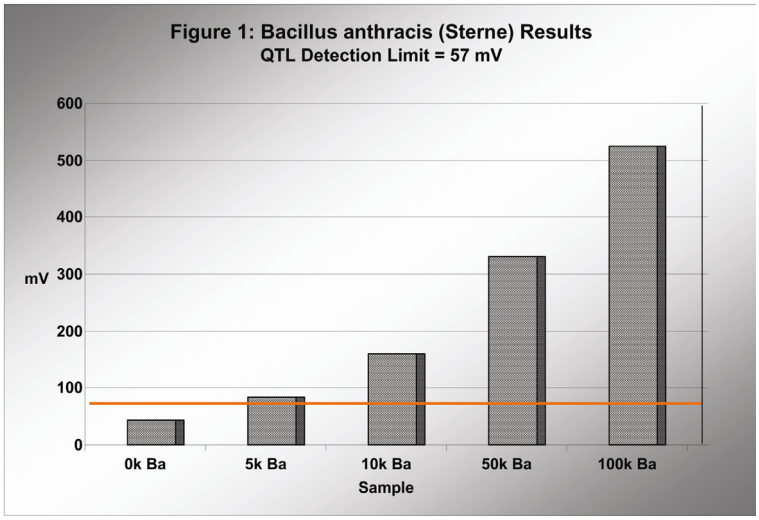
R E S E A R C H R E P O R T

Performance Verification of the QTL Biosensor at the University of Alabama (UAB)

QTL Biodetection has developed a hand-held Biosensor to identify biological agents. The tests at the University of Alabama at Birmingham were conducted to provide an independent verification of the QTL internal data.

Tests were performed in September-November, 2004 in the laboratory of Dr. Charles Turnbough, Professor of Microbiology at UAB, using a prototype hand-held detector and cartridges developed by QTL. The Turnbough laboratory provided distilled water and suspensions of *Bacillus anthracis* (Sterne) and *Bacillus anthracis* (Δ Ames) spores whose concentrations were determined by hemocytometry. The *Bacillus anthracis* (Sterne) is a non-virulent "vaccine" strain while the *Bacillus anthracis* (Δ Ames) lacks a plasmid present in the virulent *Bacillus anthracis* (Ames). These non-virulent spores have an outer surface that appears to be identical to that of virulent spores.

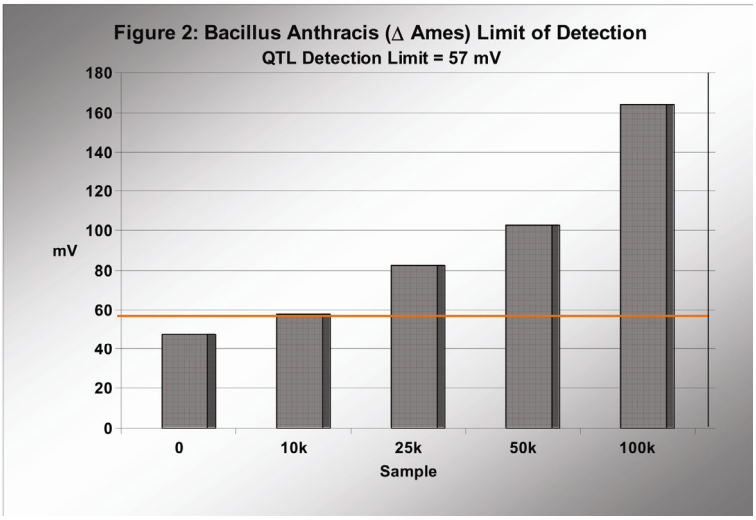


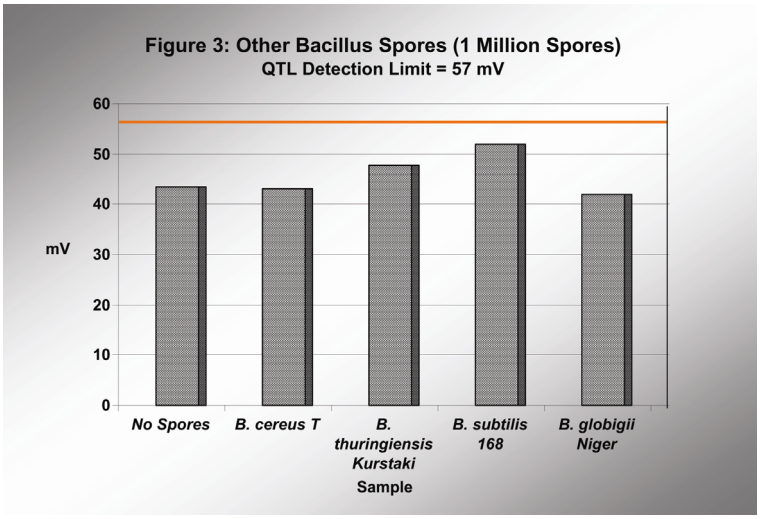
Bacillus Anthracis (Sterne) Results

Initial experiments were carried out with negative control samples (containing only MAG and TAG) to verify that the hand-held detector was functioning normally. Subsequently, tests were carried out with 100,000, 50,000, 10,000 and 5,000 B.a. (Sterne) spores (**Figure 1**). Each assay was carried out multiple times as noted in the tables. The QTL Detection Limit for B.a. (Sterne) is less than 5,000 spores. A preparation of fresh, unwashed ('dirty") spores of B.a. (Sterne) at a level of 100,000 gave very similar results to those shown in the table and figure for purified spores. This reinforces the conclusion that the assay detects intact spores only.

Bacillus Anthracis (Ames) Limit of Detection

Similar experiments were carried out with B.a. (Δ Ames) spores (**Figure 2**). Very good sensitivity was observed for the Δ Ames spores; the QTL Detection Limit is approximately 12,000 spores with a statistically significant false positive rate of one in a million. With a false positive rate of one in a thousand, the QTL Detection Limit is below 10,000 spores.



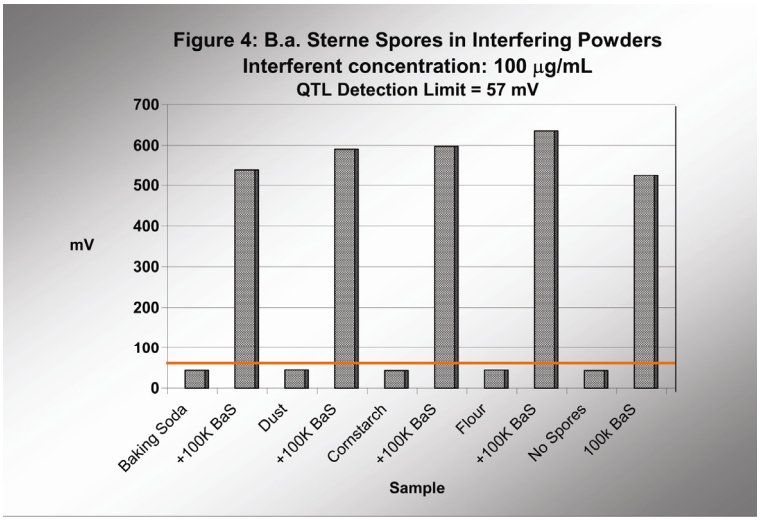


Other Bacillus Spores (1 Million Spores)

The assay was then performed using four "nearest neighbor" *Bacillus* spores at a level of a million spores per assay (100-fold excess over the QTL Detection Threshold for B.a., see **Figure 3**). None of these four spores tested showed a response significantly different from the background.

B.a. Sterne Spores in Interfering Powders

Finally the assay has been tested for background and signal for 100,000 B.a. (Sterne) spores in the presence of potential interferents (or suspect powders). As shown in **Figure 4**, none of these substances produce changes in either the background ("blank") or samples containing spores.



Notes: The detector/cartridge system as tested here required adding a sample of a potential bioagent in water to a detection mixture containing capture and detection reagents for the bioagent. The final system will feature dried reagents stored within the cartridges. In the specific tests developed at QTL, these reagents are antibody-functionalized magnetic beads (MAG) and fluorescent tags (TAG). Upon mixing with the bioagent, a "sandwich" is formed between the MAG, analyte and TAG; this group is then captured by a magnet in the detector near the cartridge window. The captured bioagents are rinsed with a wash buffer and the signal is read in the detector. QTL has developed the assay and tested it in-house. The detection reagents, "MAG" and "TAG", respectively were provided as suspensions in proprietary aqueous buffer solutions. QTL also provided samples of a buffer solution used in diluting test solutions and tablets for preparing PBS-Tween pH 7.4 buffer rinse solutions.

QTL Biodetection has developed its tests to provide extremely low false positives. The QTL Detection Limit is set to give, on a statistical basis, less than one in one million false positives. The acceptable false positive rate (such as one in a thousand) can be selected to meet the different needs of first responders, military, HazMat and site decontamination personnel. Current strip tests have false positive rates much higher, in the range of several per hundred.

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