First Responder Biodetection: Technology Foraging and Testing

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Project Overview

The US Department of Homeland Security (DHS), Science and Technology (S&T) Directorate, including the Chemical and Biological Division, manages a portfolio that includes projects for the development, testing, and transitioning of next-generation detection technologies. Pacific Northwest National Laboratory (PNNL), as part of an effort funded by the DHS, has been tasked to assess currently available needs for hand portable biodetection equipment, as relevant for first responders. This assessment is comprised of technology foraging to identify commercial off the shelf (COTS) biodetection equipment, and testing hand portable PCR-based biodetection equipment. PNNL recently released the report “Biodetection Tools for First Responders,” which provides an overview of COTS biodetection equipment, including non-specific (e.g., protein and FTR) and specific DNA and antibody-based biological detection technologies. Select portable biodetection equipment is currently under evaluation. Together, both the technology foraging and the testing work towards improving long-term biological response capabilities to critical biological events.

Testing To Date: Hand Portable PCR Platforms

> 5 PCR platforms are currently being evaluated: FilmArray (BioFire Diagnostics), RAZOR (BioFire Diagnostics), T-COR4 (Tetracon), BioSeeq Plus (Smiths Detection), and POCKIT (GeneReach USA)

> Tested against DNA stocks:
  - Inclusivity panels:
    - Multiple strains of Bacillus anthracis DNA
    - Concentrations tested: 2,000 copies/mL (except 20,000 copies/mL using BioSeeq Plus)
  - Exclusivity panels:
    - Near-neighbor DNA
    - Concentration tested: 20,000 copies/mL (except 200,000 copies/mL using BioSeeq Plus)

> Tested Ba-specific instrument assays:
  - FilmArray: Multi-threat assay (Chromsome + plasmid)
  - RAZOR: Ba-3 assay (Chromsome + plasmid)
  - T-COR4: Ba pX02 assay
  - BioSeeq Plus: Ba pX02 assay
  - POCKIT: Ba pX02 assay

Criteria for Successful Testing

> Criteria for successful testing are based upon achieving an estimated 95% lower confidence limit on the probability of detection of ≥0.95.
> Assumes for the testing that all inclusivity samples are equivalent, and all exclusivity samples are equivalent at an acceptable minimum detection level (AMDL) that is appropriate for the application.
> At least 34 samples must be tested without a single failed result, or
> At least 53 samples must be tested with no more than one single failed result, or
> At least 86 samples must be tested with no more than two failed results.

Instruments in the Testing Pipeline

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Next Steps

> While there are many biodetection platforms available for suspicious powder assessment, the amount of information obtained from these tools can range from general (e.g., FTIR) to specific (e.g., PCR).
> There are limited commercial or near commercial off-the-shelf biodetection platforms with assays able to detect <10<sup>6</sup> Bacillus anthracis spores.
> At present, PNNL has performed initial evaluation of PCR-based platforms.
> Testing results:
  - T-COR4, FilmArray, and RAZOR instruments consistently detected Bacillus DNA and correctly classified exclusivity DNA.
  - BioSeeq PLUS did not consistently detect Bacillus DNA (3 false negatives for the inclusivity samples).
  - POCKIT did not consistently classify exclusivity DNA (3 false positives for the exclusivity samples).

Summary

> Suspicous powder testing:
  - Evaluation of performance with 21 common interferent or hoax powders (e.g., talc, flour)
  - Performed with all types of biodetection platforms (e.g., FTIR, protein test, PCR, immunoassays, etc.)

Next Steps

> Live agent testing:
  - Bacillus anthracis Sterne spores
  - Evaluation of all platforms
  - PCR: pX01 assay
  - Bacillus anthracis Ames spores
  - Evaluation on PCR platforms only
  - PCR: pX02 assay
  - Ricin toxin
  - Evaluation on all platforms, except where ricin-specific assay not available (PCR: BioSeeq Plus)

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