

# DHS Science and Technology Directorate

## Bioassays: Public Health Actionable Assay

### Biological Agent Detection Presents Continuing Challenges

In the event of a biological attack, first responders and public health agencies need fast, reliable and accurate tests that can detect disease-causing agents and alert response organizations to initiate appropriate actions in the interest of public health and safety. However, some tests currently in use can suffer from a variety of issues that lessen their usefulness. For example, a test may miss a dangerous bacteria, toxin or virus because there is only a very small amount of it in the sample. It may report the presence of a threat when there is none, incorrectly identify a threat or be unable to identify a threat at all.

To meet these challenges, the Department of Homeland Security (DHS) Science and Technology Directorate (S&T) has established the Public Health Actionable Assay (PHAA) project. PHAA is charged with spearheading the development of tests, standards, materials and technologies that advance the biological detection and diagnostics capabilities of our federal partners, first responders and other DHS customers to enhance their current capabilities.

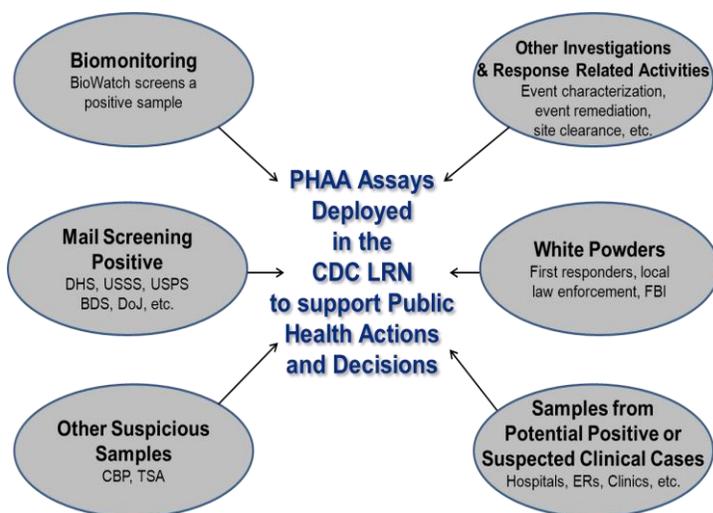
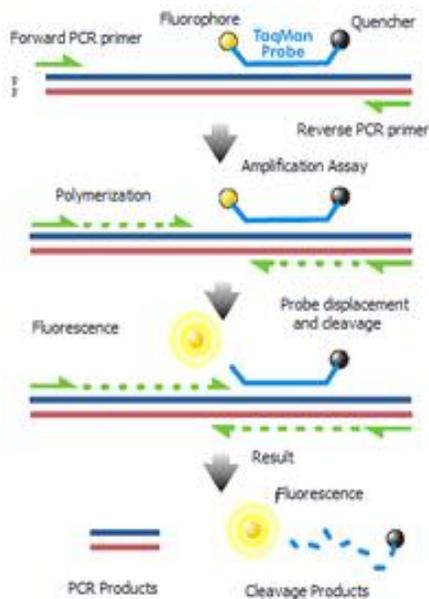
### Augmenting Detection Capabilities

S&T works with federal partners such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Department of Justice (DOJ), the Department of Agriculture (USDA), the offices of the Assistant Secretary for Preparedness and Response (DHSS/ASPR) and the Biomedical Advanced Research and Development Authority (DHHS/BARDA) within the Department of Health and Human Services to address capability gaps and prioritize our rapid PHAA development efforts. Tests are designed to detect agent

specific nucleic acid sequences, which can be used to identify agent specific disease-causing species, a subset within that species or even individual genes that give a biological threat its pathogenicity and virulence characteristics. These tests are intended to be highly specific and highly sensitive to minimize

false positives and false negatives. S&T has risen to this challenge by transitioning suites of assays covering nearly 20 bacterial and viral agents, which include over 140 signatures that are currently undergoing testing, evaluation and validation. The results of these analyses will greatly enhance and expand the capabilities of our partners and customers.

S&T's Bioassays research efforts develop innovative compounds and techniques that will improve test performance, allow for the detection of multiple threats simultaneously and enable methods to move from the lab to the field or facilitate the use of methods that offer greater detail about a threat. These innovations will be transitioned for operational application or technology development efforts to support DHS customers and first responders.



### Increasing Confidence Through Consistency

There are various detection tests and systems available and each may have been evaluated differently. This lack of consensus regarding how to judge the detection capabilities of a test can lead to doubt about a test's accuracy and reliability. To provide a solution, S&T collaborates with academia, public health and Federal partners (DHHS/ASPR, DHHS/BARDA, CDC, FDA, USDA, DHHS, DOJ and others as is appropriate), to establish standards for objective evaluation of lab-based detection technologies via the PHAA program. PHAA-developed standards include panels of organisms that must be tested to prove accuracy, performance criteria and evaluation protocols. While adherence to these standards is voluntary, adoption will be advantageous since the trust of the user in a detection test or system will be increased by demonstrating the ability to rapidly identify a threat without reacting to similar organisms, or being impeded by potentially interfering materials, in the environment.



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To Learn More about the Bioassays program, contact [SandT-Chembio@hq.dhs.gov](mailto:SandT-Chembio@hq.dhs.gov).