Purpose: Provide a brief assessment of strengths and weakness in preparedness with diagnostics for biological threats to the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Diagnostics Integrated Program Team (IPT).

STRENGTHS

- When we have them, they:
  - Help to ascertain full scope of an incident
  - Help to reliably distinguish infected from non-infected due to improved screening
  - Help to determine appropriate intervention strategies and decisions, including quarantine and isolation
  - Spare vaccines, treatments, and quarantine when they are not needed (saving valuable resources)

- The Panel can see that these areas are addressed by current diagnostic development and thinking from federal Departments and agencies

WEAKNESSES

- We don't have enough

- The need for diagnostics is an enormous capability gap

- Development of rapid point-of-care diagnostics largely ignored

- While drugs are certainly needed, we believe a more balanced portfolio is needed with diagnostics in general, and point-of-care diagnostics in particular

- We continue to rely on response – if we are going to keep doing that, and all indications are that we are continuing along the same path now – then we need to be better able to respond and diagnostics would help with that – **we need to foster effective response capabilities**

- Processes to develop diagnostics are too **ad hoc**
16 years after the 2001 anthrax incident the deployed diagnostics portfolio is largely unchanged.

More laboratories are in the Laboratory Response Network (LRN), with a greater collective capacity for PCR testing. Environmental sampling now exists in the BioWatch program. Other than blood culture for patient management, antigen detection has not been enhanced.

No plan is in place for operational use (e.g., whether the Strategic National Stockpile would send out kits; whether the LRN would have enough capacity, whether a surge manufacturing capability for reagents would suffice). These issues would need to be considered in framing anthrax diagnostics product-specific requirements (PSRs), which, in turn, would inform operational planning. PSRs are needed to support acquisition.

Rapid point-of-care diagnostics significantly improve outbreak management

- Some basic requirements
  - RAPID
  - Patient-side
  - Hundreds or thousands to distribute broadly
  - Able to be used by even those with limited training
  - Should better enable health care providers to identify diseases they have not seen before and that are in early presentation
  - Should inform other-than-clinical decisions, too (e.g., those based on attribution)

Recommendation 30 from the *Blueprint for Biodefense* (2015) – Incentivize development of rapid point-of-care diagnostics

- Action Item a. Develop requirements for rapid point-of-care diagnostics for all material biological threats and emerging infectious diseases (medium term – 1-3 years, which means 2016-2018)
  - We talk about prioritizing diagnostics for material biological threats and emerging infectious diseases, but this presupposes that the material threat determinations are current and remain accurate.
  - Further, you can't prioritize an emerging infectious disease before it has actually emerged.
We see that Biomedical Advanced Research and Development Authority (BARDA) has prioritized (to some extent, even as evidenced by this IPT) the development and acquisition of rapid point-of-care diagnostics, but the Panel thinks there should be even greater priority to produce a more balanced portfolio.

We know that BARDA has engaged in plans but we are still hearing that academia and industry are not fully engaged + operational planning is weak because it involves so many other parties.

We realize that simply saying that industry needs more incentives is not enough - lack of a conventional diagnostics market to drive development.