

#### **COVID-19: CHALLENGES FACED ALONG THE WAY**

- Access to diagnostic tests
- Access to validation material
- Complexities of EUA process
  - Despite FDA being an excellent partner
- Acquisition of equipment and reagents
- Ongoing supply shortages
- Staffing

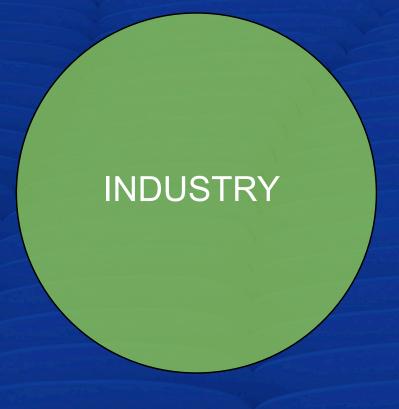


PUBLIC HEALTH LABORATORIES

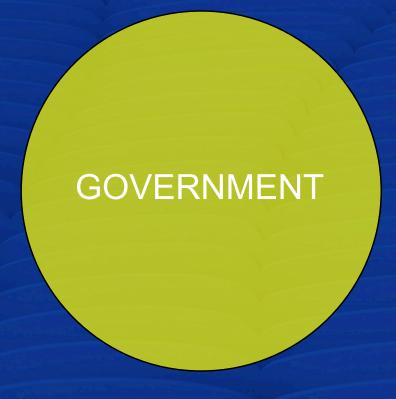
- Foundation of public health response
- Epidemiologic surveillance
- Early access to positive samples
- CDC best positioned to lead early test development efforts



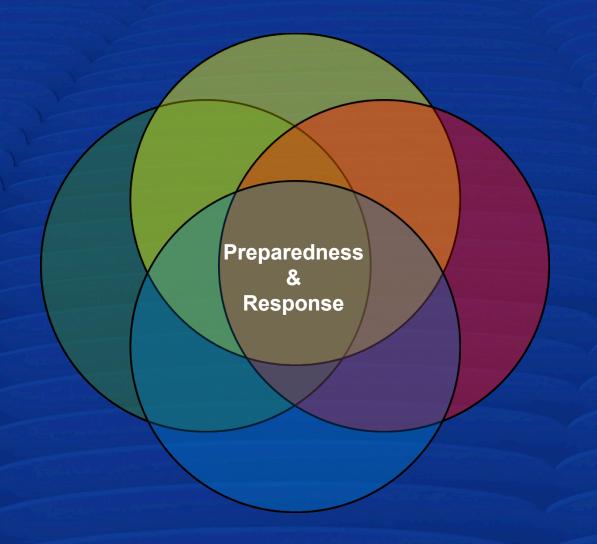
- Frontline of patient care
- Have the infrastructure for hospital and clinic-based testing
- Provide the most rapid turnaround time for testing



- Necessary resources for test development and commercialization
- Ability to produce reagents/equipment at scale
- GMP production facilities help ensure high quality and reproducibility

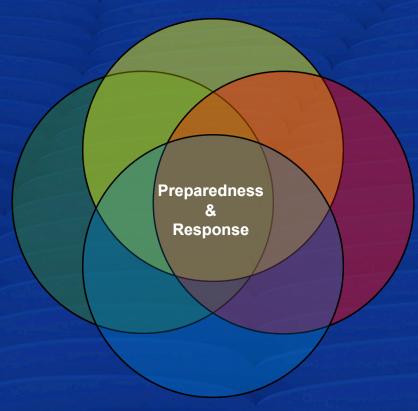


- Coordination of public health response
- Funding
- Prioritization and decision-making





#### A PATH FORWARD



- Proactive versus reactive
- A coordinated strategy to develop and implement testing is needed to respond to emerging infectious diseases
- Widespread testing during <u>early</u> phase of an outbreak is needed to prevent broad community transmission

Binnicker MJ. 2020. Emergence of a novel coronavirus disease (COVID-19) and the importance of diagnostic testing: Why partnership between clinical laboratories, public health agencies and industry is essential to control the outbreak. Clin Chem 66(5):664-666.

## A PATH FORWARD: CURRENT



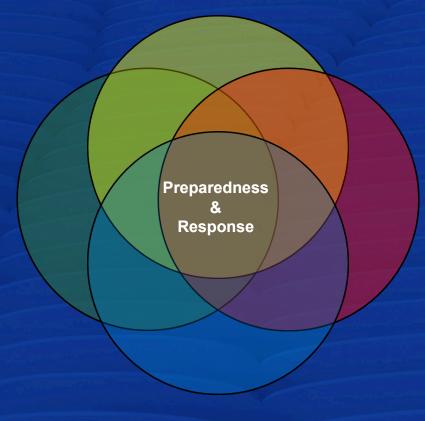


## A PATH FORWARD: FUTURE?





#### A PATH FORWARD: POTENTIAL SOLUTIONS



- CDC/Public Health identify strategic partners in clinical labs and industry
- Coordinate test development with industry partners to streamline path to test availability and mass production of necessary reagents/components
- Clinical laboratory partners identified outside of an outbreak/pandemic that have necessary equipment and are vetted as high-quality testing labs

Bertuzzi S and Patel R. 2020. We need a new kind of National Guard. New York Times, April 27, 2020

## PARTNERSHIP IS ESSENTIAL

