

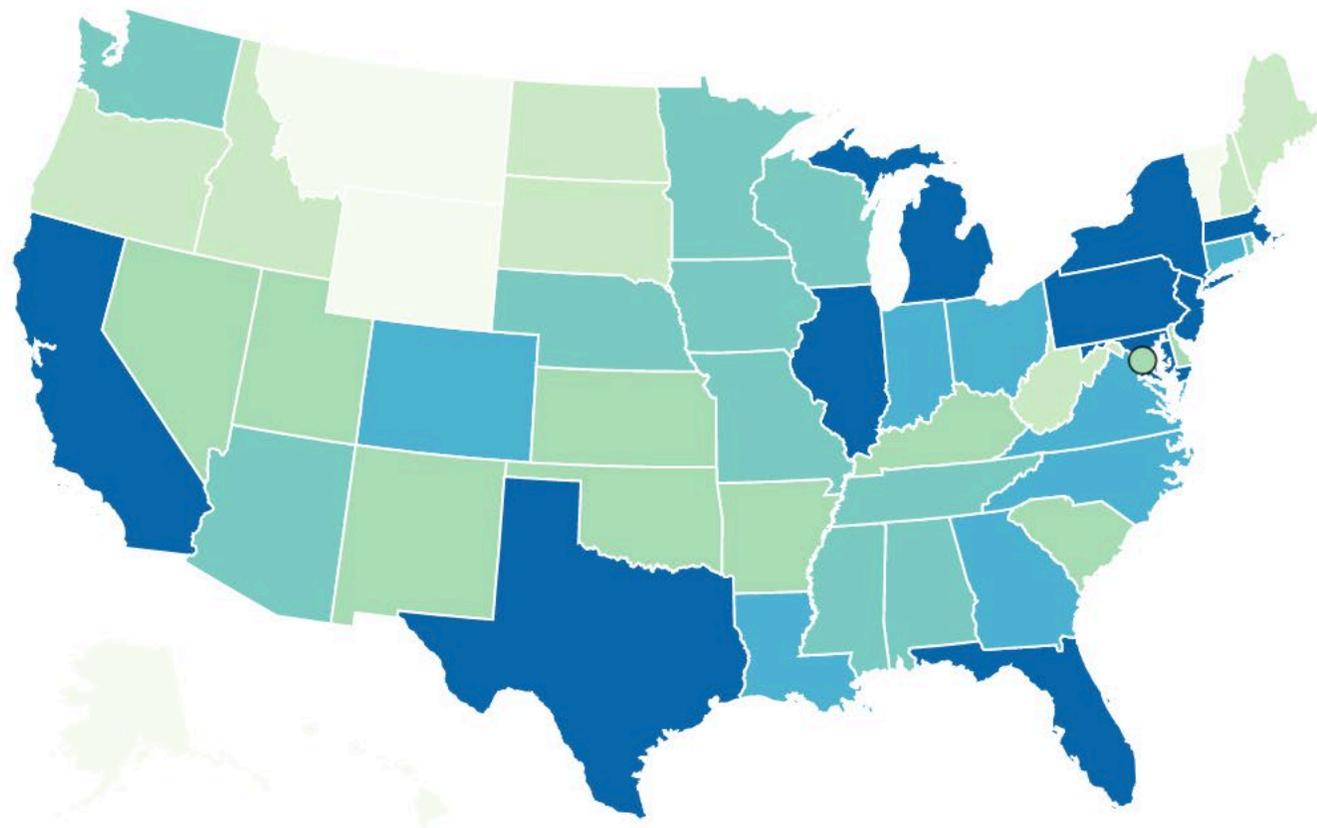
# Rapid Acceleration of Diagnostics (RADx) OD Projects

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# COVID-19 Cases Across the U.S.



## Reported Cases

- 0 to 1,000
- 1,001 to 5,000
- 5,001 to 10,000
- 10,001 to 20,000
- 20,001 to 40,000
- 40,001 or more

AS GU MH FM MP PW PR VI



# COVID-19 Testing Across the U.S.

## United States Laboratory Testing

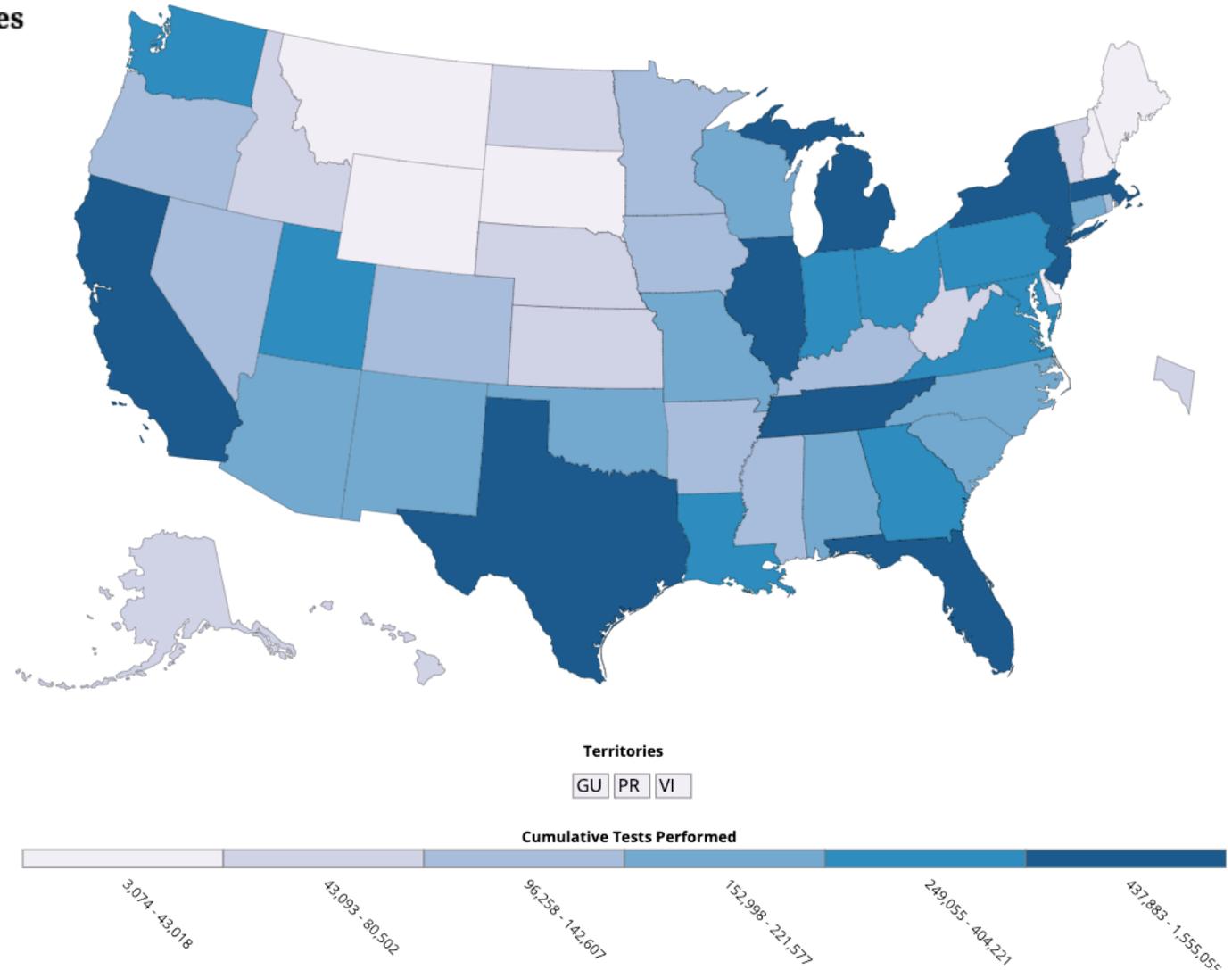
Commercial and Reference, Public Health, and Hospital Laboratories

Preliminary data: Reported by U.S. Laboratories including Commercial and Reference, Public Health, and Hospital  
Totals may include antibody data from some states

USA  
**13,627,379**  
TESTS REPORTED  
CDC | Updated: May 22 2020 7:03PM

USA  
**1,771,749**  
POSITIVE TESTS  
CDC | Updated: May 22 2020 7:03PM

USA  
**13%**  
OVERALL %  
POSITIVE  
CDC | Updated: May 22 2020 7:03PM



## For Native Americans, COVID-19 is 'the worst of both worlds at the same time'

The Skywalk over the Grand Canyon was closed by the Hualapai tribe to increase social distancing measures during the pandemic.

Stan Lawrimore/Unsplash



## *The Striking Racial Divide in How Covid-19 Has Hit Nursing Homes*

Homes with a significant number of black and Latino residents have been twice as likely to be hit by the coronavirus as those where the population is overwhelmingly white.

## Rural America Could Be the Region Hardest Hit by the COVID-19 Outbreak



## *Black Americans Face Alarming Rates of Coronavirus Infection in Some States*

Data on race and the coronavirus is too limited to draw sweeping conclusions, experts say, but disparate rates of sickness — and death — have emerged in some places.

## Many Who Need Testing For COVID-19 Fail To Get Access

April 3, 2020 · 5:00 AM ET

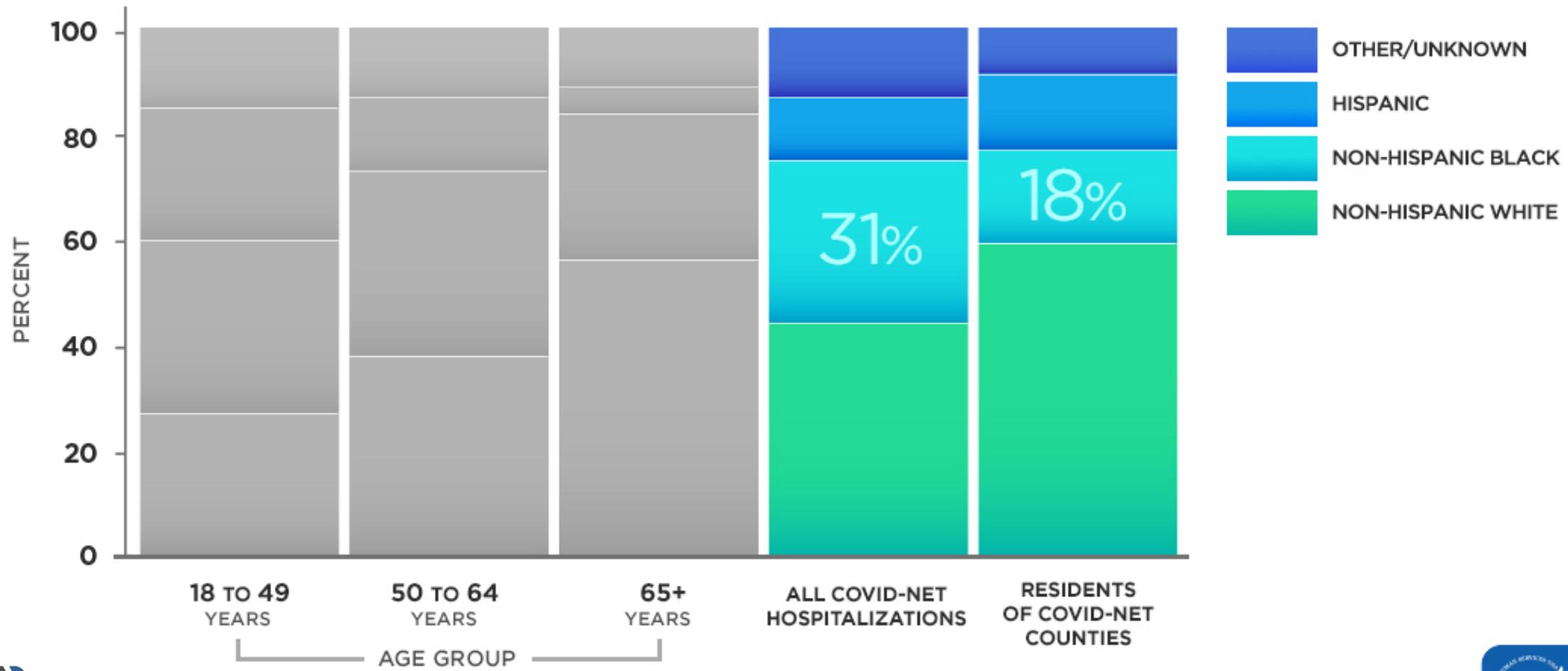
## COVID-19 in Prisons and Jails in the United States

Laura Hawks, MD<sup>1,2</sup>; Steffie Woolhandler, MD, MPH<sup>2,3</sup>; Danny McCormick, MD, MPH<sup>1,2</sup>

» [Author Affiliations](#) | [Article Information](#)

*JAMA Intern Med.* Published online April 28, 2020. doi:10.1001/jamainternmed.2020.1856

# When comparing to residents who live in COVID-NET counties, **non-Hispanic black people** were disproportionately hospitalized with COVID-19.



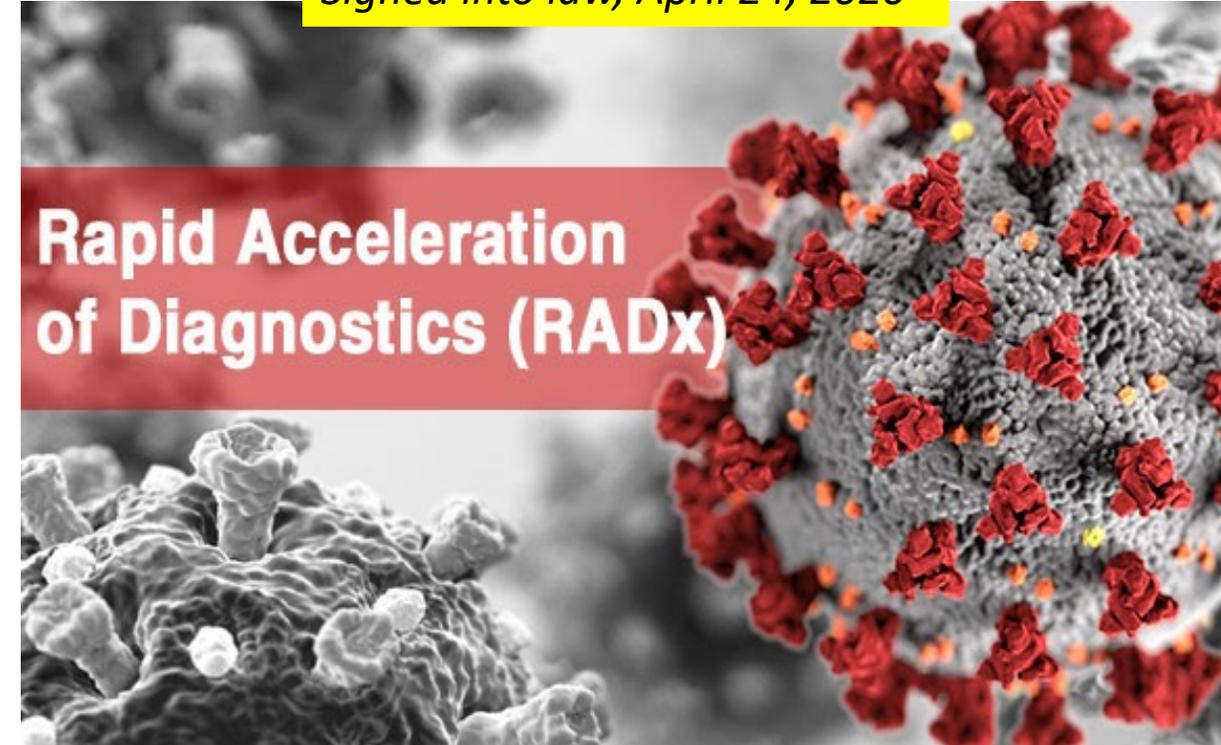
COVID-NET is a surveillance system that tracks COVID-19 hospitalizations in selected counties in 14 states. Data from March 1-April 18, 2020.  
\*Note: Data are currently insufficient to draw conclusions about race in hospitalized patients that are < 18 years old.



# Rapid Acceleration of Diagnostics (RADx) Initiative

Signed into law, April 24, 2020

Rapid Acceleration  
of Diagnostics (RADx)



<https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>



## Supplemental Appropriations Language:

*...not less than **\$1,000,000,000** shall be transferred to the “National Institutes of Health—Office of the Director” to **develop, validate, improve, and implement testing and associated technologies**; to accelerate research, development, and implementation of **point of care** and other **rapid testing**; and for **partnerships** with governmental and non-governmental entities to research, develop, and implement the activities outlined in this proviso...*



# Rapid Acceleration of Diagnostics (RADx) Initiative

## Goal:

Accelerate innovation in, development and commercialization of, and implementation of COVID-19 testing

## Approach:

- Fund early innovative diagnostic technologies
- Advance late-stage diagnostic technologies to expand testing infrastructure
- Identify effective testing implementation strategies in underserved populations
- Work closely with other government agencies (FDA, BARDA, CDC)



# RADx Projects



## **RADx Tech – \$500M**

*Highly competitive, rapid three-phase challenge to identify the best candidates for at-home or point-of-care tests for COVID-19*



## **RADx Underserved Populations (RADx-UP) – \$500M**

*Interlinked community-based demonstration projects focused on implementation strategies to enable and enhance testing of COVID-19 in vulnerable populations*



## **RADx Radical (RADx-Rad) – \$200M**

*Develop and advance novel, non-traditional approaches or new applications of existing approaches for testing*



## **RADx Advanced Testing Program (RADx-ATP) – \$230M**

*Rapid scale-up of advanced technologies to increase rapidity and enhance and validate throughput – create ultra-high throughput machines and facilities*



## **Data Management Support – \$70M**

*Build an infrastructure for and support coordination of the various data management needs of many of the COVID-19 efforts*

# OD Strategy for RADx



## **RADx-Underserved Populations (RADx-UP) Project – \$500M**

**Goal:** Leverage existing community partnerships to implement culturally relevant testing strategies in underserved populations

### **Phase I (FY20-22, \$200M):**

#### ***Phase Ia:***

- Coordination and Data Collection Center (CDCC) – up to \$30M , 1 site; U24 cooperative agreement
- Collaborative network of clinical research centers/consortia – up to \$5M/site, ~25 sites; various mechanisms

#### ***Phase Ib:***

- Collaborative network of clinical research grants across the country – up to \$1M/site, 30 sites; competitive revisions/new R01s
- Social, Ethical, and Behavioral Implications (SEBI) program – up to \$5M, 5-8 sites; competitive revisions/new R01s

NIH



# OD Strategy for RADx



## **RADx-Underserved Populations (RADx-UP) Project – \$500M**

### **Phase II (FY22-24, \$300M):**

- CDCC – up to \$50M, 1 site
- SEBI program – up to \$5M, 5-8 sites; competitive revisions/new R01s
- Renewal or expansion of Phase I components + new awards for synthetic network of clinical research sites and centers – up to \$245M; competitive revisions/new awards

### **Anticipated Timeline:**

- Phase I FOAs published in June
- Phase I awards made by end of FY20
- Phase II awards made in FY21/22



# OD Strategy for RADx



## **RADx Radical (RADx-Rad) – \$200M**

**Goal:** Develop novel approaches to identify the SARS-CoV-2 virus and that could be applicable to other, as yet unknown, viruses

### **Mechanism:**

- Range of **grant mechanisms** including cooperative agreements, SBIR awards, R01s, and other mechanisms as needed to support 2-3 year awards

### **Anticipated Timeline:**

- FOAs published in summer
- Awards made by end of CY20



# OD Strategy for RADx



## **RADx Advanced Testing Program (RADx-ATP) – \$230M**

**Goal:** Scale up existing technologies to increase rapidity and enhance and validate through-put, including through large capacity regional testing hubs that leverage large NIH clinical networks

### **Mechanism:**

- Contract mechanisms for 2 years

### **Anticipated Timeline:**

- FOAs published in summer
- Awards made by end of FY20



# OD Strategy for RADx



## **Data Management Support – \$70M**

**Goal:** Develop a platform to integrate data, on individuals and populations, from a variety of sources, including serology and genetic test results, output from smart sensors, self-reported clinical symptoms, and EHR data

### **Mechanism:**

- Contract mechanisms – approximately 10 awards for 5 years; established as hub and spoke model

### **Anticipated Timeline:**

- FOAs published in summer
- Awards made by end of FY20



