

NIH Tribal Consultation 2020 Rapid Acceleration of Diagnostics Underserved Populations (RADx-UP)

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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



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



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

April 3, 2020 · 5:00 AM ET

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.

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.

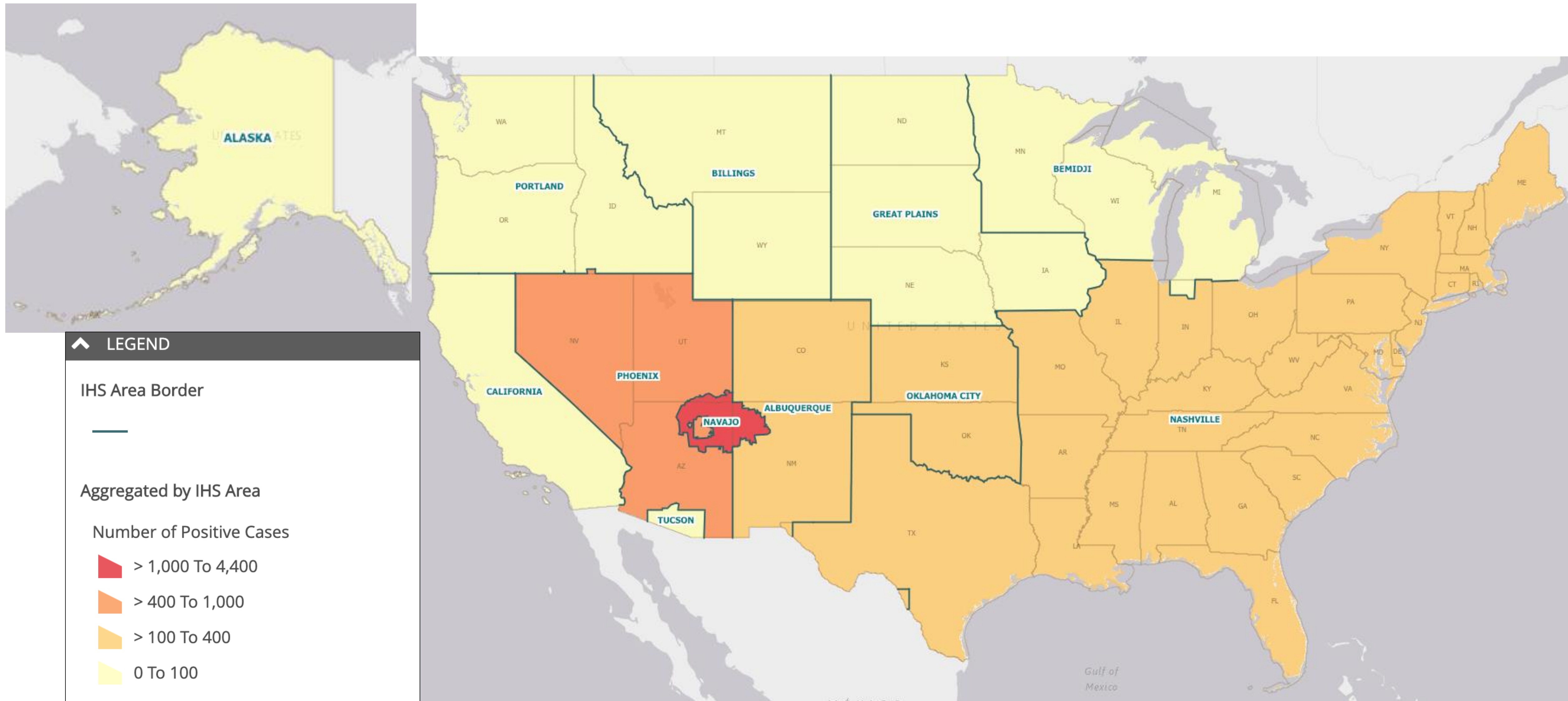
COVID-19 in Prisons and Jails in the United States

Laura Hawks, MD^{1,2}; Steffie Woolhandler, MD, MPH^{2,3}; Danny McCormick, MD, MPH^{1,2}

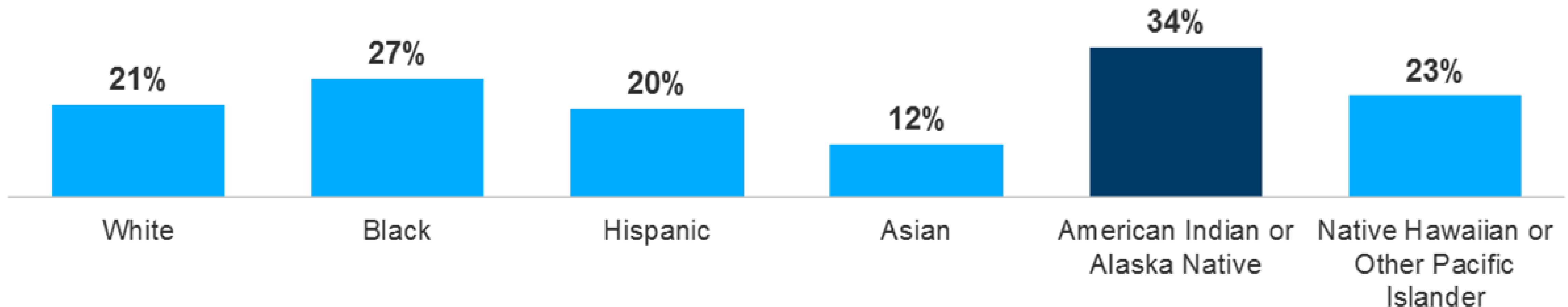
» [Author Affiliations](#) | [Article Information](#)

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

COVID-19 Reported Cases by IHS Area



Share of Adults Ages 18-64 at Higher Risk of Serious Illness if Infected with Coronavirus by Race/Ethnicity



NOTE: Data includes adults ages 18-64; excludes adults living in nursing homes or other institutional settings. Persons of Hispanic origin may be of any race, but are categorized as Hispanic for this analysis; other groups are non-Hispanic.

SOURCE: KFF analysis of 2018 Behavioral Risk Factor Surveillance System.

COVID-19 Testing Across the U.S.

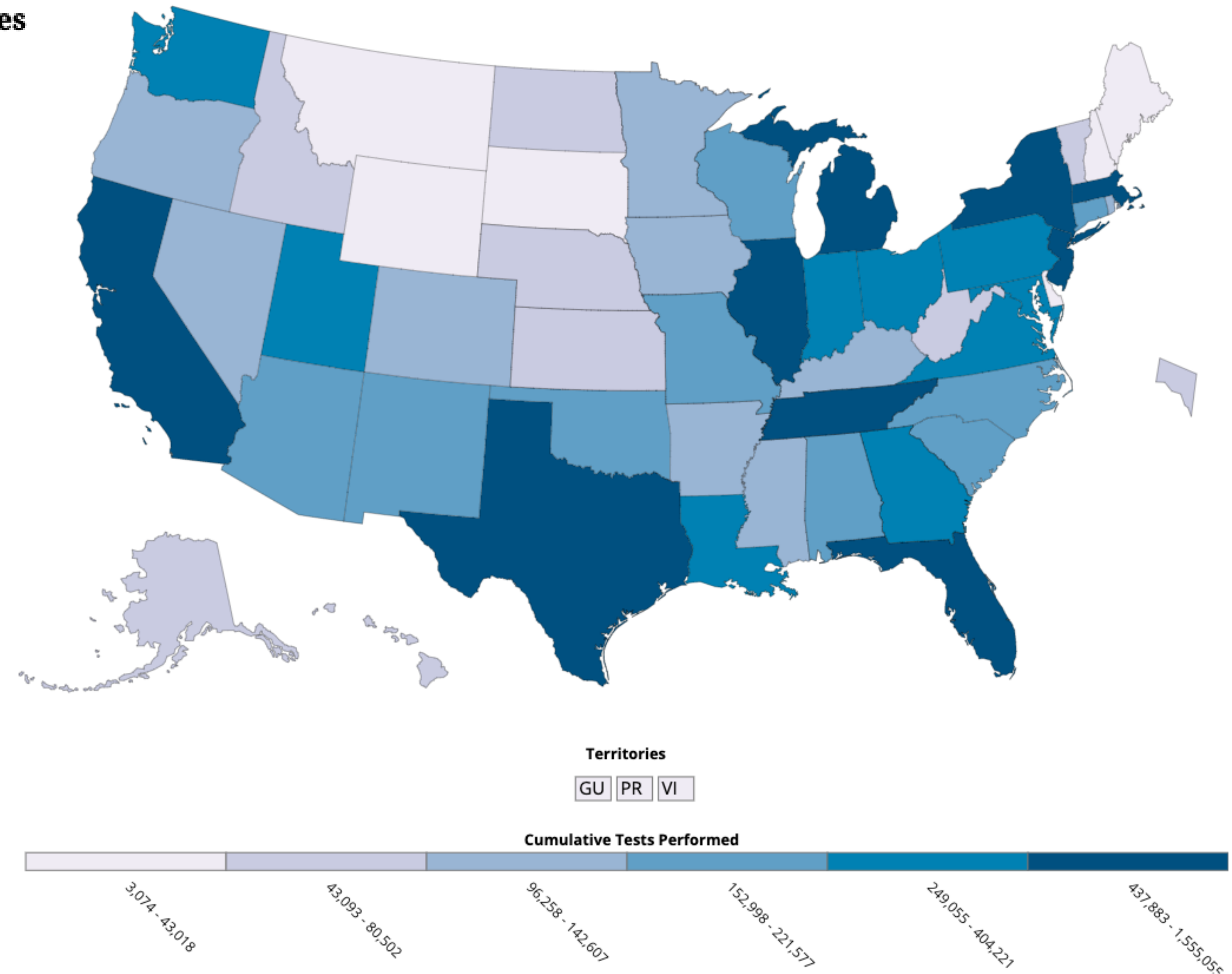
United States Laboratory Testing Commercial and Reference, Public Health, and Hospital Laboratories

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

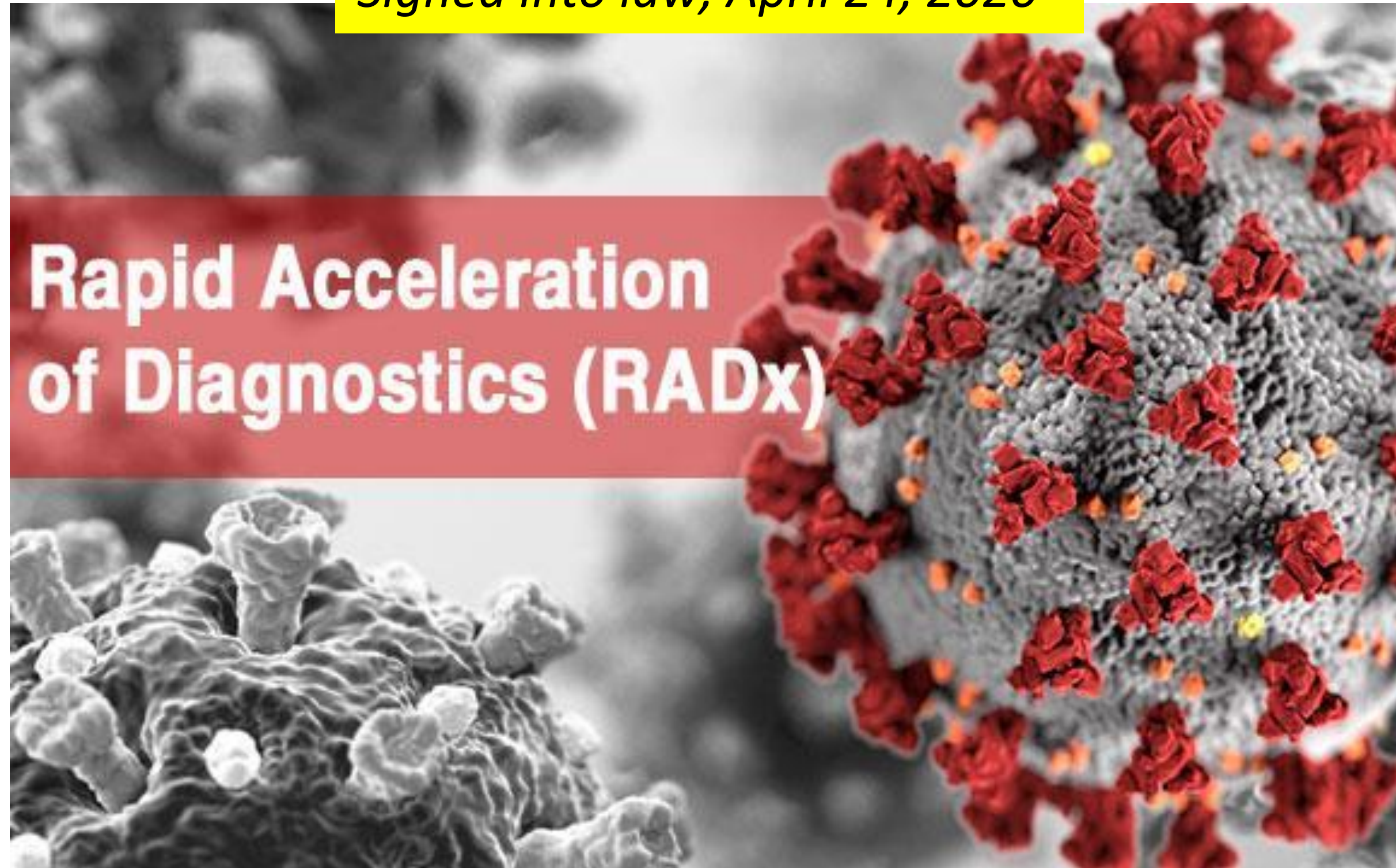
USA
13%
OVERALL %
POSITIVE
CDC | Updated: May 22 2020 7:03PM



<https://www.cdc.gov/covid-data-tracker/index.html>

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 “**1111**” 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



RADx-Underserved Populations (RADx-UP) Project



As part of the RADx initiative, NIH proposes to:

- Develop a series of interlinked **community-engaged projects** focused on **implementation strategies to enhance testing** of underserved, under-resourced, underrepresented, rural, and/or vulnerable populations

Will do so by:

- Specifying strategies to address **social determinants of health** that present barriers to test completion and follow-up
- Conducting **evidence-based outreach** and dissemination activities to inform communities about the project and its findings
- Creating a **sustainable infrastructure** for future crises



RADx-Underserved Populations (RADx-UP) Project



Coordination and Data Collection Center (CDCC)

- Provide leadership and project management
- Facilitate connections across the initiative
- Data harmonization, storage, management
- Coordinate governance

Collaborative Clinical Research Network

- Research centers and consortia, grants across the country
- Work closely with communities to develop and rapidly implement interventions
- Serve as a resource for more routine testing once the vaccine trials accelerate
- Apply scientific and technological advancements

Social, Ethical, and Behavioral Implications (SEBI) Program

- Understand the range of ethical, social, and behavioral issues associated with testing/diagnostic technologies and information/data collection and sharing



RADx-Underserved Populations (RADx-UP) Project



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

Phase Ia:

- 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
- SEBI program
 - up to \$5M, 5-8 sites; competitive revisions/new R01s



RADx-Underserved Populations (RADx-UP) Project



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 collaborative 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





RADx-Underserved Populations (RADx-UP) Project



Discussion Questions:

- What are some of the most challenging issues your communities are dealing with?
- What research questions, including around COVID-19 testing, are most important to your respective communities during the current COVID-19 pandemic?
- What special considerations for Tribes should be in place as we are developing funding opportunities?
- How can we better encourage and facilitate research partnerships to respond to the current and prepare for future public health emergencies?



Rapid-Response Consultation on Including Existing AI/AN Samples in an *All of Us* Research Program Study of COVID-19 Antibodies

All of Us
RESEARCH PROGRAM



National Institutes
of Health

Thursday, May 28, 2020

Outline

1. Brief Update on *All of Us* Consultation
2. Presentation Focus
3. COVID-19 Serology Study
4. Expected Study Outcomes
5. Challenges, Opportunities, Risks & Benefits
6. Questions & Comments

***All of Us* Tribal Consultation & Engagement Timeline**

- ◉ **April 2018:** *All of Us* Tribal Collaboration Working Group Report released
- ◉ **May 2019:** Sent “Dear Tribal Leader” letter, framing letter and published Federal Register Notice
- ◉ **May - October 2019:** Multiple consultations and listening sessions held nationwide
- ◉ **September - October 2019:** Request for Information (RFI) published
- ◉ **November 30, 2019:** End of current tribal consultation
- ◉ **January - February 2020:** *All of Us* Tribal Collaboration Working Group meetings and development of a draft of report summarizing tribal concerns and proposed next steps to address them
- ◉ **March 2020:** NIH Tribal Advisory Committee (TAC) review of draft report
 - Given the rapidly evolving COVID-19 pandemic, TAC has requested additional time to review
- ◉ **Mid - 2020:** After TAC’s review, tentative public release of *All of Us* report
 - Will send the report to tribal leaders via a “Dear Tribal Leader” letter and provide a 60-day comment period for their feedback
 - The finalized report will be posted followed by a recontact campaign and proposed 6-month window for AI/AN individuals (current participants) to deliberate
- ◉ **Late - 2020:** Exploring “deeper dive” sessions & workshops via national meetings, webinars, etc.

Should *All of Us* include samples from current self-identified AI/AN participants who joined the program between Fall 2019 and March 2020 in the COVID-19 antibody analysis?

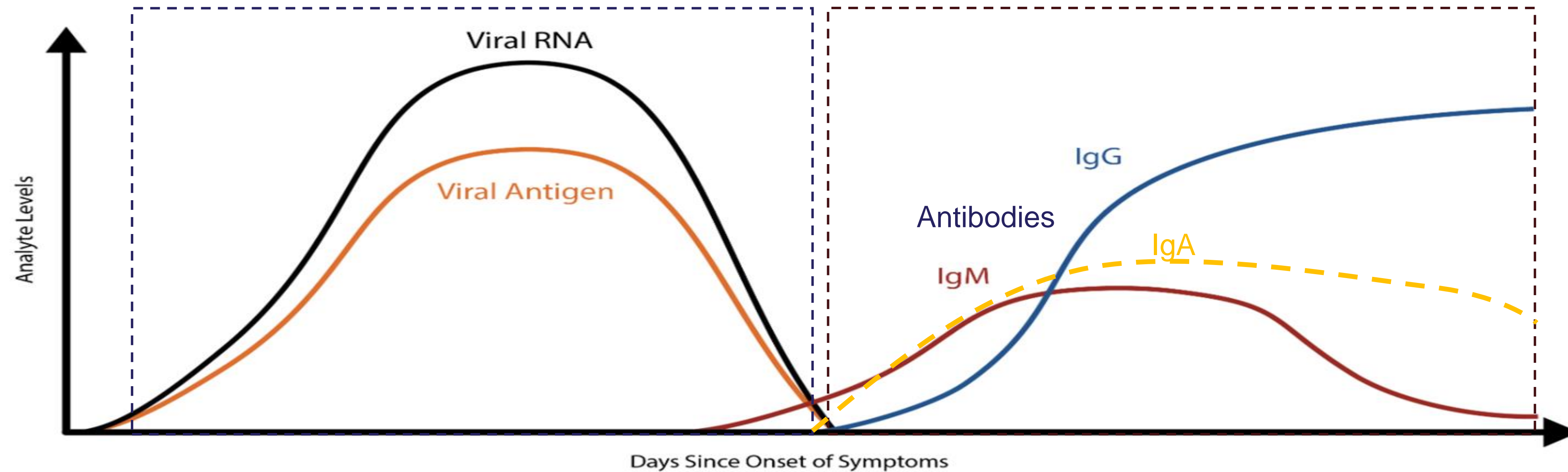
COVID-19 Antibody Testing



**Active Infection
Nasal Swab**



**Past Exposure
Blood Test**



Both tests are useful to understanding the disease

COVID-19 Antibodies among *All of Us* Participants

Objective: Look for the presence of antibodies that will help us understand what percentage of the U.S. might have been exposed to SARS-CoV-2 and when

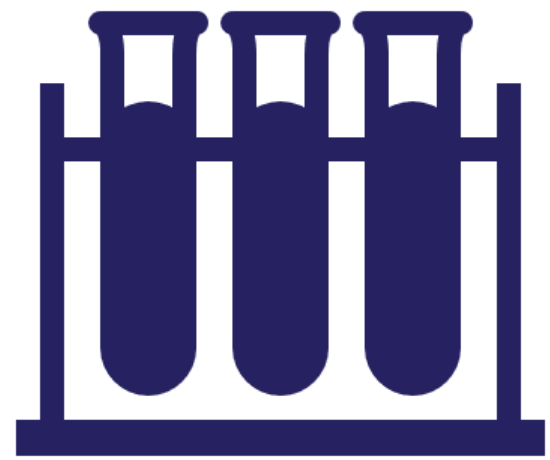
Methods:

- Population: *All of Us* participants who enrolled between 11/1/19 - 3/16/20
- Outcome: COVID-19 Ab (IgG), IL-6
- Covariates: Age, sex at birth, race/ethnicity, geography, date of sample

Test in batches of 5,000 starting with the most recently collected (March 16, 2020) and extending back at least until November 1, 2019 until we have no positive antibody results.

Will follow up positive serology with further neutralization assays.

Expectations and Limitations



Only existing samples will be analyzed – no new samples
(Nov 2019 – March 2020)



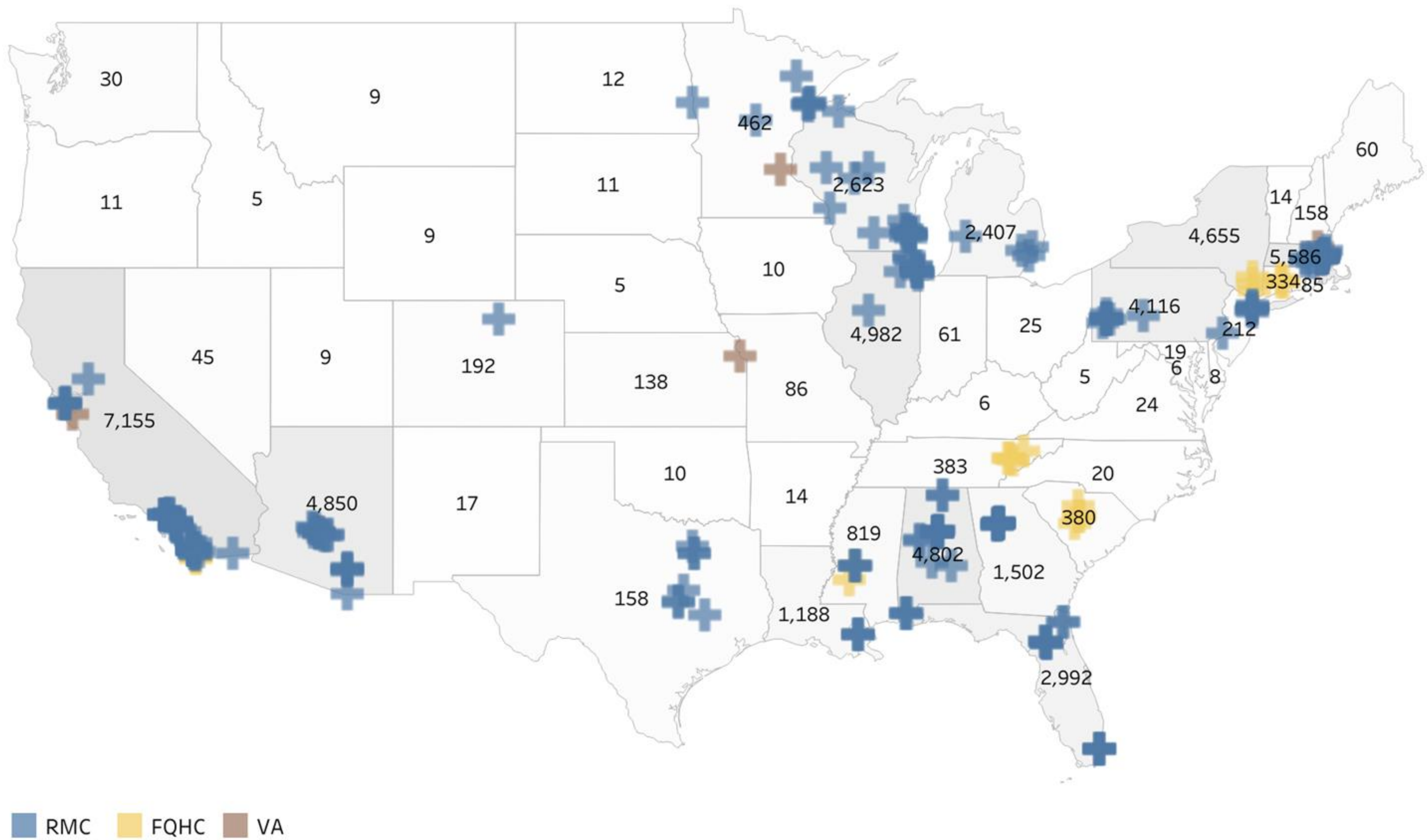
AI/AN samples make up a very small proportion of those
available (less than 2%)



Aggregate results will be available first. Motivated to
return individual results, if possible

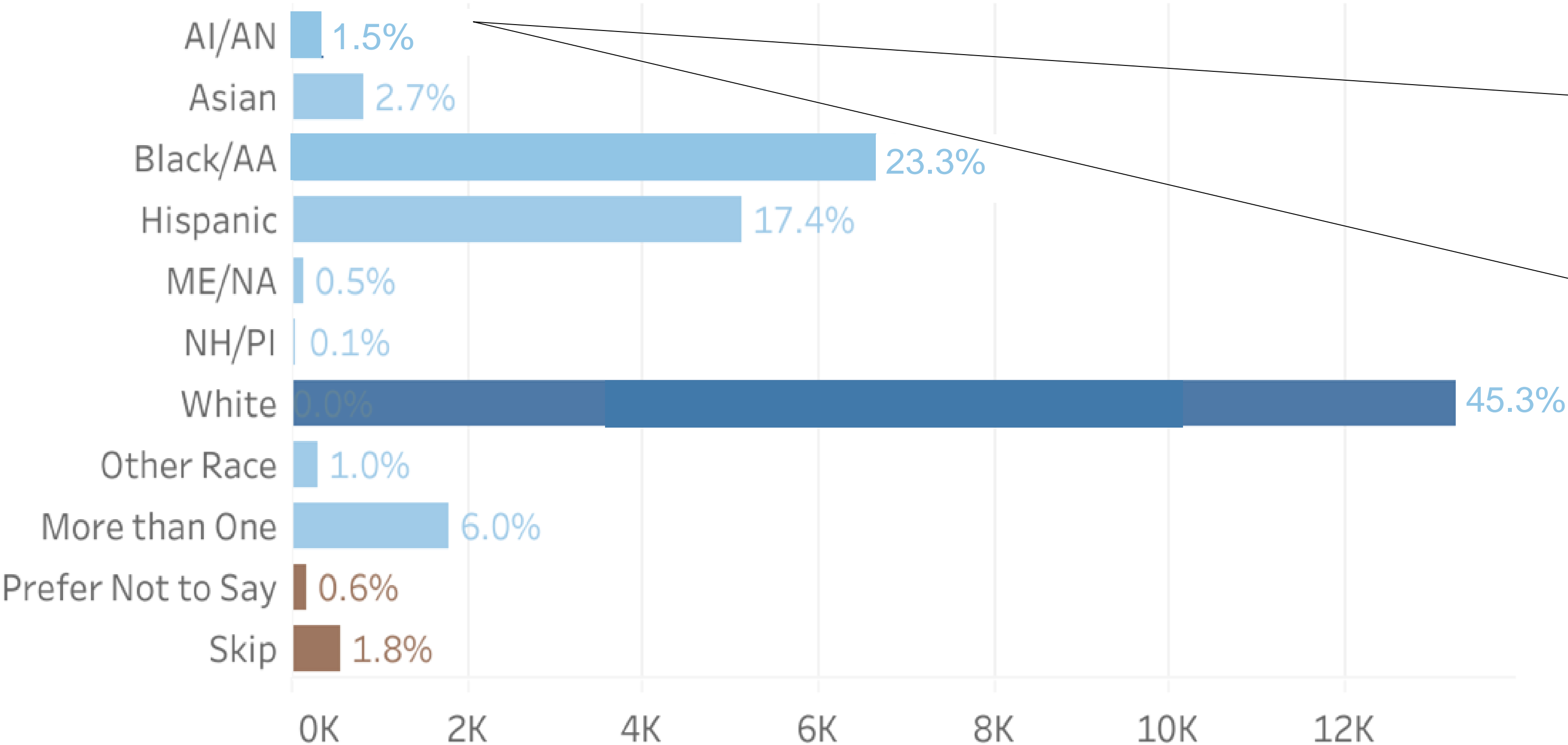
Geographic Distribution of Samples; RMCs, FQHCs, and VA 11/1/19 - 3/16/20

Note: 1,678 participants from FQHCs



Demographic Distribution of Samples 1/1/20 - 3/16/20

Self-Identified Race and Ancestry



American Indian or Alaska Native

☒ American Indian

☐ Alaska Native

☐ Central or South American Indian

☐ None of these fully describe me

Return of Results to Participants

- An initial message to all participants will let them know that we are doing this testing and the impact it can have on understanding COVID-19.
- *All of Us* plans on returning COVID-19 antibody information to participants after testing. Important to hold to our value that participants have access to their information.
- Aggregate results showing overall trends in all participant samples are expected to be available first.
- Individual antibody test results will be given to specific participants if appropriate, based on what we understand about the results.
- Timing of return of information and findings is not known. Expectation in the summer.
- Support will be provided by the *All of Us* Call Center, Enrollment Sites, and Engagement Partners.

Challenges, Opportunities, Risks & Benefits

Potential Challenges & Risks

- AI/AN data will be generated earlier than expected and made available to researchers (for COVID study participants only, no genomic data)
- Minimal benefit to AI/AN community due to low number of samples

Potential Opportunities & Benefits

- Demonstrated commitment to the health of AI/AN communities
- Public health
- Includes a population experiencing disproportionate COVID impact & health disparities
- Individual return of results could provide benefit to participants

Should *All of Us* include samples from current self-identified AI/AN participants who joined the program between Fall 2019 and March 2020 in the COVID-19 antibody analysis?

Questions & Discussion

All of Us welcomes additional feedback by
Tuesday, June 2

AOUTribal@nih.gov

Feedback



**Additional feedback is welcome by
Tuesday, June 2**

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