

# NCI Serology Studies

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Principal Deputy Director

NCI Council of Research Advocates (NCRA)  
meeting

*July 16, 2020*

# Topics for today

- Frederick National Laboratory for Cancer Research
- Serology at Frederick National Lab
- Serology dashboard
- Serology network
- Cancer prevention & screening

# Frederick National Laboratory for Cancer Research (FNLCR)

- The only Federally-Funded Research and Development Center (FFRDC) dedicated exclusively to biomedical research

*Operated in the public interest by Leidos Biomedical Research, Inc. on behalf of the National Cancer Institute*

## Mission

Provide a unique national resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis and treatment of cancer and AIDS.



# Adaptive Coronavirus Treatment Trial (ACCT): Hospitalized COVID-19 patients on Remdesivir treatment improved faster than those on placebo

The NEW ENGLAND JOURNAL of MEDICINE

The White House

ORIGINAL ARTICLE

## Remdesivir for the Treatment of Covid-19 — Preliminary Report

J.H. Beigel, K.M. Tomashek, L.E. Dodd, A.K. Mehta, B.S. Zingman, A.C. Kalil, E. Hohmann, H.Y. Chu, A. Luetkemeyer, S. Kline, D. Lopez de Castilla, R.W. Finberg, K. Dierberg, V. Tapson, L. Hsieh, T.F. Patterson, R. Paredes, D.A. Sweeney, W.R. Short, G. Touloumi, D.C. Lye, N. Ohmagari, M. Oh, G.M. Ruiz-Palacios, T. Benfield, G. Fätkenheuer, M.G. Kortepeter, R.L. Atmar, C.B. Creech, J. Lundgren, A.G. Babiker, S. Pett, J.D. Neaton, T.H. Burgess, T. Bonnett, M. Green, M. Makowski, A. Osinusi, S. Nayak, and H.C. Lane, for the ACTT-1 Study Group Members\*

April 29, 2020

May 22, 2020



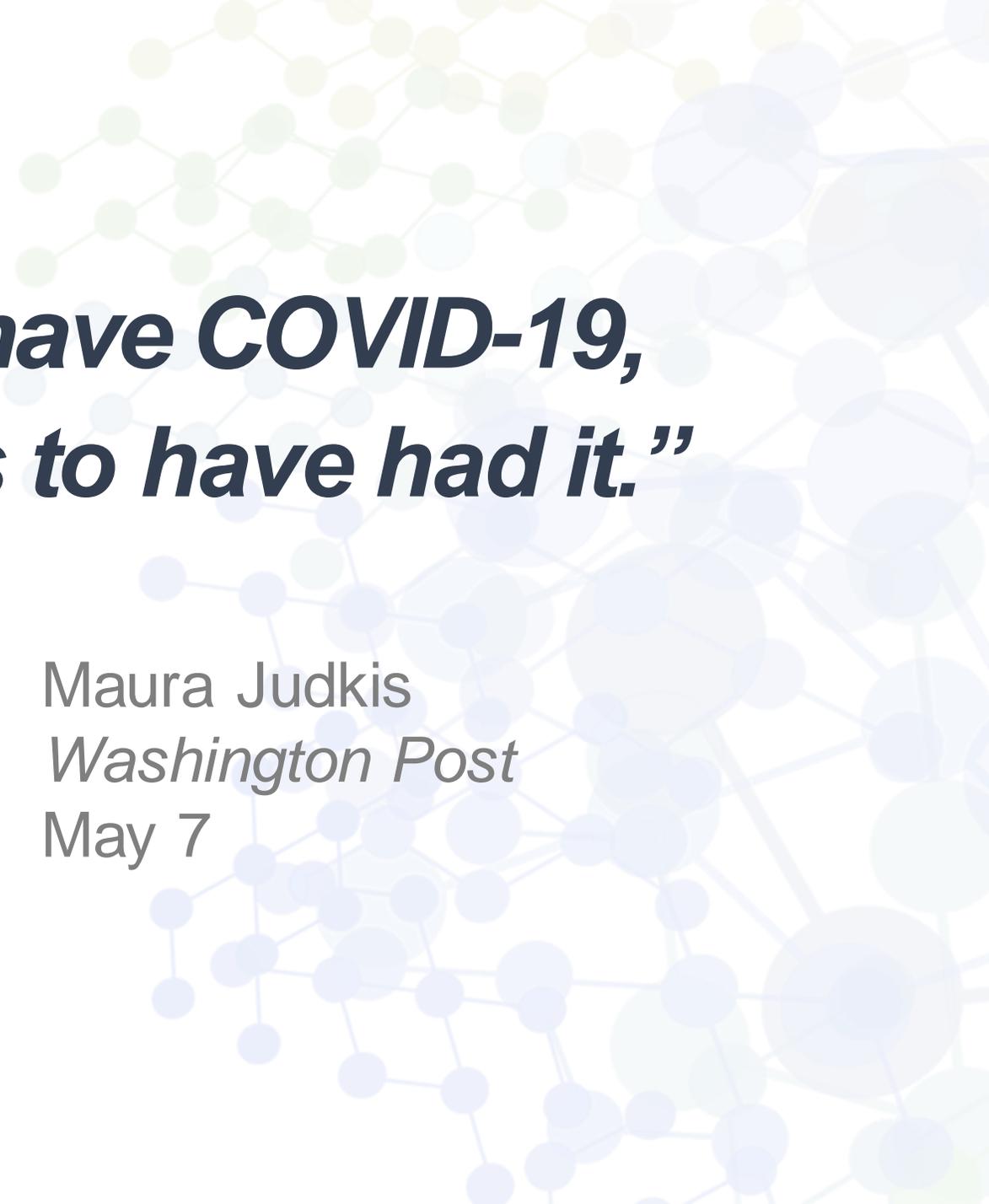
# Supplemental funding from Congress

- Enacted April 24th
- \$306M for NCI to **develop, validate, improve, and implement serological testing and associated technologies**
- COVID-19-focused and **distinct from annual appropriation**

134 STAT. 620	PUBLIC LAW 116–139—APR. 24, 2020
	Public Law 116–139 116th Congress
	An Act
Apr. 24, 2020 [H.R. 266]	Making appropriations for the Department of the Interior, environment, and related agencies for the fiscal year ending September 30, 2019, and for other purposes.
Paycheck Protection Program and Health Care Enhancement Act. 15 USC 9001 note.	<i>Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,</i>
	<b>SECTION 1. SHORT TITLE.</b> This Act may be cited as the “Paycheck Protection Program and Health Care Enhancement Act”.
	<b>SEC. 2. TABLE OF CONTENTS.</b> The table of contents for this Act is as follows:
	Sec. 1. Short title. Sec. 2. Table of contents. Sec. 3. References.



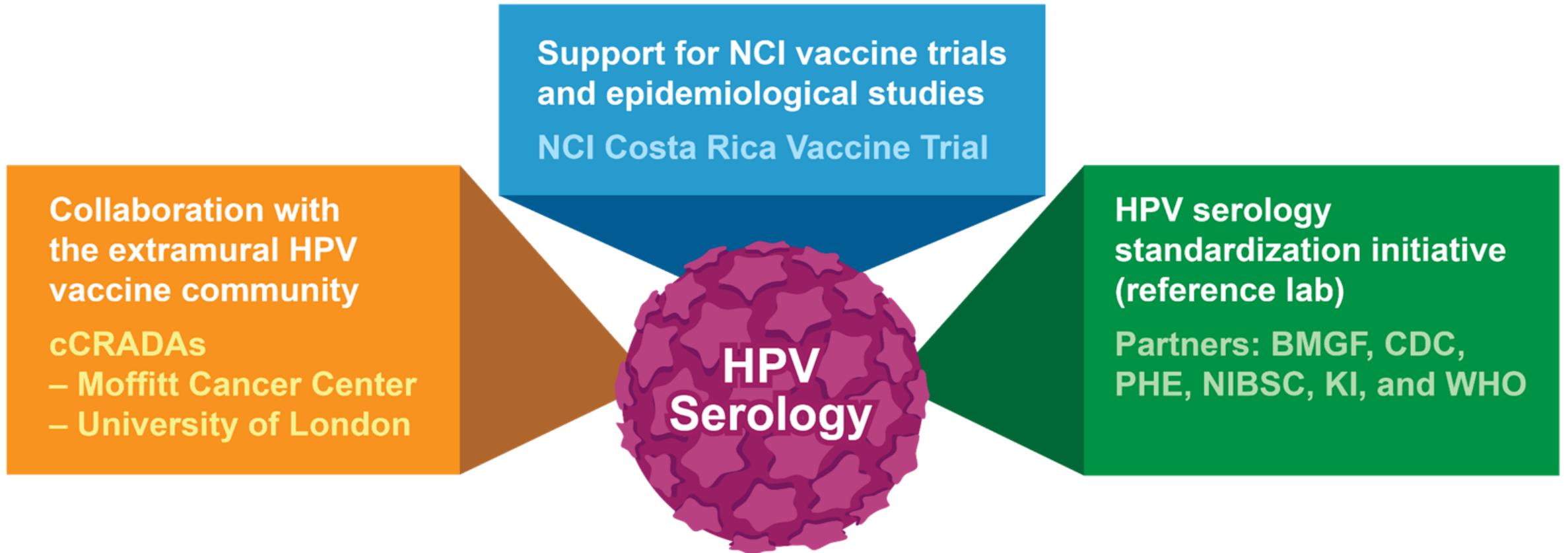
# **FNLCR Serology Laboratory**



***“No one wants to have COVID-19,  
but everyone wants to have had it.”***

Maura Judkis  
*Washington Post*  
May 7

# FNLCR HPV Serology Laboratory



*Thanks to Ligia Pinto, FNLCR*

# Convert part of HPV serology lab to SARS-CoV-2 serology

## Ongoing project:

Characterize performance of many SARS-CoV-2 serology devices submitted to FDA; submit our results to FDA

*A collaborative research effort with several groups: NIAID, FDA, CDC, Mount Sinai, others*

## Future project:

Serological responses of cancer patients in COVID-19; longitudinal trial of cancer patients

# Summary of initial 70 commercial serology devices evaluated by FNLCR serology laboratory

- Focus on IgG antibody tests; IgM becomes positive at about the same time as IgG and decreases faster than IgG
- **Sensitivity** (detect true positives): Varies from 30% to 100%
- **Specificity** (does not detect false-positives): Varies from 87% to 100%
- Results sent to FDA to help FDA determine suitability for Emergency Use Authorization (EUA)
- FDA web site with data for EUA tests:  
<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance>

# Seroprevalence studies; specificity

- Antibody tests can be used now for seroprevalence studies; antibody tests should be able to identify everyone who had symptomatic infection and most who had asymptomatic infection
- Importance of high specificity: If a test has 95% specificity and the seroprevalence rate is found to be 5%,
  - **50% of the positives will be false-positives**

# Additional activities at FNL serology lab

- FNL protein expression lab is producing large amounts of SARS-CoV-2 antigens for use in serologic assays, at FNL and NIBIB
- Serology lab is developing quantitative SARS-CoV-2 antibody assays
  - Until now, assay results have been qualitative
- Serology lab is developing a “standard” pooled serum for US govt and beyond; collaboration with NIAID, CDC, BARDA
  - Will eventually be linked to WHO standard serum when it is available

# Some SARS-CoV-2 serology questions

- **It is not currently known:**
  - whether being antibody-positive is associated with protection against reinfection
  - what **antibody levels** may be associated with protection
  - how long protection will last
- NCI is co-funding extramural research with NIAID and CDC to address these questions
- For candidate SARS-CoV-2 vaccines, **will induction of neutralizing antibodies confer protection?**
  - The serological standard will enable direct comparisons of immunogenicity between candidate vaccines



# **Tracking SARS-CoV-2 seroprevalence**

# Developing a SARS-CoV-2 serology data warehouse and dashboard

- Early June: HHS, CDC, NIAID ask NCI to develop data warehouse & dashboard for tracking SARS-CoV-2 seroprevalence and other US-based serology studies
- Builds on FNL dashboard expertise developed with NCI Clinical Trials Reporting Program (CTRP), other databases
  - Collaboration between NIAID, CDC, NCI
- Key features:
  - A publicly accessible data warehouse to systematically document and track SARS-Cov-2 serology studies and associated test results
  - A tracking dashboard to visualize SARS-Cov-2 serology data and present results overall and by key strata

Search

Narrow Results

- Age Group  
(All)
- Sampling Strategy  
(All)
- Country  
(All)
- Study Group  
(All)
- Study Start Date  
(All)
- National Clinical Trial  
(All)
- Published  
(All)

20 items found

Study Title	Subjects Enrolled	Age Group	Sampling Strategy	Study Group
NCI COVID-19 in Cancer Patients, NCCAPS Study	2,000	Adults	Longitudinal	NCI
A Phase 2 Trial of Infliximab in Coronavirus Disease 2019 (COVID-19)	17	Adults	Prospective	Tufts Medical Center
Application of Desferal to Treat COVID-19	50	Children and Adults	Cross-sectional	Kermanshah Univ Medical Sciences
A Study Evaluating the Efficacy and Safety of High-Titer Anti-SARS-CoV-2 Plasma in Hospitalized Patients With COVID-19 Infection	131	Adults	Recruited	Medical College of
Study to Evaluate the Efficacy and Safety of Tocilizumab Versus Corticosteroids in Hospitalised COVID-19 Patients With High Risk of Progression	310	Adults	Recruited	University of Medicine
Effectiveness and Safety of Medical Treatment for SARS-CoV-2 (COVID-19) in Colombia	1,600	Adults	Recruited	Universidad Nacional Colombia
Inhaled Nitric Oxide for Preventing Progression in COVID-19	42	Adults	Recruited	Tufts Medical Center
Hyperbaric Oxygen Therapy (HBOT) as a Treatment for COVID-19	48	Adults	Recruited	Ochsner Health System
A Study of Hydroxychloroquine Compared to Placebo as Treatment for People With COVID-19	120	Adults	Recruited	MSKCC
A Study of N-acetylcysteine in Patients with COVID19 Infection	86	Adults	Recruited	MSKCC
BCG Vaccine for Health Care Workers as Defense Against COVID 19	1,800	Adults	Recruited	Texas A&M
A Study to Evaluate the Safety, Tolerability and Pharmacokinetics (PK) of TAK-981 in Adult				

**Study Group:** NCI  
**Author:** Korde L  
**Population:** Cancer patients that have tested positive for COVID-19  
**Study Type:** Seroprevalence  
**Sampling Strategy:** Longitudinal  
**Age Group:** Adults  
**Assay:** Not Provided  
**Study Period:** 5/21/2020 - 5/31/2023  
**Seroprevalence:** 1.89%  
**Country:** USA  
**Collection Location:** 20852  
**Publication Status:** Unpublished  
**NCTID:** NCT04387656  
**PMID:** Not Applicable

Sortable

Dynamic Popups showing any data elements deemed appropriate.

Total Number of Studies

20

Total Number of Subjects

19,261

Average Number of Subjects

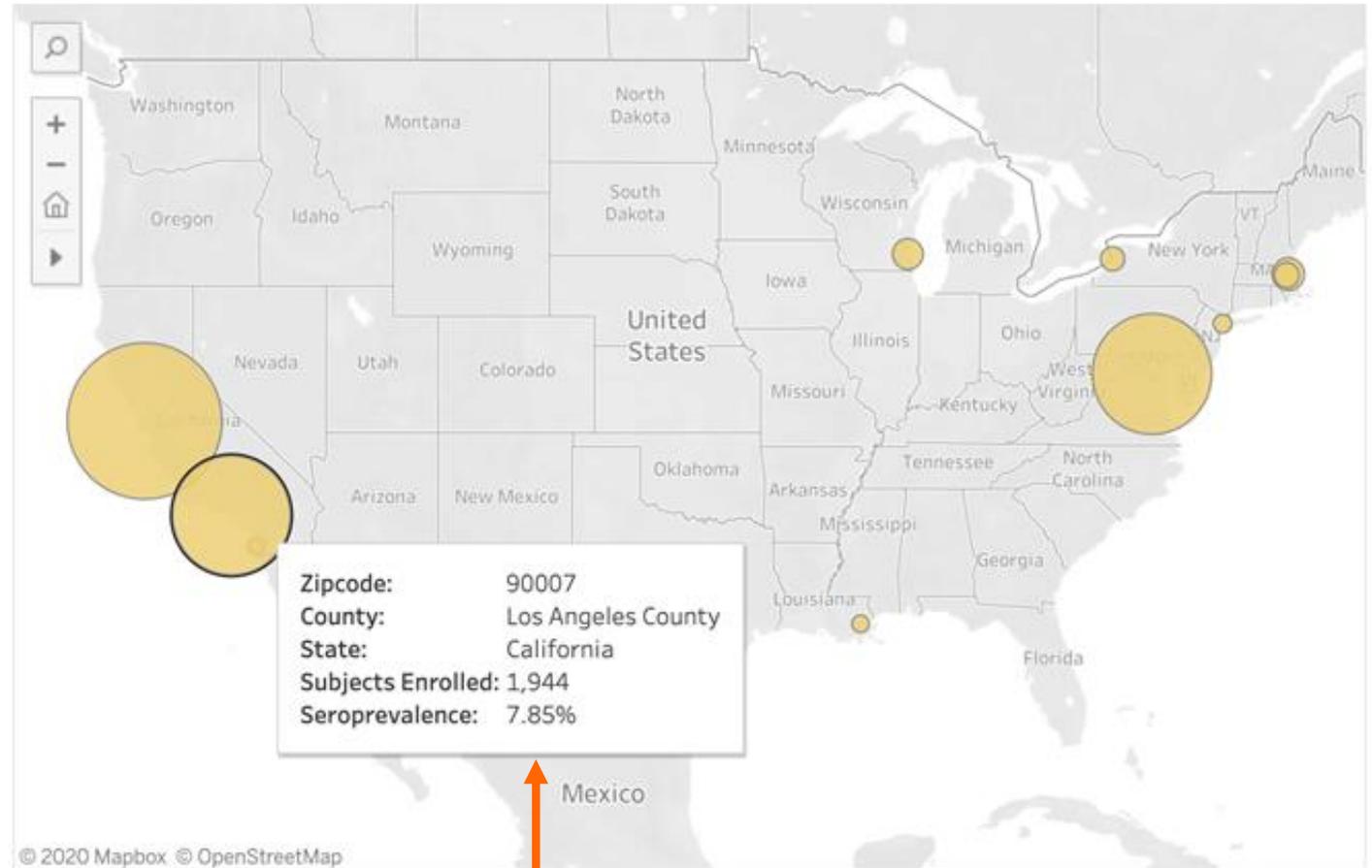
963

Average Duration

12 months

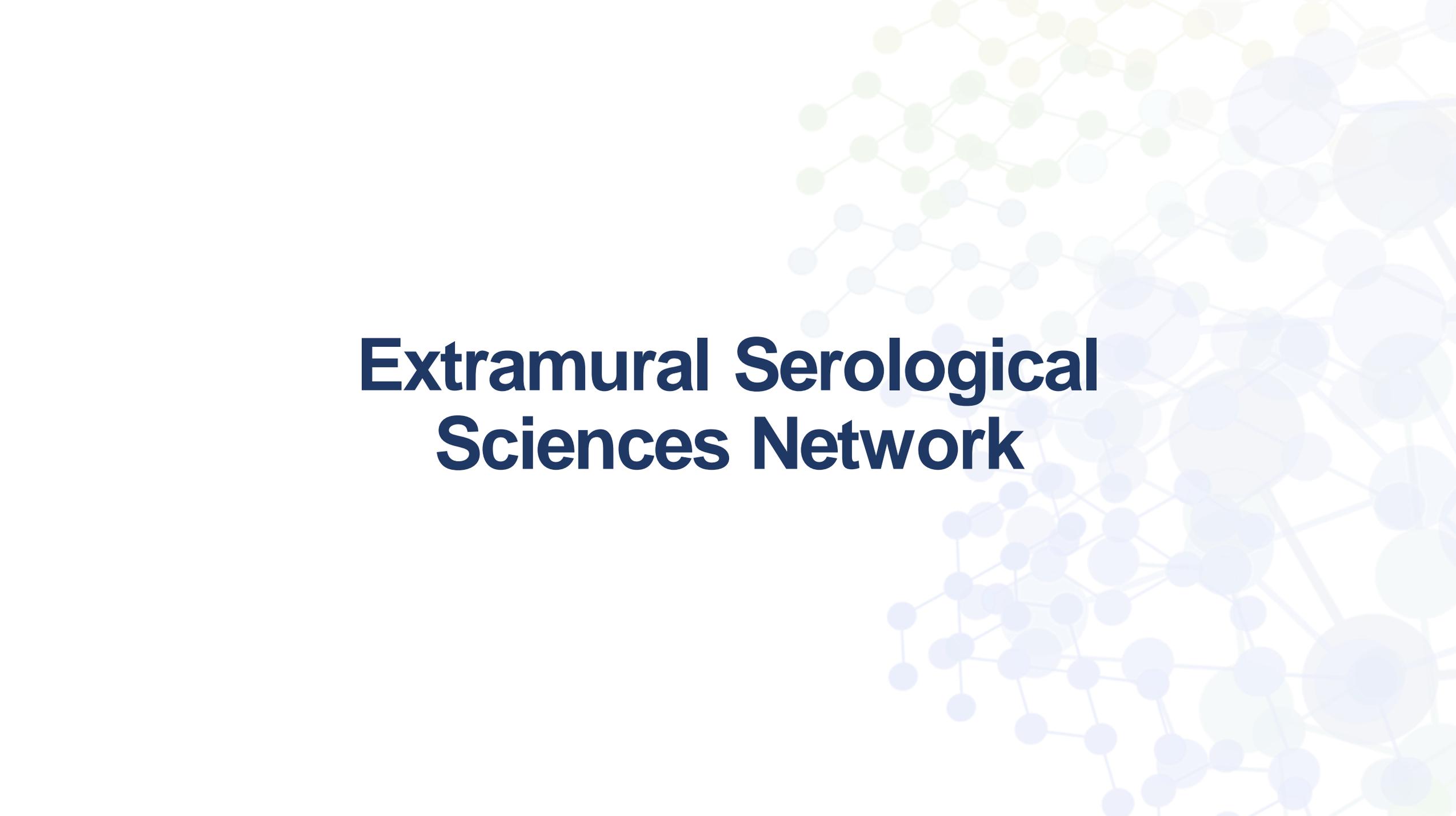
Average Seroprevalence

2.71%



Clear highlight of seroprevalence

Dynamic popups showing any data elements deemed appropriate.



# **Extramural Serological Sciences Network**

# Serological Sciences Network for COVID-19 (SeroNet)

## GOALS

To rapidly expand understanding of all aspects of the immune response associated with SARS-CoV-2 viral infection.

- Increase national capacity for high-quality serological testing
- Develop serological assays for deployment to test for SARS-CoV-2 induced immune responses
- Understand the mechanisms driving the serological, humoral and **cellular immune responses**
- Determine the serological correlates of disease pathogenesis and protection against future infection

# Serological Sciences for COVID-19 (SeroNet)

[RFA-CA-20-038](#) Closes 7/22

SARS-CoV-2 Serological Sciences Centers of Excellence (U54 Clinical Trial Optional)

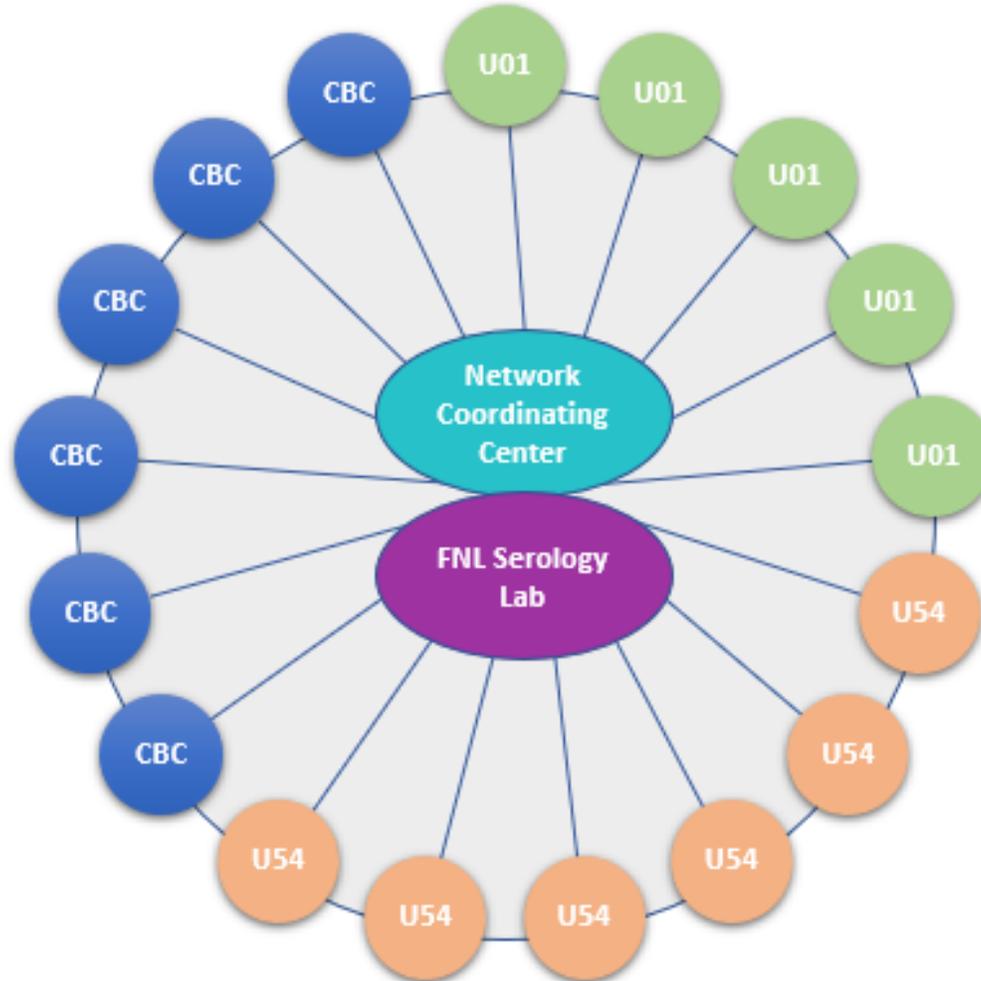
[RFA-CA-20-039](#) Closes 7/22

Research Projects in SARS-CoV-2 Serological Sciences (U01 Clinical Trial Optional)

[RFP Solicitation S20-119](#) Closes 7/16

Serological Sciences Network Capacity Building Centers

# SeroNet “hub and spokes”



**4-8 CBCs:** Serological Sciences Capacity Building Centers (RFP)

**4-8 U54s:** Serological Sciences Centers of Excellence (RFA)

**5-10 U01s:** Serological sciences projects (RFA)

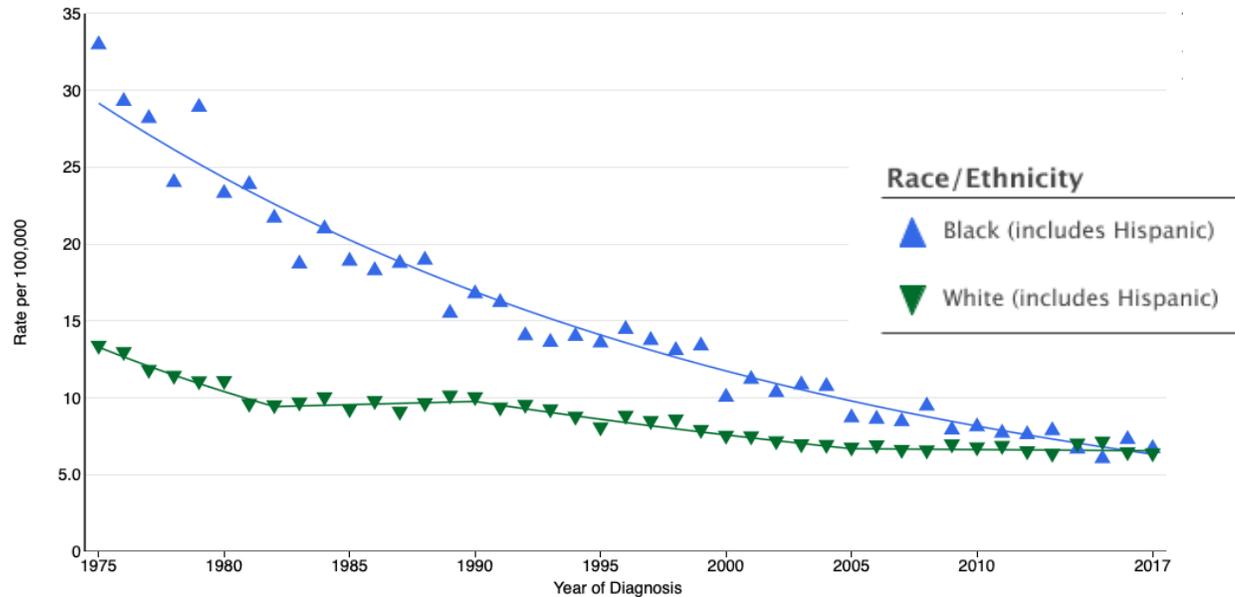
# **COVID-19 and cancer screening**



# President's Cancer Panel

- Cancer screening in the COVID-19 era
  - Cervical, colorectal, breast, lung
- Can we get screening uptake to be ever higher than prior to COVID-19 epidemic?
- Are there opportunities to bring screening to the patient instead of the patient to screening?

# Using the COVID-19 to help overcome higher cervical cancer mortality rates in minority women



Cervical cancer Incidence

## Annual Standardized Rates 2013-2017

**Blacks: 3.4**  
**Hispanics: 2.6**  
**Native Americans: 2.5**  
**Whites: 2.1**  
**Asian Pac. Islanders: 1.8**

- FDA is willing to consider self-collected vaginal specimens for cervical cancer screening. Could enable screening of “hard to reach” women, which could decrease cervical cancer incidence and mortality.

# Thanks to

- Ligia Pinto, Troy Kemp, Jim Cherry: NCI Frederick Serology lab
- Dom Espisito, FNL Protein Expression Lab
- Ned Sharpless, Dinah Singer, Jim Doroshow
- Tony Kerlavage, Stephen Chanock, Neal Freedman, Jonas de Almeda
- Brent Coffey and his FNL team
- Florian Krammer, Carlos Cordon-Carlo: Mount Sinai Medical Center
- Many colleagues at NIAID, FDA, CDC, BARDA