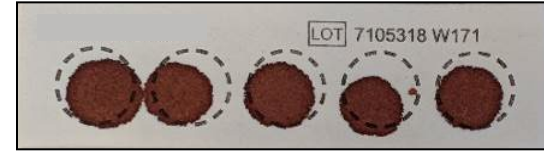




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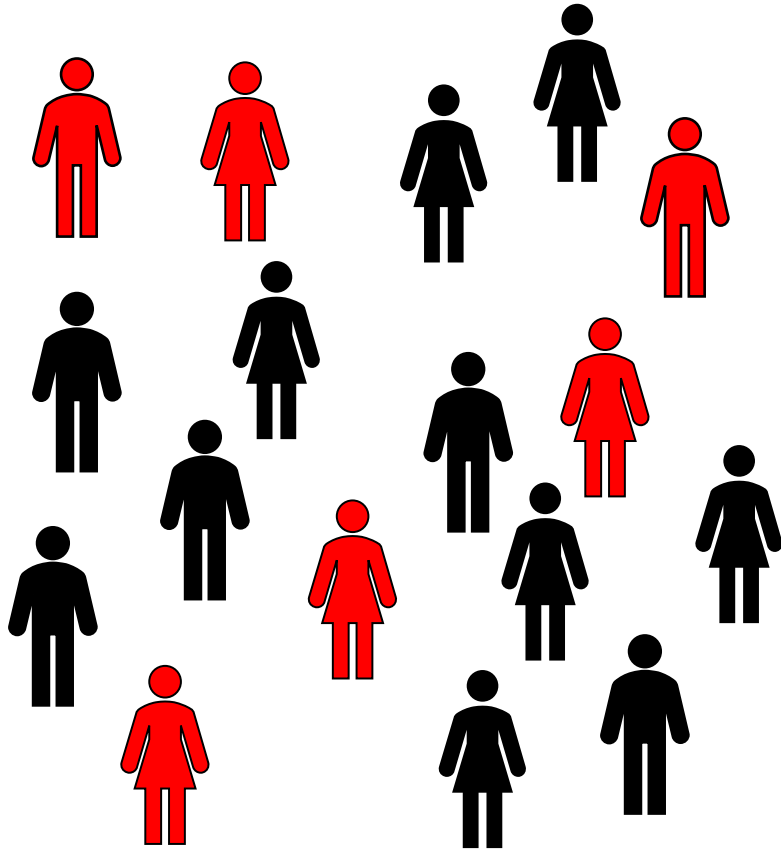
Dried Blood Spots: A Convenient and Easy-to-Collect Sample for Large-Scale Immunological Surveillance

Linda Styer, Jean Rock, Erica Yauney, Katherine Nemeth, Amanda Damjanovic, Rachel Bievenue, Eli Rosenberg, James Tesoriero, Colleen Flanigan, Michele Caggana, Monica Parker

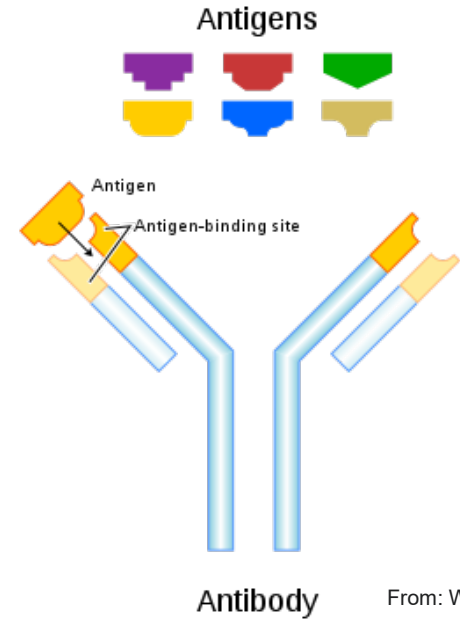
New York State Department of Health: Wadsworth Center, AIDS Institute, Office of Public Health
Department of Biomedical Sciences, SUNY Albany School of Public Health

Funding: CDC Foundation: Emergency Response Fund
CDC: ELC CARES NU50CK000516
National Cancer Institute: SeroNet U01CA260508

How many were infected?



IgG antibodies in blood are a marker of infection



From: Wikimedia Commons



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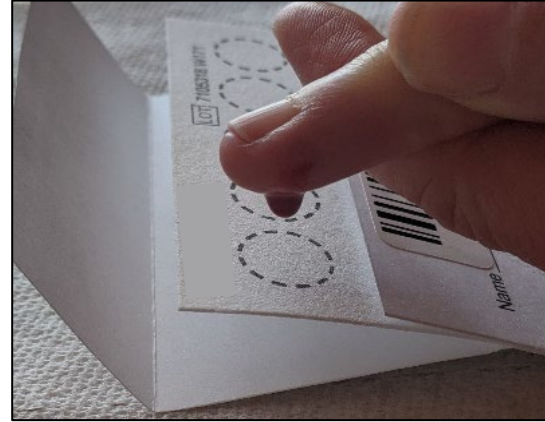
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Venipuncture



- Requires trained health professional
- Performed in lab/clinic
- Fear of needles

Dried Blood Spots (DBS)



- Minimally trained staff or self-collected
- Community sites or at home



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DBS Collection and Storage



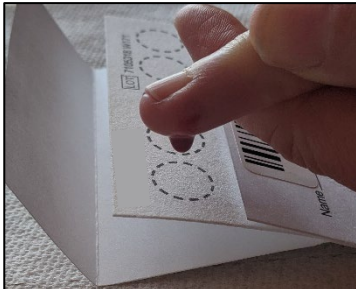
Wipe with
alcohol wipe



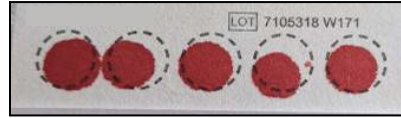
Poke with
safety lancet



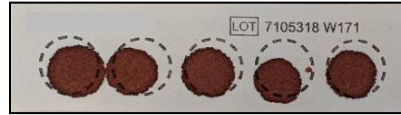
Wipe away
first drop



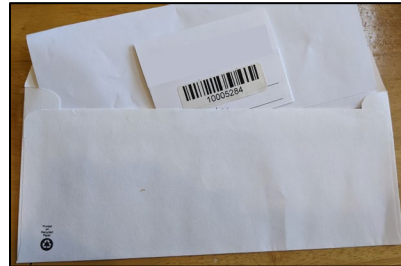
Drop blood
onto card



Dry for 3 hours



Send in
regular mail



DBS stable for
days to weeks



<https://www.wadsworth.org/programs/newborn/screening/providers/specimen-collection>

Newborn DBS
use heel sticks



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Previous experience with DBS serology

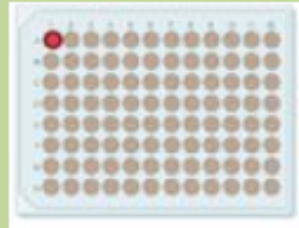
2010 to Present:

HIV and HCV DBS
referral testing



2017:

Developed HIV
Luminex assay for
newborn screening
program



2018:

Implemented HT
HIV testing on
newborn DBS
(1000-2000/day)



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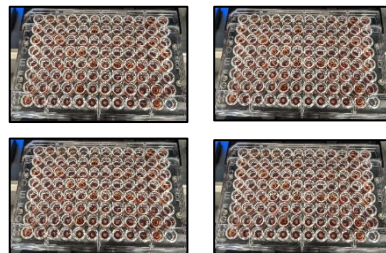
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High-throughput HIV IgG microsphere immunoassay (MIA)

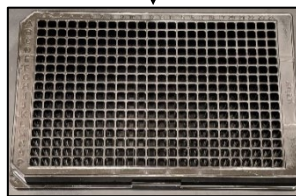
3mm punch from DBS
into 96 well plate



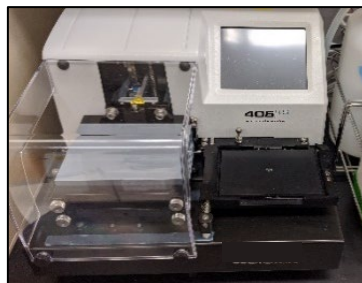
Liquid handler or by hand
using 12-channel pipette



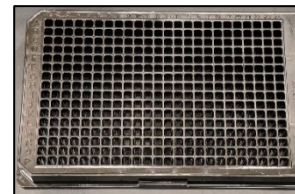
Add buffer,
elute 1hr @
room temp



Add eluate &
antigen-coated
magnetic beads
30 min @ 37°C



Wash plate



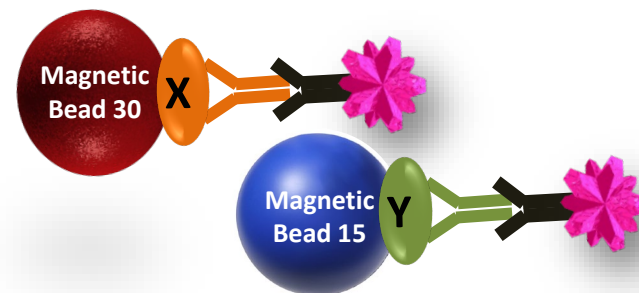
Add secondary
anti-IgG antibody
30 min @ 37°C



Wash plate

Read on
FlexMAP 3D

Output: MFI



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Objective: Modify HIV MIA to detect antibodies to other pathogens for large-scale surveillance projects

2019: Hepatitis C Virus (HCV) seroprevalence study of women recently giving birth using newborn DBS

SARS-CoV-2 Seroprevalence Studies

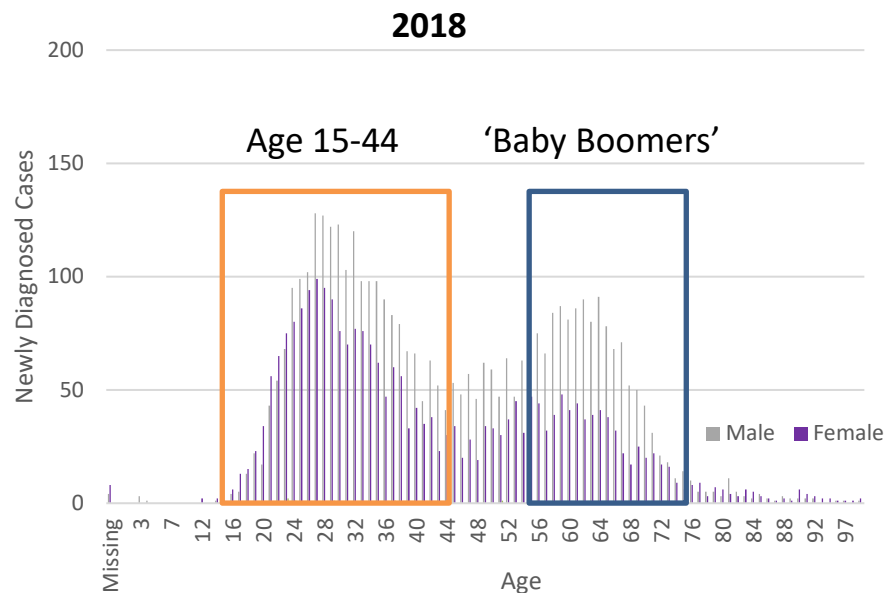
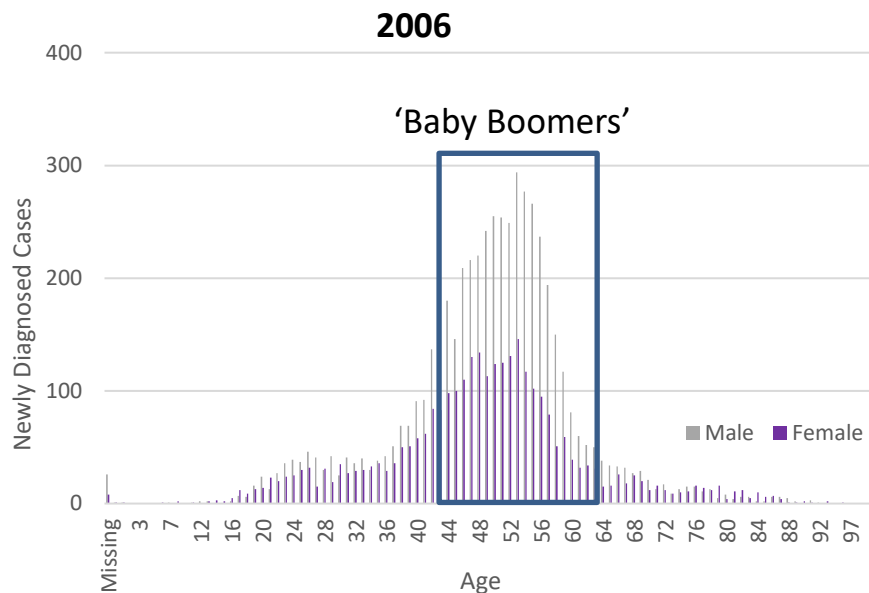
- Apr 2020 - NYS serological testing survey
- July 2020 – Newborn DBS Nov 2019-Nov 2021
- Feb 2021 – Self-collected DBS for vaccine Ab response



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2019: Hepatitis C Virus (HCV) seroprevalence among women recently giving birth



Cases include those from New York State (excluding New York City)
Source: NYS DOH Communicable Disease Electronic Surveillance System, 2019
Data current as 8/7/2019. Data preliminary and subject to change



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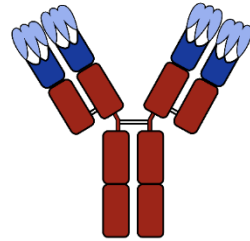
Actively infected women (HCV RNA positive) can transmit HCV to their babies

6% with active infections will transmit HCV to baby

11% will transmit if co-infected with HIV



Approach: Modify MIA to test remnant newborn DBS for HCV antibodies



Babies passively acquire maternal IgG antibodies, including antibodies to HCV

Study Methods

1) 3mm punch from **all DBS received** in 6 wks

29,323 DBS in 353 96-well plates

2) Obtain demographic data

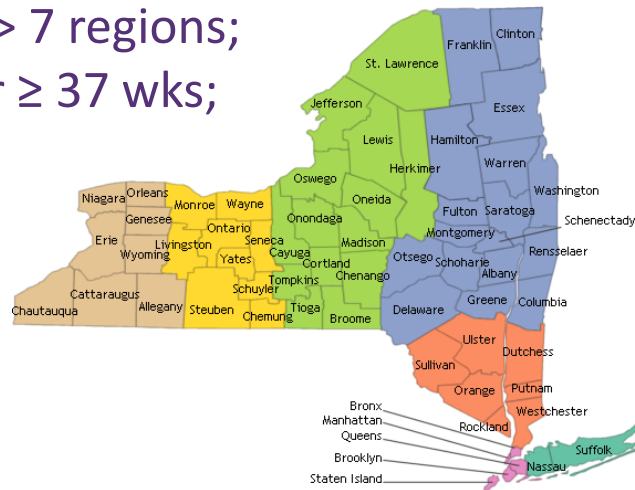
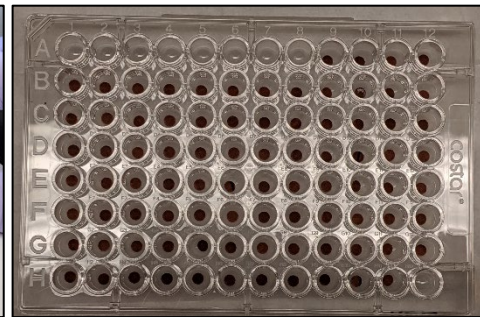
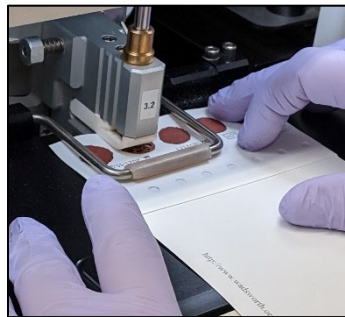
Age at collection; mom's county of residence -> 7 regions;

birthweight: $<$ or $\geq$ 2500g; gestational age: $<$ or $\geq$ 37 wks;

generic patient ID to identify repeat samples

3) Blind sample plates, de-identify & de-link data

4) Test 18,581 on HCV MIA



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HCV seroprevalence in Central and Western NYS was 3-4 times higher than the rest of the state

NYS Region	# DBS in 6 wks	# tested	# HCV Ab reactive	Seroprevalence % (95% CI)*
Central	2,132	1,419	30	2.1 (1.5-3.0)
Western/ Finger Lakes	3,481	2,380	36	1.5 (1.1-2.1)
Hudson/ Northeast	4,398	3,459	23	0.7 (0.4-1.0)
Long Island	3,277	2,676	17	0.6 (0.4-1.0)
New York City	12,283	8,647	42	0.5 (0.4-0.7)
Total NYS	25,571	18,581	148	0.8 (0.7-0.9)

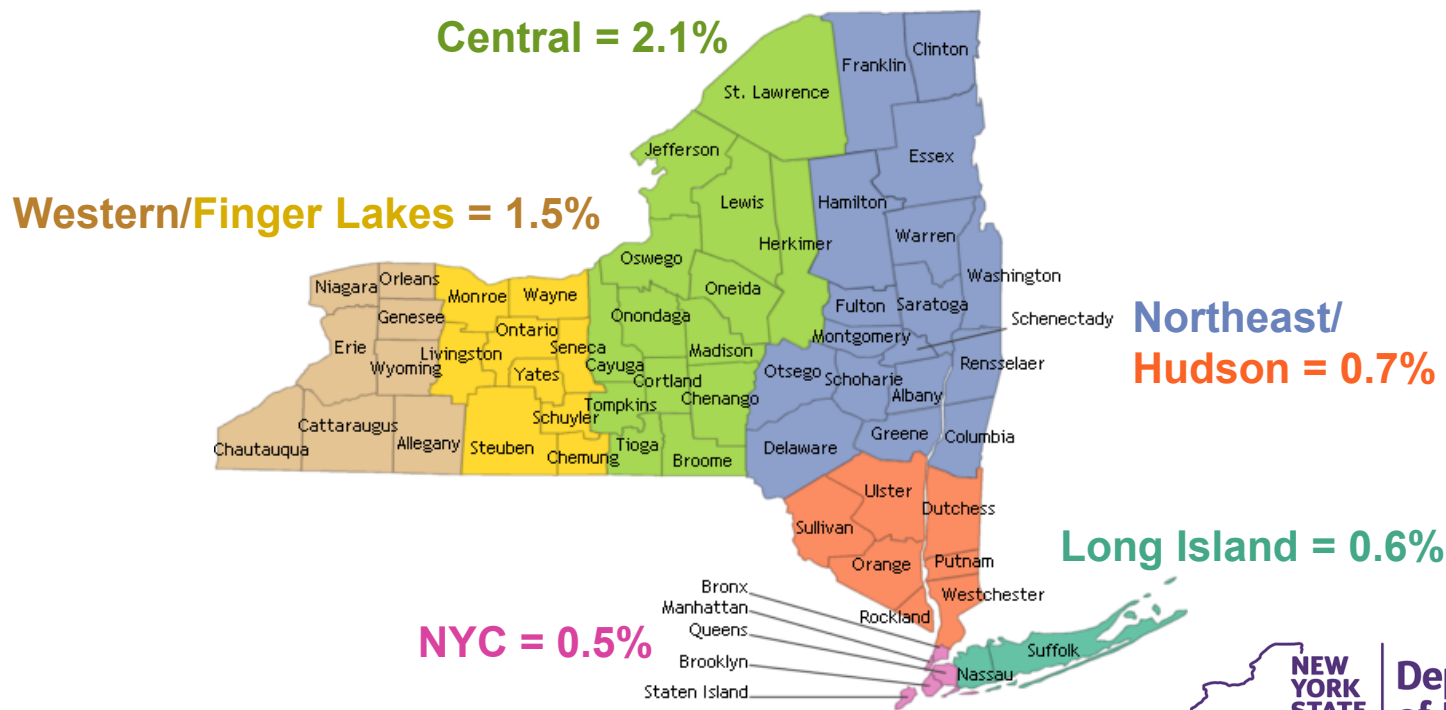
* Overall $\chi^2 = 57.43$, p value < .0001



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HCV seroprevalence in Central and Western NYS was 3-4 times higher than the rest of the state



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2020 - 2021: Detection of antibodies to SARS-CoV-2 for serological surveillance

3/20/20 – “Let’s develop a SARS-CoV-2 Ab assay using DBS”

July 2020 – Begin testing 400,000+ newborn DBS from Nov 2019 to Nov 2021 for serological survey of women recently giving birth in NYS

3/1/20 – 1st COVID-19 case in NYS

4/19/20 – New York State Serological Testing Survey using DBS – ‘Grocery Store Study’

Feb 2021–Study of post-vaccination antibody response using self-collected DBS

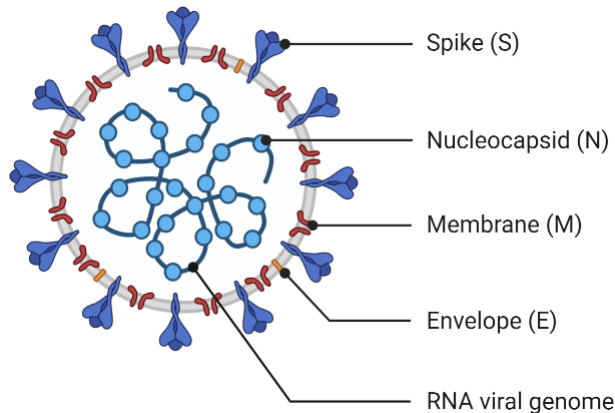


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April 2020 – NYS SARS-CoV-2 Serological Testing Survey

- 15,101 DBS collected at 99 grocery stores in 26 counties in NYS over 10 days
- Tested using MIA that detected Ab to nucleocapsid (N) antigens of SARS-CoV-1 (and then SARS-CoV-2)



SARS CoV-2 Structure

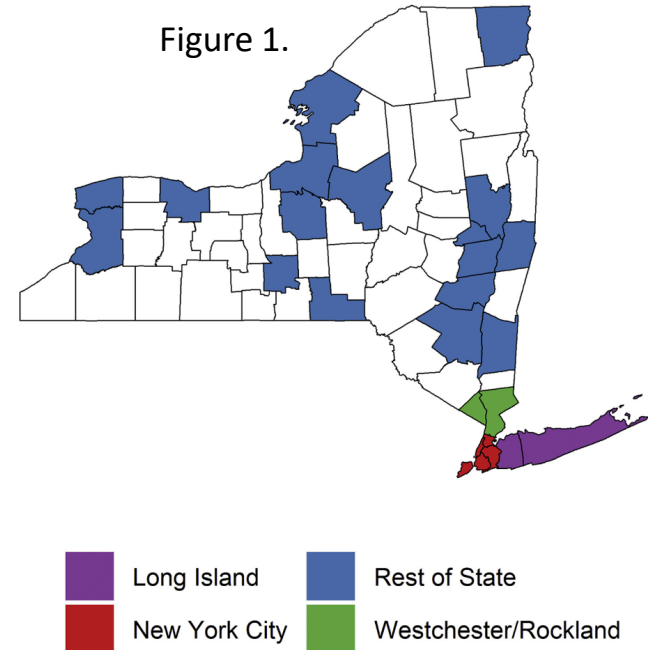


Table 1.		Adjusted estimated cumulative incidence	
	%	(95% CI)	p-value
Overall	14.0	(13.3-14.7)	
Sex			0.03
Male	14.8	(13.8-15.8)	
Female	13.3	(12.4-14.2)	
Race and Ethnicity			<.0001
Hispanic or Latino	29.2	(27.2-31.2)	
NH-White	8.1	(7.4-8.7)	
NH-Black/African American	20.2	(18.1-22.3)	
NH-Asian	12.4	(9.4-15.4)	
Multiracial/Other	11.9	(6.4-17.5)	
Age group			0.0002
18-34	14.6	(13.1-16.1)	
35-44	15.3	(13.7-17.0)	
45-54	16.0	(14.6-17.5)	
55+	12.1	(11.2-13.1)	
Region			<.0001
New York City ^b	22.7	(21.5-24.0)	
Westchester/ Rockland Counties	16.1	(13.2-19.0)	
Long Island ^c	13.2	(11.4-15.1)	
Rest of NYS ^d	3.6	(3.0-4.1)	



Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Annals of Epidemiology

Original article

Cumulative incidence and diagnosis of SARS-CoV-2 infection in New York

Eli S. Rosenberg, PhD ^{a,*}, James M. Tesoriero, PhD ^b, Elizabeth M. Rosenthal, MPH ^a, Rakkoo Chung, PhD ^b, Meredith A. Barranco, MPH ^a, Linda M. Styer, PhD ^c, Monica M. Parker, PhD ^c, Shu-Yin John Leung, MA ^b, Johanne E. Morne, MS ^b, Danielle Greene, DrPH ^b, David R. Holtgrave, PhD ^a, Dina Hoefer, PhD ^b, Jessica Kumar, DO ^b, Tomoko Udo, PhD ^a, Brad Hutton, MPH ^b, Howard A. Zucker, MD ^b

^a University at Albany School of Public Health, State University of New York, Rensselaer

^b New York State Department of Health, Albany, NY

^c Wadsworth Center, New York State Department of Health, Albany, NY

Seroprevalence rates were 10 times higher than lab-confirmed COVID-19 cases



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July 2020 – SARS-CoV-2 Serosurvey of Women Recently Giving Birth in NYS

- Tested ALL newborn DBS Nov 2019 to Nov 2021 (>400,000 DBS)
- Questions:
 - Earliest COVID-19 Ab+?
 - Seropositivity over time by region
- Tested using MIA that detects Ab to SARS-CoV-2 S & N antigens

Note: Time lag between maternal infection and infant birth



Original Investigation | Infectious Diseases

Utility of Newborn Dried Blood Spots to Ascertain Seroprevalence of SARS-CoV-2 Antibodies Among Individuals Giving Birth in New York State, November 2019 to November 2021

Amanda Damjanovic, PhD; Linda M. Styer, PhD; Katherine Nemeth, BSc; Erica Yauney, MPH; Jean M. Rock, MPH; Rachel Bievenue, BSc; Rebecca Hoen, PhD; Dylan Ehrbar, BSc; Denise M. Kay, PhD; Michele Caggana, ScD; Monica M. Parker, PhD

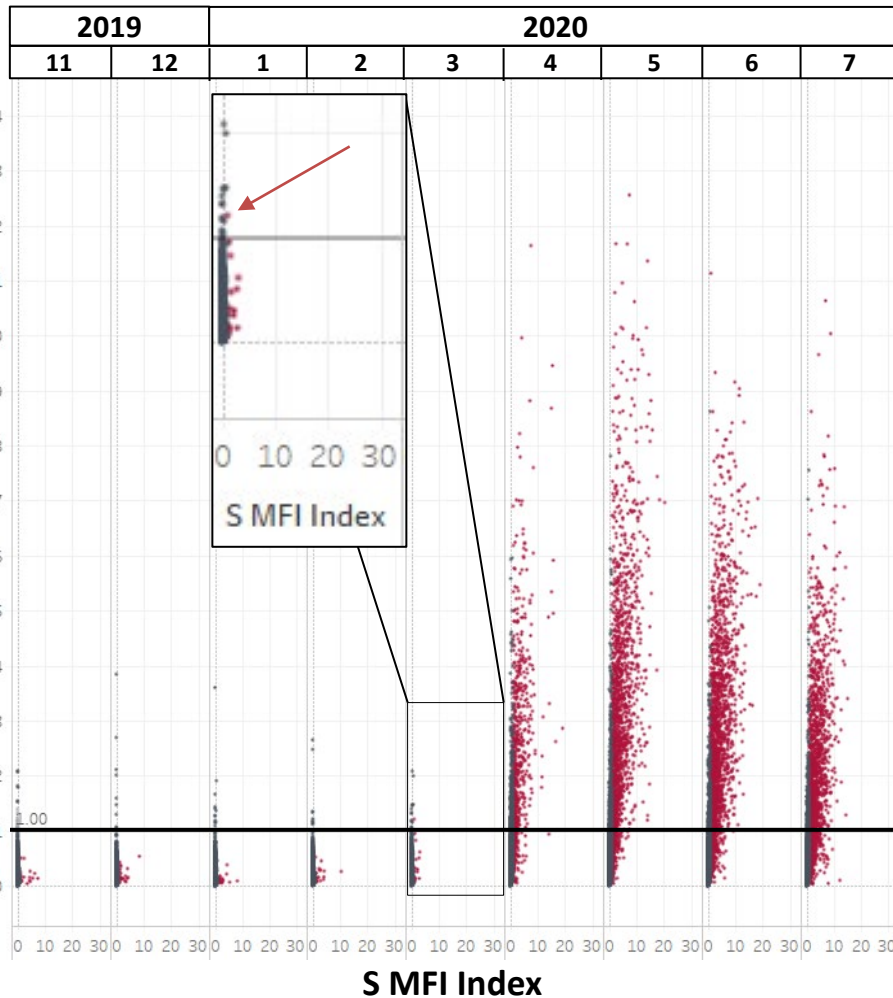


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N MFI Index

Year and Month of Birth



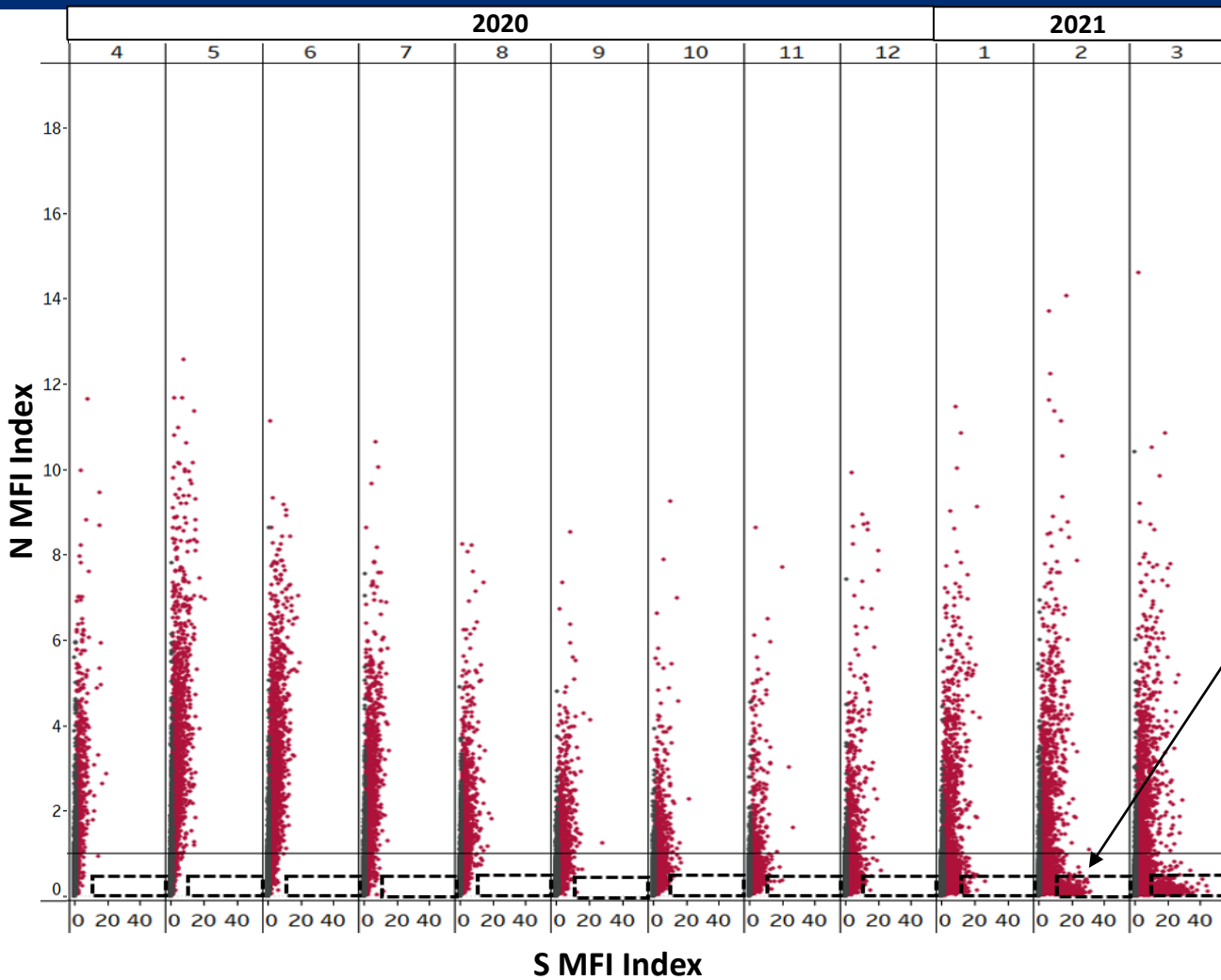
Earliest SARS CoV-2 antibody positive infants week of March 29, 2020

- 6 babies
- NYC and a nearby downstate county



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**COVID-19
vaccination
detectable
starting in
Feb 2021**

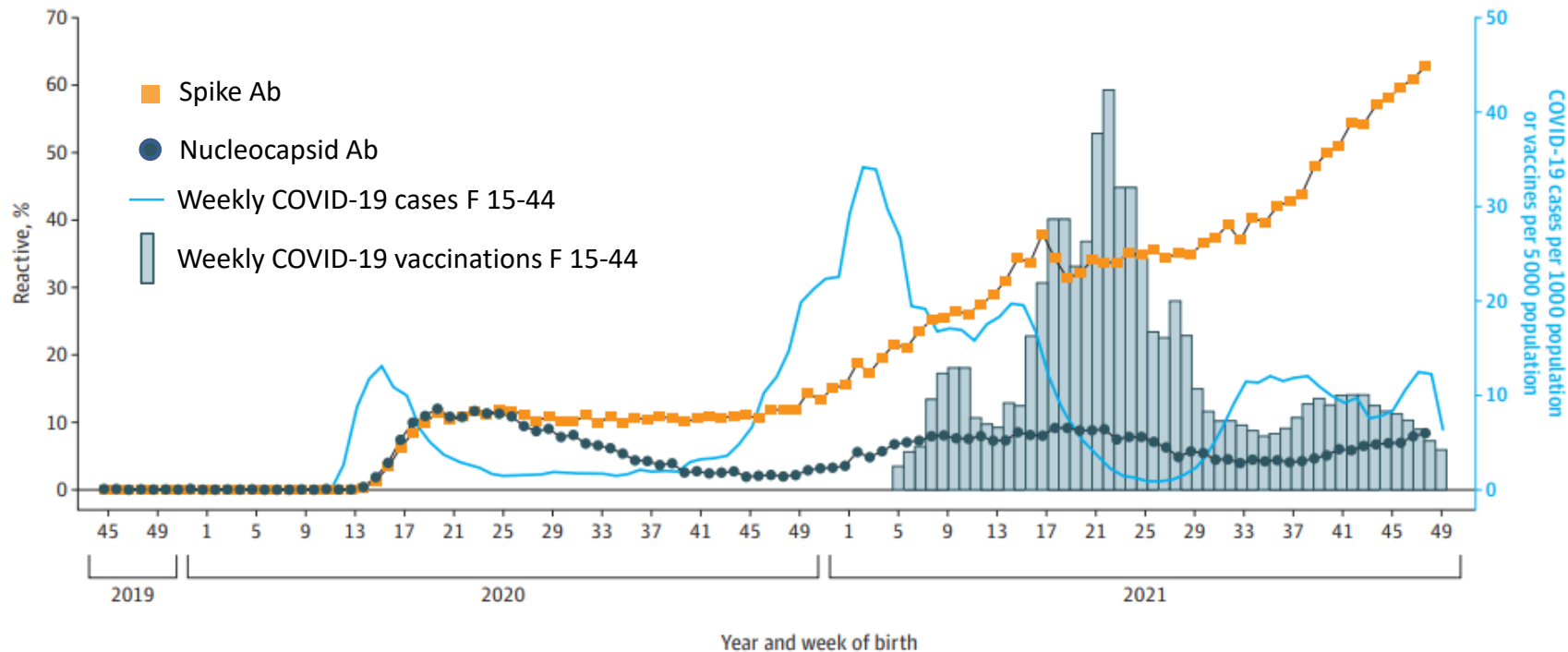


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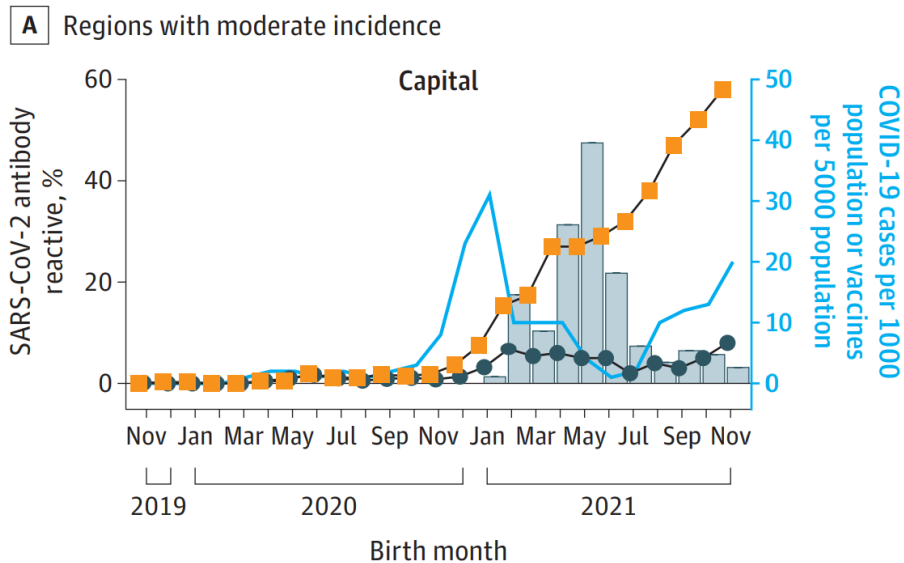
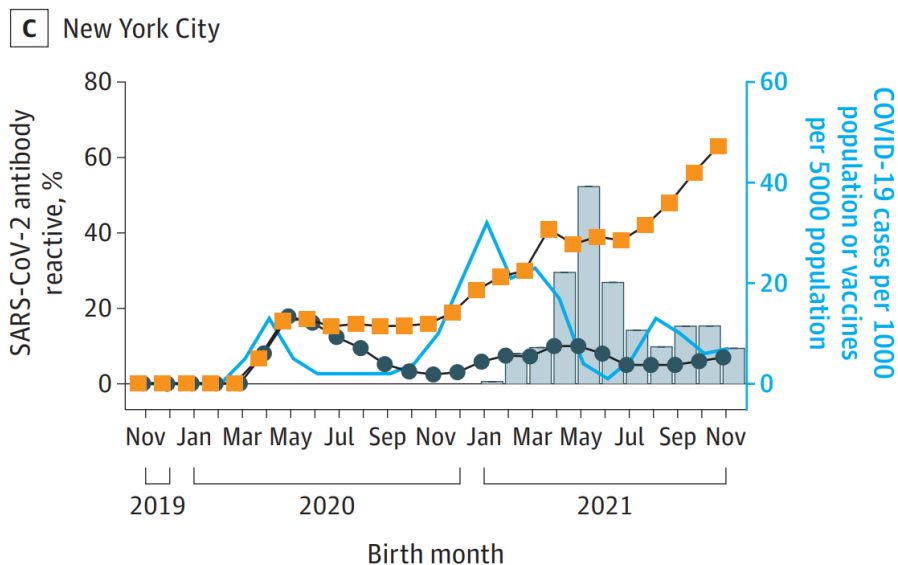
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Seropositivity increased after rise in cases and vaccines in NYS

B Weekly COVID-19 cases and vaccinations



High incidence regions had early peak in cases and Abs



Low/moderate incidence regions had low cases and Abs thru Fall 2020



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Feb 2021– Post-Vaccination IgG Antibody Response Study Using Self-Collected DBS

- Wadsworth Center employees self-collected DBS before & after COVID-19 vaccination (n=175 enrolled, 168 complete sets)
- 7 previously COVID-19 infected, rest naïve
- Of 509 DBS, only 2 were unsatisfactory (99.6% success rate)



RESEARCH ARTICLE
Month YYYY Volume XX Issue XX e01336-22

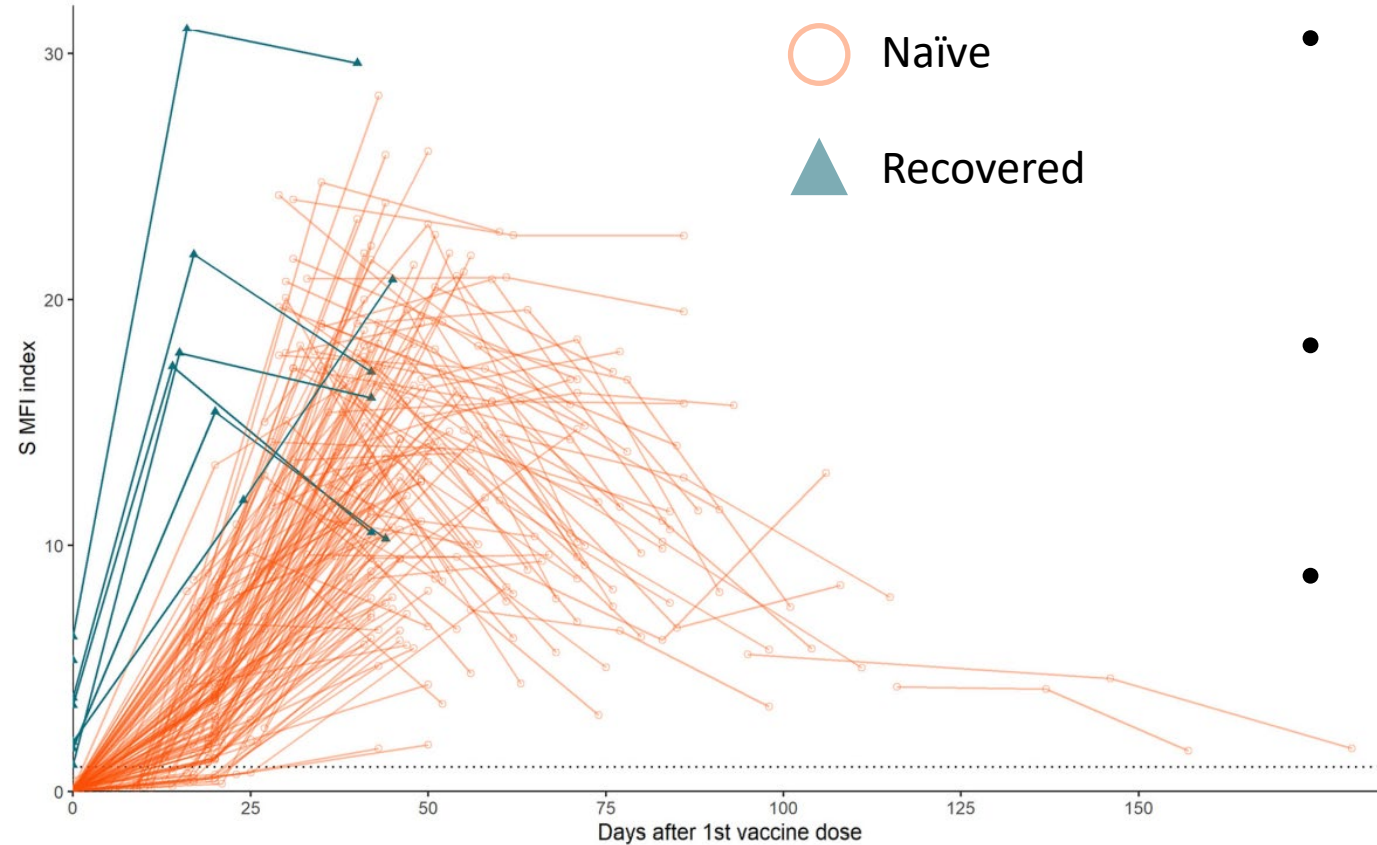
Use of Self-Collected Dried Blood Spots and a Multiplex Microsphere Immunoassay to Measure IgG Antibody Response to COVID-19 Vaccines

Katherine L. Nemeth^{a,*}, Erica Yauney^a, Jean M. Rock^a, Rachel Bievenue^a, Monica M. Parker ^a, Linda M. Styer ^{a,b}



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- Vaccination induces higher Ab levels than natural infection
- Recovered had higher Abs after 1st dose than naïve.
- Abs peaked ~60 days post Dose 1 and declined



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Four serological surveys using DBS and MIA

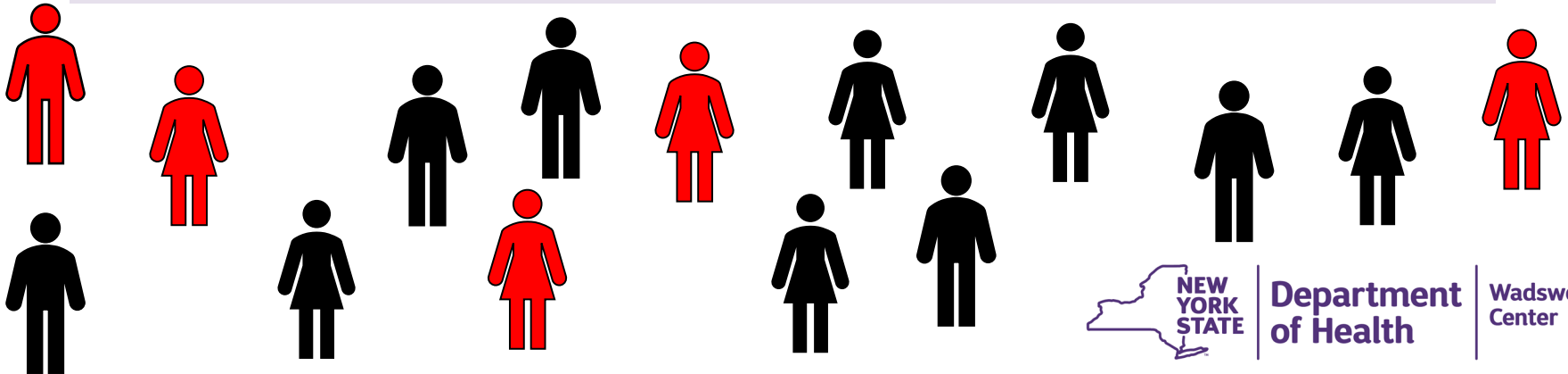
- Serosurvey of HCV among women giving birth in NYS
 - High HCV seroprevalence (~2%) in Central/Western/Finger Lakes; NYS = 0.8%
- NYS SARS-CoV-2 Serological Testing Survey
 - Overall 14% in NYS; 23% in NYC; 4% rest of state
- SARS-CoV-2 among women giving birth, Nov 2019-2021
 - First Ab positives in late March 2020 in NYC area
 - Regional correlation between cases and seropositivity
 - Detect uptake of vaccines
- Post-vaccine study using self-collected DBS



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Large-scale testing of DBS using a high-throughput, flexible MIA is an effective way to assess the prevalence of infectious diseases in the population



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Acknowledgements

Bloodborne Viruses Lab

Monica Parker, Jean Rock,
Rachel Bievenue, Erica Yauney,
Katie Nemeth, Amanda
Damjanovic, Tim Sullivan,
Tom Miller, Lea Ryman, Bryanna
Freitas

Newborn Screening Laboratory

Lea Krein, Amanda Showers,
Denise Kay, Norma Tavakoli,
Monica Martin, Rhonda Hamel,
Michele Caggana

Funding: CDC Foundation: Emergency Response Fund
CDC: ELC CARES NU50CK000516
National Cancer Institute: SeroNet U01CA260508

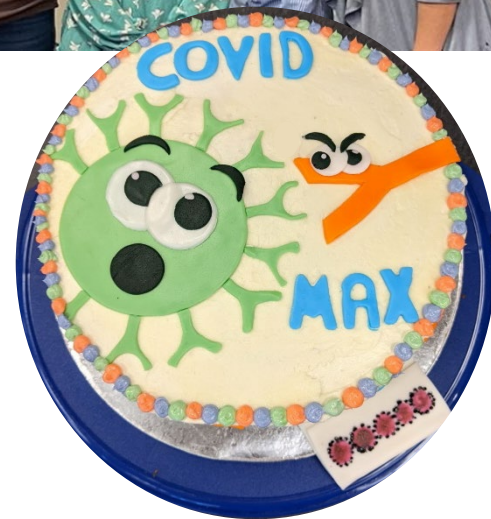


Other Wadsworth Center Labs

Bill Lee, Jen Yates, Danielle Hunt, Nick
Mantis, Dylan Ehrbar, many others

NYSDOH

Colleen Flanigan, S-Y Leung, Rebecca
Hoen, D Samananayake, many others



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