

# Clinical Laboratory COVID-19 Response Call

Monday, October 4, 2021, at 3:00 PM EDT

- **Welcome**
  - Jasmine Chaitram, CDC Division of Laboratory Systems (DLS)
- **Daily Testing vs. Self-Isolation for School-Based COVID-19 Contacts**
  - Bernadette Young, University of Oxford
- **“Test To Stay” Studies**
  - Ebony Thomas, CDC State, Tribal, Local, and Territorial Support Task Force
- **CMS Update**
  - Felicidad Valcarcel, Centers for Medicare and Medicaid Services (CMS)
- **FDA Update**
  - Toby Lowe, U.S. Food and Drug Administration (FDA)



# Division of Laboratory Systems (DLS)

## Vision

Exemplary laboratory science and practice advance clinical care, public health, and health equity.

## Mission

Improve public health, patient outcomes, and health equity by advancing clinical and public health laboratory quality and safety, data and biorepository science, and workforce competency.



# Four Goal Areas



## Quality Laboratory Science

- Improve the quality and value of laboratory medicine and biorepository science for better health outcomes and public health surveillance



## Highly Competent Laboratory Workforce

- Strengthen the laboratory workforce to support clinical and public health laboratory practice



## Safe and Prepared Laboratories

- Enhance the safety and response capabilities of clinical and public health laboratories



## Accessible and Usable Laboratory Data

- Increase access and use of laboratory data to support response, surveillance, and patient care

# New COVID-19 Self-Testing Videos

- **CDC Self-Testing Webpage**

<https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html>

- **CDC Testing Webpage**

<https://www.cdc.gov/coronavirus/2019-ncov/testing/index.html>

- **YouTube**

<https://www.youtube.com/watch?v=L8F1BnLtyio>

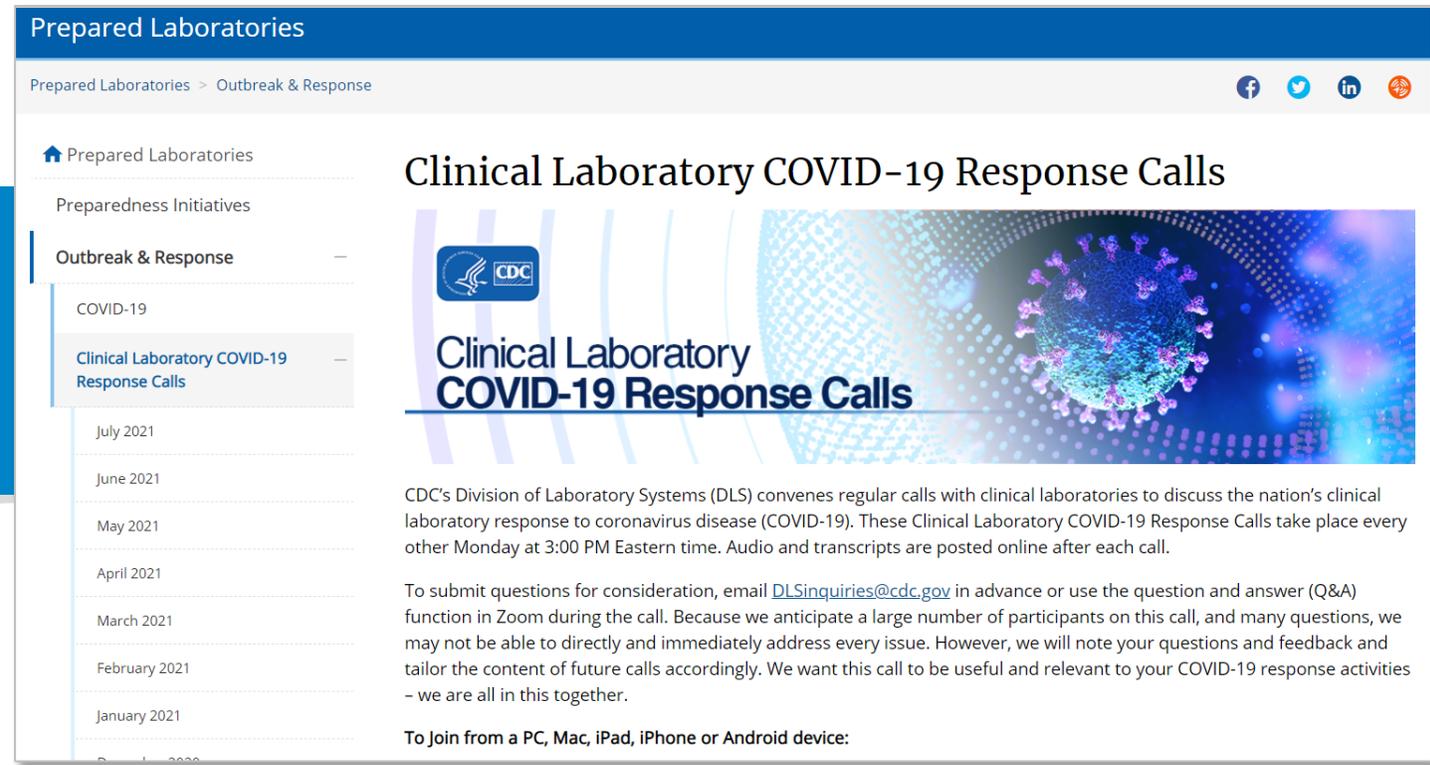
<https://www.youtube.com/watch?v=Xli2t4skfx0>



# CDC Preparedness Portal

<https://www.cdc.gov/csels/dls/preparedlabs/covid-19-clinical-calls.html>

Find CLCR call information,  
transcripts, and audio recordings on  
the CDC Preparedness Portal



The screenshot displays the 'Prepared Laboratories' section of the CDC Preparedness Portal. The main heading is 'Clinical Laboratory COVID-19 Response Calls'. Below the heading is a CDC logo and a large image of a coronavirus particle. The text describes the regular calls convened by the Division of Laboratory Systems (DLS) to discuss the nation's clinical laboratory response to COVID-19. It provides details on the call schedule (every other Monday at 3:00 PM Eastern time) and the availability of audio and transcripts. A section for submitting questions is also present, along with a note about joining from various devices.

Prepared Laboratories

Prepared Laboratories > Outbreak & Response

Prepared Laboratories

Preparedness Initiatives

Outbreak & Response

COVID-19

Clinical Laboratory COVID-19 Response Calls

July 2021

June 2021

May 2021

April 2021

March 2021

February 2021

January 2021

## Clinical Laboratory COVID-19 Response Calls

CDC's Division of Laboratory Systems (DLS) convenes regular calls with clinical laboratories to discuss the nation's clinical laboratory response to coronavirus disease (COVID-19). These Clinical Laboratory COVID-19 Response Calls take place every other Monday at 3:00 PM Eastern time. Audio and transcripts are posted online after each call.

To submit questions for consideration, email [DLSinquiries@cdc.gov](mailto:DLSinquiries@cdc.gov) in advance or use the question and answer (Q&A) function in Zoom during the call. Because we anticipate a large number of participants on this call, and many questions, we may not be able to directly and immediately address every issue. However, we will note your questions and feedback and tailor the content of future calls accordingly. We want this call to be useful and relevant to your COVID-19 response activities – we are all in this together.

To Join from a PC, Mac, iPad, iPhone or Android device:

# Schedule for Clinical Laboratory COVID-19 Response Calls

The next call will be on **Monday, October 18**  
from **3:00 PM to 4:00 PM EDT**



# We Want to Hear from You!

## Training and Workforce Development

Questions about education and training?

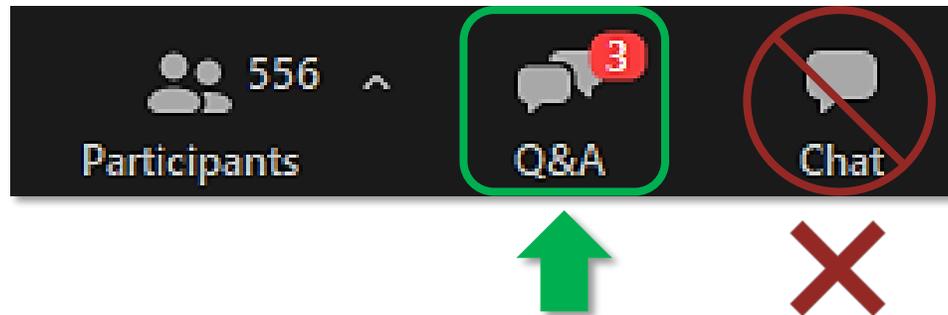
Contact [LabTrainingNeeds@cdc.gov](mailto:LabTrainingNeeds@cdc.gov)



# How to Ask a Question

- **Using the Zoom Webinar System**

- Click the **Q&A** button in the Zoom webinar system
- Type your question in the **Q&A** box and submit it
- **Please do not submit a question using the chat button**



- For media questions, please contact CDC Media Relations at [media@cdc.gov](mailto:media@cdc.gov)
- If you are a patient, please direct any questions to your healthcare provider



*Slide decks may contain presentation material from panelists who are not affiliated with CDC. Presentation content from external panelists may not necessarily reflect CDC's official position on the topic(s) covered.*



# Daily contact testing vs. self-isolation for school- based COVID-19 contacts

Summary findings from a cluster-randomized controlled trial

4<sup>th</sup> October 2021

Dr Bernadette Young (MBBS, DPhil, MRCP, FRCPath)

(on behalf of the Investigators)

# Why compare daily testing to isolation?

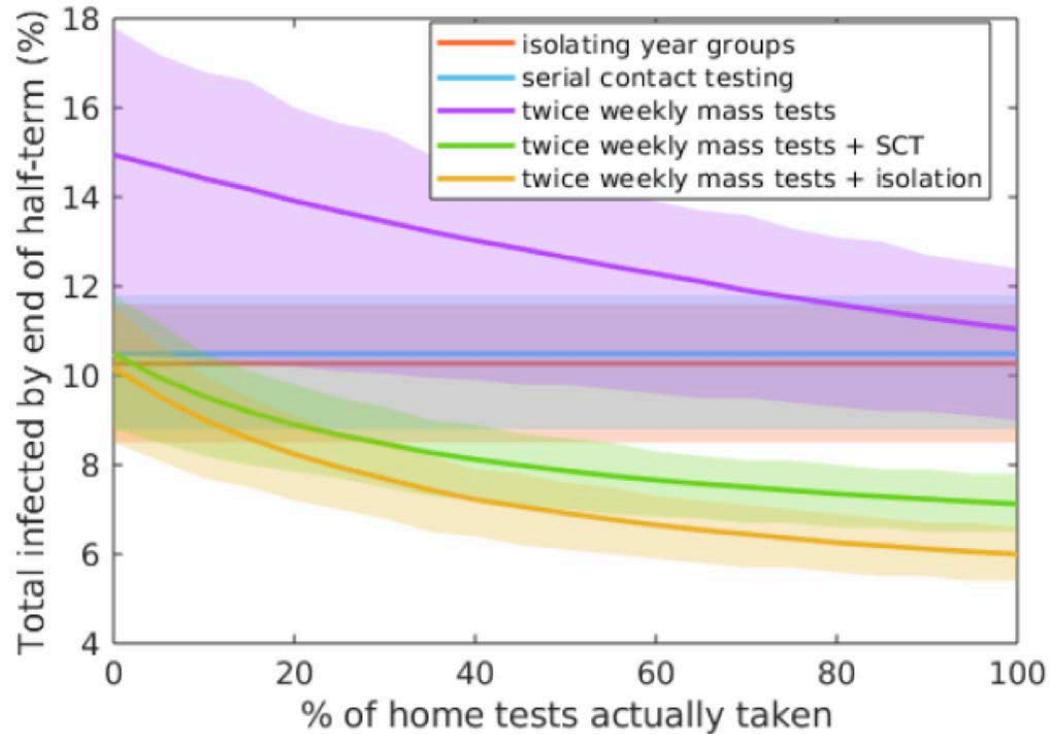
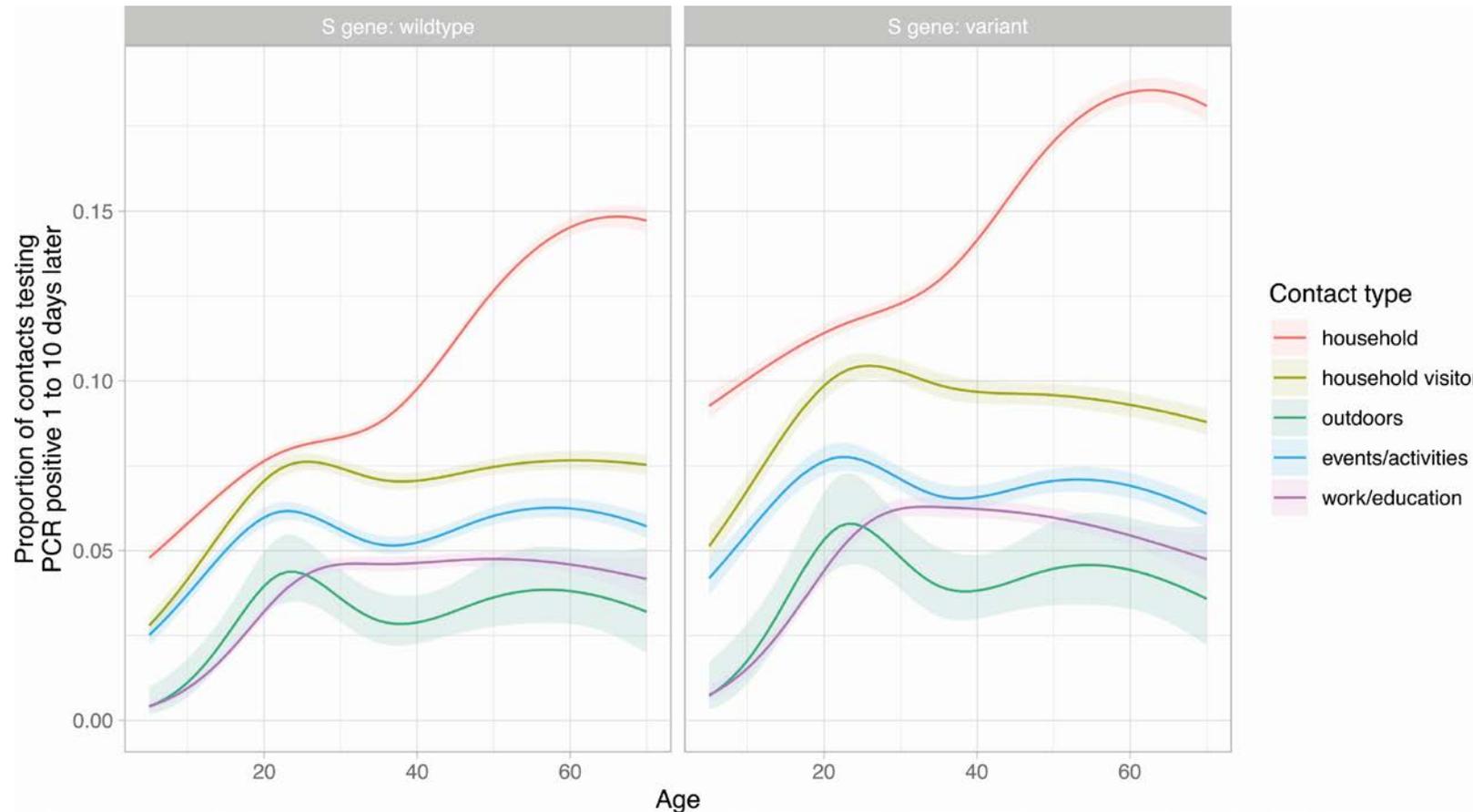


Figure from: Scientific Influenza Pandemic Group on Modelling (SPI-M)

- Serial testing of contacts may be offer better control of transmission
  - Modelling studies
- If combined with twice weekly testing, may be more effective in reducing transmission (depending on uptake)
- Pilot testing suggested daily testing with LFDs for contacts was feasible and acceptable

# What is the risk in schools?



How many school based contacts need to isolate to prevent one transmission?

“Number needed to quarantine”

Cases and contacts in England 1/9/20 – 28/2/21

Figure from: Lee et al *Clin Infect Dis*, ciab421, <https://doi.org/10.1093/cid/ciab421>

# Study design and methods

- Cluster-randomised, controlled trial
  - Randomisation by school or college to a group, which followed either policy of isolation of contacts OR offering daily testing
  - Representative gave consent for school or college to join
  - Individuals gave consent to participate
- Trial protocol was reviewed and approved by Public Health England Research Ethics Governance Group
- Local DsPH and public health officials retained oversight
- An Independent Data Monitoring Committee had open weekly oversight of the data to review for evidence of safety concerns
  - Investigators were blind to data during the study

# Trial procedures



## Control Group (self-isolation)

- Individuals (close contacts) self-isolate at home for 10 days.
- Invited to do 2 x Research PCR tests (one on day 2 and one on day 7) posted to and from the individual's house and the lab.
- PCR tests run retrospectively, results available on request 2 weeks later..

## Intervention Group (DCT)

- Individuals may return to school/college and have a rapid test every morning in school/college over 7 consecutive days. They can engage in all school/college activities only after a negative result is returned but (self-isolate in the evenings and weekends).
- The Orient Gene LFD (Lateral Flow Device) used
- Invited to do 2 x Research PCR tests (one on day 2 and one on day 7) at school
- PCR tests run retrospectively, results available on request 2 weeks later.

# Participating schools

- 201 schools were randomized to...
  - 99 control schools
  - 102 intervention schools

## 1. Is it safe?

- Compare in-school COVID-19 transmission
  - Estimated by rates of symptomatic PCR-Positive infections recorded in NHS Test and Trace

## 2. Does it improve attendance?

- Number COVID-19-related school absences amongst those eligible to attend

Secondary outcomes – proportion close contacts testing positive, participation in DCT, performance characteristics LFD testing

# Baseline characteristics

**201 schools randomised,  
representative of secondary  
schools and further education  
colleges across England**

Schools randomly assigned to the  
control or intervention, stratified  
by school characteristics

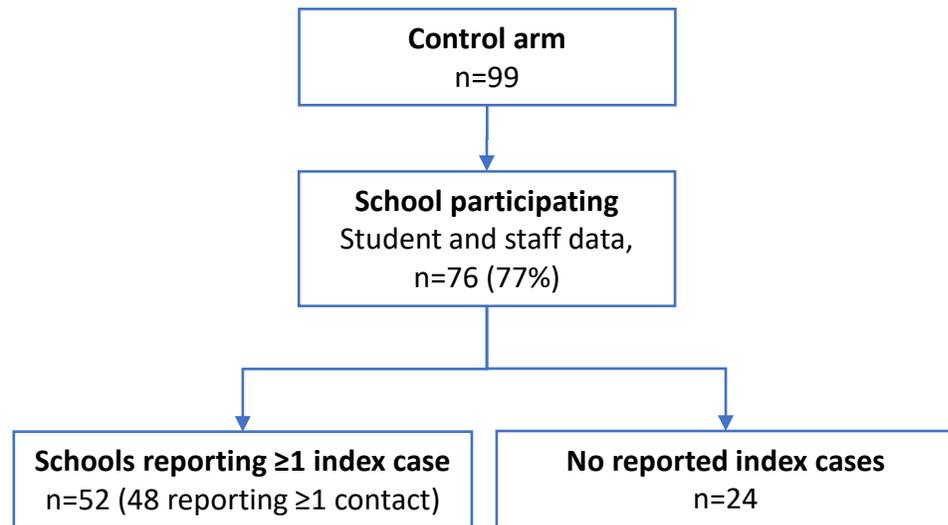
**>200,000 students**

**>20,000 staff**

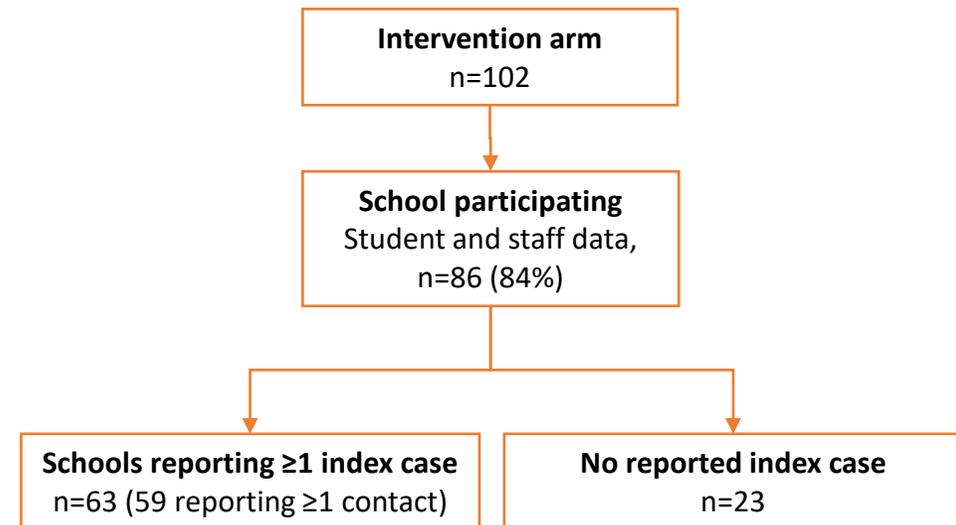
Characteristic	Control n = 99	Intervention n = 102
Strata		
Government-funded, 11-18y, free school meals ≤17%	32 (32%)	34 (33%)
Government-funded, 11-16y, free school meals ≤17%	8 (8.1%)	8 (7.8%)
Government-funded, 11-18y, free school meals >17%	22 (22%)	24 (24%)
Government-funded, 11-16y, free school meals >17%	19 (19%)	18 (18%)
Any residential school	5 (5.1%)	6 (5.9%)
Special needs or alternate provision	5 (5.1%)	5 (4.9%)
Further education college, 16-18y	3 (3.0%)	2 (2.0%)
Independent day school ≥500 pupils	3 (3.0%)	3 (2.9%)
Independent day school <500 pupils	2 (2.0%)	2 (2.0%)
Students attending school	1,014 (529, 1,376)	1,025 (682, 1,359)
Missing data	3	1
School staff	142 (91, 189)	125 (91, 173)
Missing data	23	17

# Index cases and contacts

- 76 and 84 actively participating control and intervention schools reported index cases and their contacts



247 index cases  
4463 contacts with  $\geq 1$  school day affected  
→ **self-isolate for 10 days**

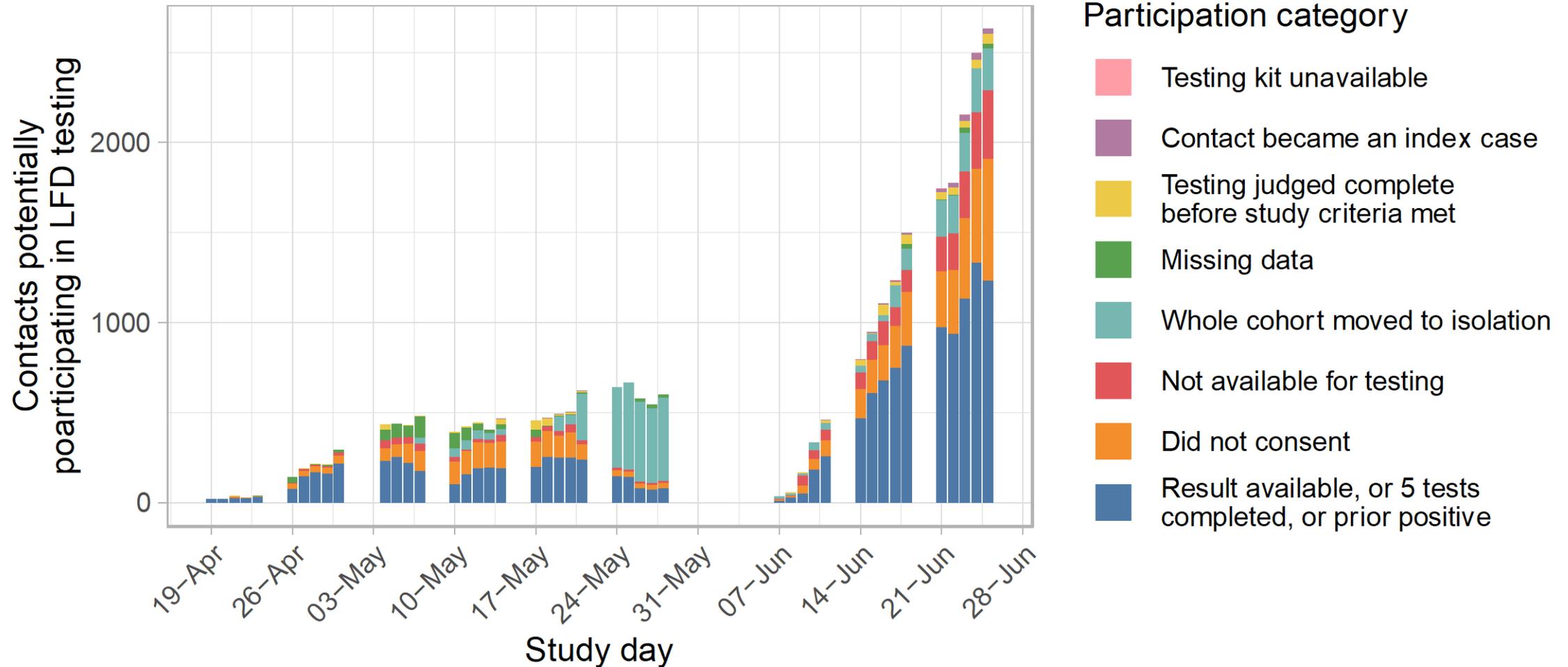


343 index cases  
5763 contacts with  $\geq 1$  school day affected  
→ **offered daily contact testing**

# Participation rates: intervention arm

5763 contacts: ~28,000 of 4.1 million school days (0.7%) in intervention arm contacts where DCT could potentially prevent COVID-related absences

**Participation ~ 50% on per day basis**

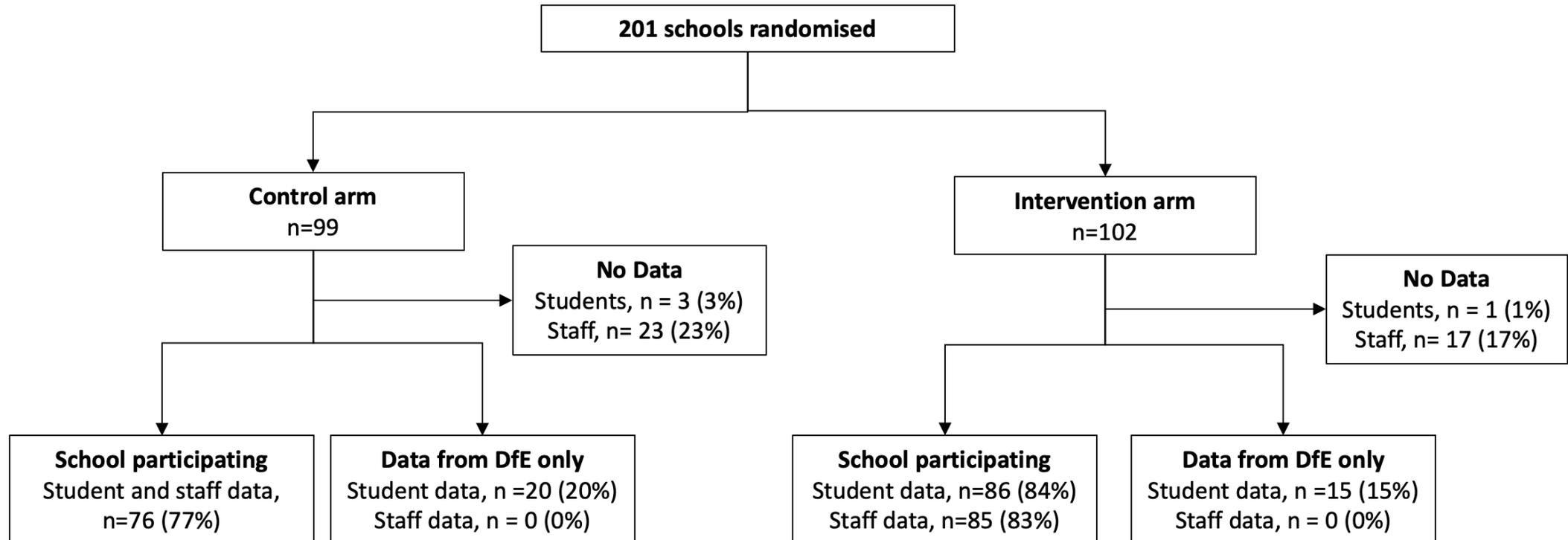


# Symptomatic infection

Details of staff and students at school linked to testing data from NHS Test & Trace

**Student data from 96/99 (97%) control and 101/102 (99%) intervention arm schools**

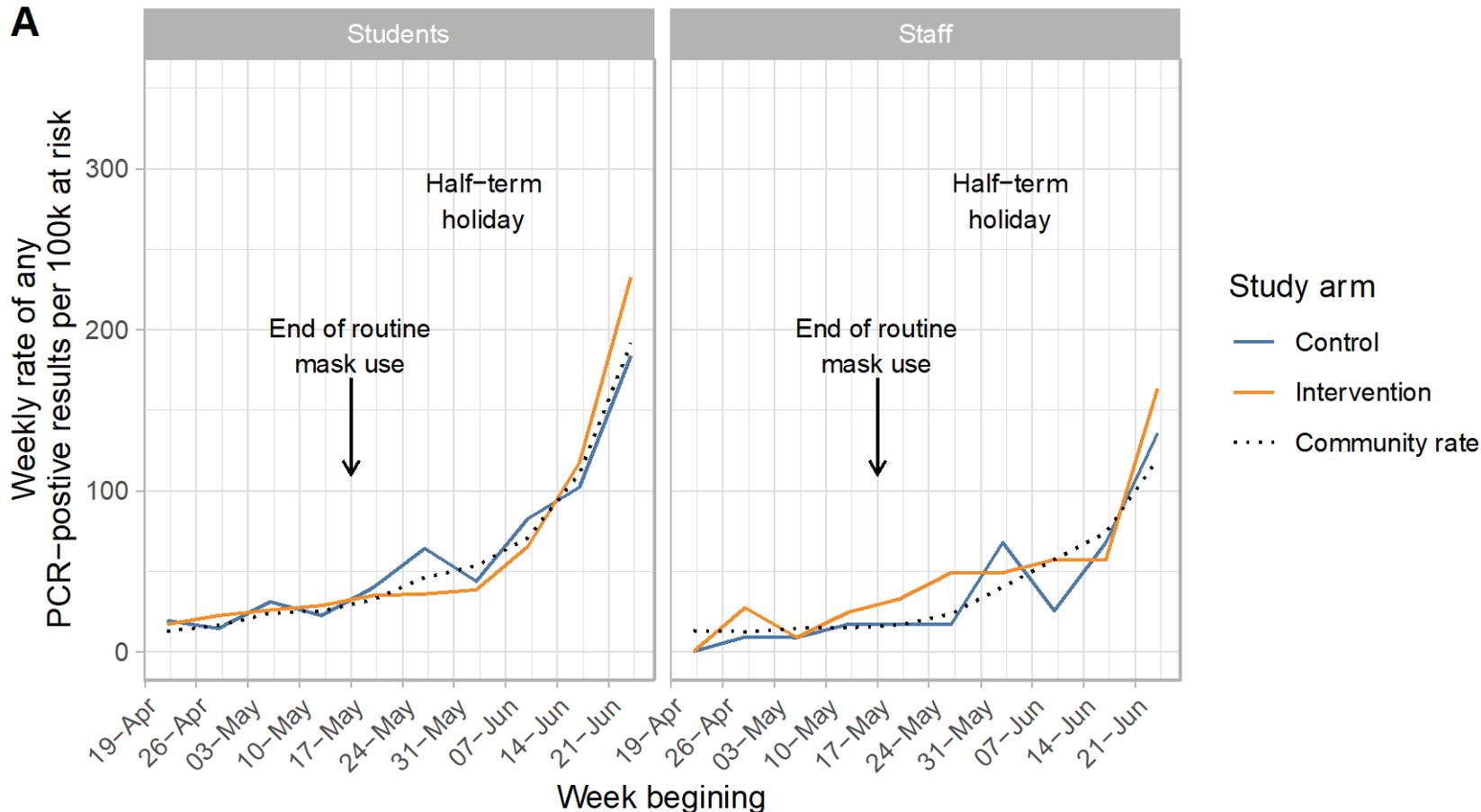
**Staff data from 76/99 (77%) control and 85/102 (83%) intervention arm schools**



# Symptomatic PCR positive results in students and staff

Control arm: 657 infections during 7.8m days-at-risk (59.1 per 100,000 per week)

Intervention arm: 740 infections during 8.4m days-at-risk (61.8 per 100,000 per week)



**No evidence on any difference in symptomatic infections between intervention and control schools**

**Rates of infection were lower in staff than students**



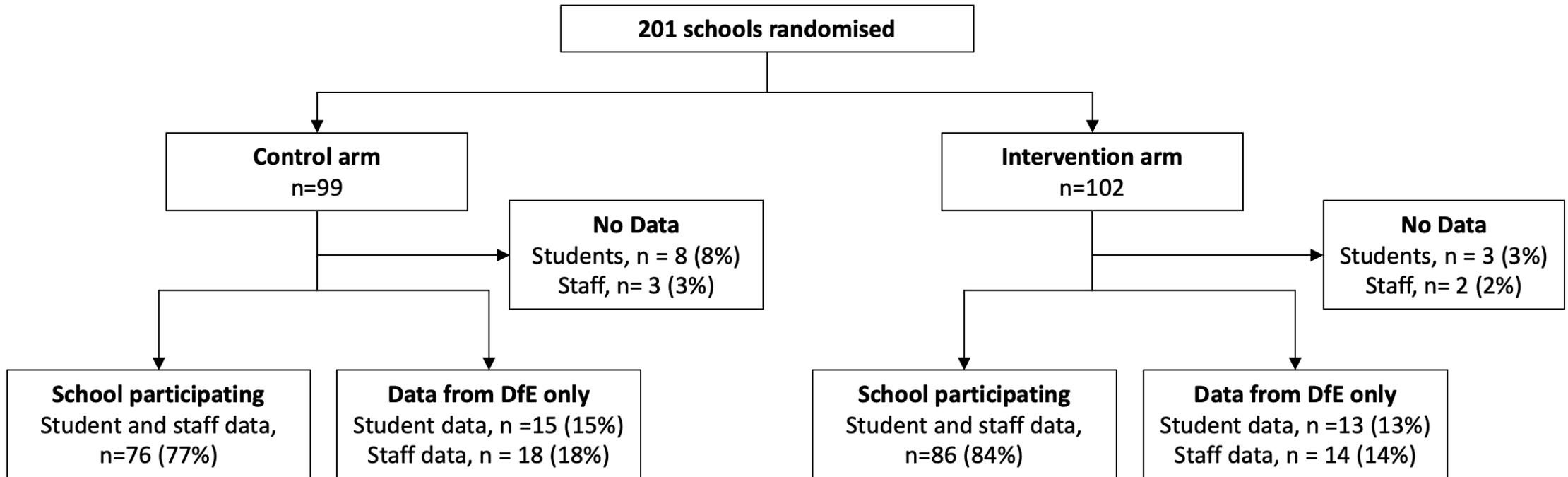
# Symptomatic PCR positive results in students and staff

Characteristic	Descriptive			ITT, Univariable			ITT, Multivariable Inc adjusted for strata and community case counts prior week			CACE, Multivariable	
	Symptomatic PCR positives	Days at risk	Rate per 100,000 per week	IRR	95% CI	p-value	IRR	95% CI	p-value	IRR	95% CI
Study arm											
Control	657	7,782,537	59.1	—	—		—	—		—	—
Intervention	740	8,379,749	61.8	1.05	0.71, 1.55	0.82	0.96	0.75, 1.22	0.72	0.86	0.55, 1.34
Participant type											
Student	1,297	14,547,064	62.4	—	—		—	—		—	—
Staff	100	1,615,222	43.3	0.69	0.55, 0.88	0.003	0.75	0.61, 0.92	0.006	0.76	0.61, 0.93

**Range of uncertainty in CACE equates to 1.2 less to 0.9 more infection per month per 1000 student school at average infection rates in the study**

# Participation – attendance data

Details from trial and DfE

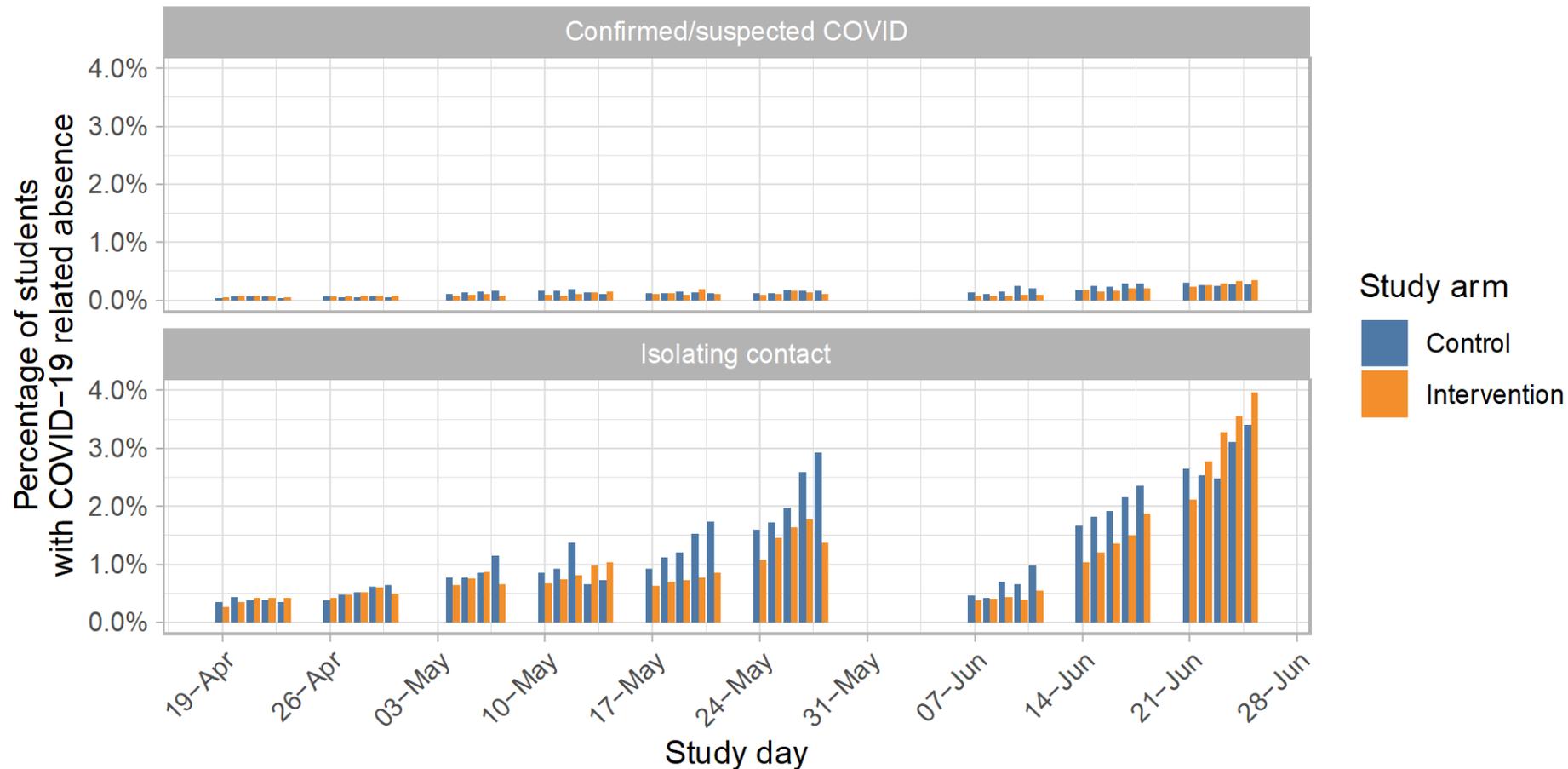


# COVID-related absences

Control: 55,718 COVID-related absences during 3.1 million person-school-days (1.8%)

Intervention: 48,609 COVID-related absences during 3.3 million person-school-days (1.5%)

## Student absences

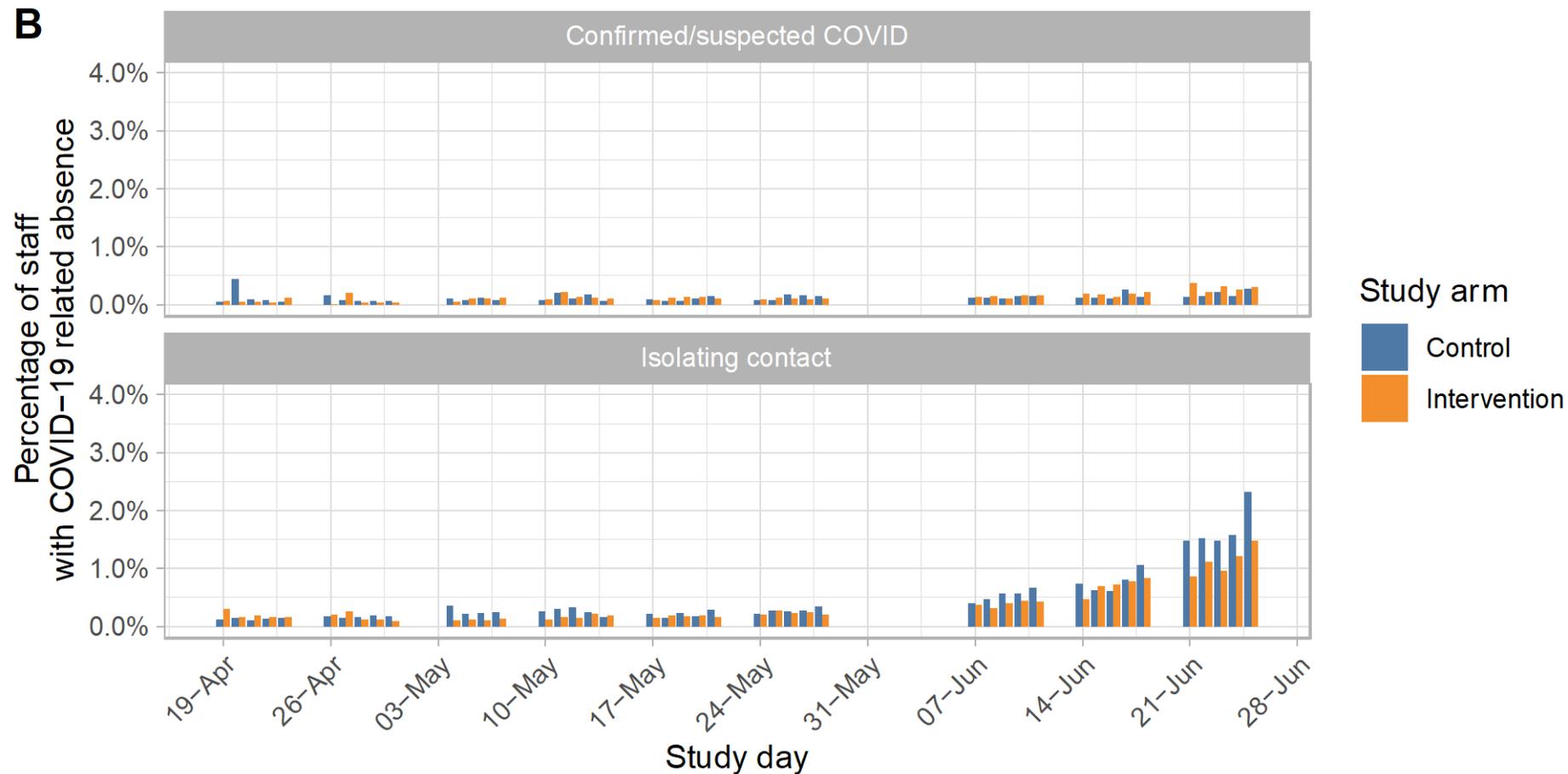


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## Staff absences



# Student COVID-related absences

Characteristic	Descriptive			ITT, Univariable			ITT, Multivariable Inc adjusted for strata			CACE, Multivariable	
	COVID-related absences	Days at risk	Rate per 1000	IRR	95% CI	p-value	IRR	95% CI	p-value	IRR	95% CI
Study arm											
Control	59,422	3,659,017	16.2	—	—		—	—		—	—
Intervention	51,541	3,845,208	13.4	0.83	0.54, 1.26	0.38	0.80	0.54, 1.19	0.27	0.61	0.30, 1.23
Participant type											
Student	104,327	6,397,918	16.3	—	—		—	—		—	—
Staff	6,636	1,106,307	6.0	0.37	0.29, 0.47	<0.001	0.39	0.31, 0.48	<0.001	0.40	0.33, 0.51

# How common is infection in contacts?

**~98% of school-based contacts did not become infected**

No evidence of different rates of PCR-positive infection in the intervention or control group

**Asymptomatic infection** (a third, ~0.5%, went on to develop symptoms and have test in T&T)

- Control: 14/886 (1.6%)
- Intervention: 44/2980 (1.5%)
  - aOR = 0.73 (0.33 – 1.61, p = 0.44)

**Symptomatic infection**

- Control: 44/4665 (0.9%)
- Intervention: 79/5955 (1.3%)
  - aOR = 1.21 (95% CI 0.82-1.79, p = 0.34)

# Summary

- In secondary school and college students and staff infection of following contact with a COVID-19 case at school occurs in less than 2%
- There was no evidence that switching from isolation at home to daily contact testing increased rates of symptomatic COVID in students and staff
- Daily contact testing is a safe alternative to home isolation following school-based exposures

# Detection of infective cases by LFD testing

- Readily available in 2021
- Rapid result
- Minimal infrastructure required to operate

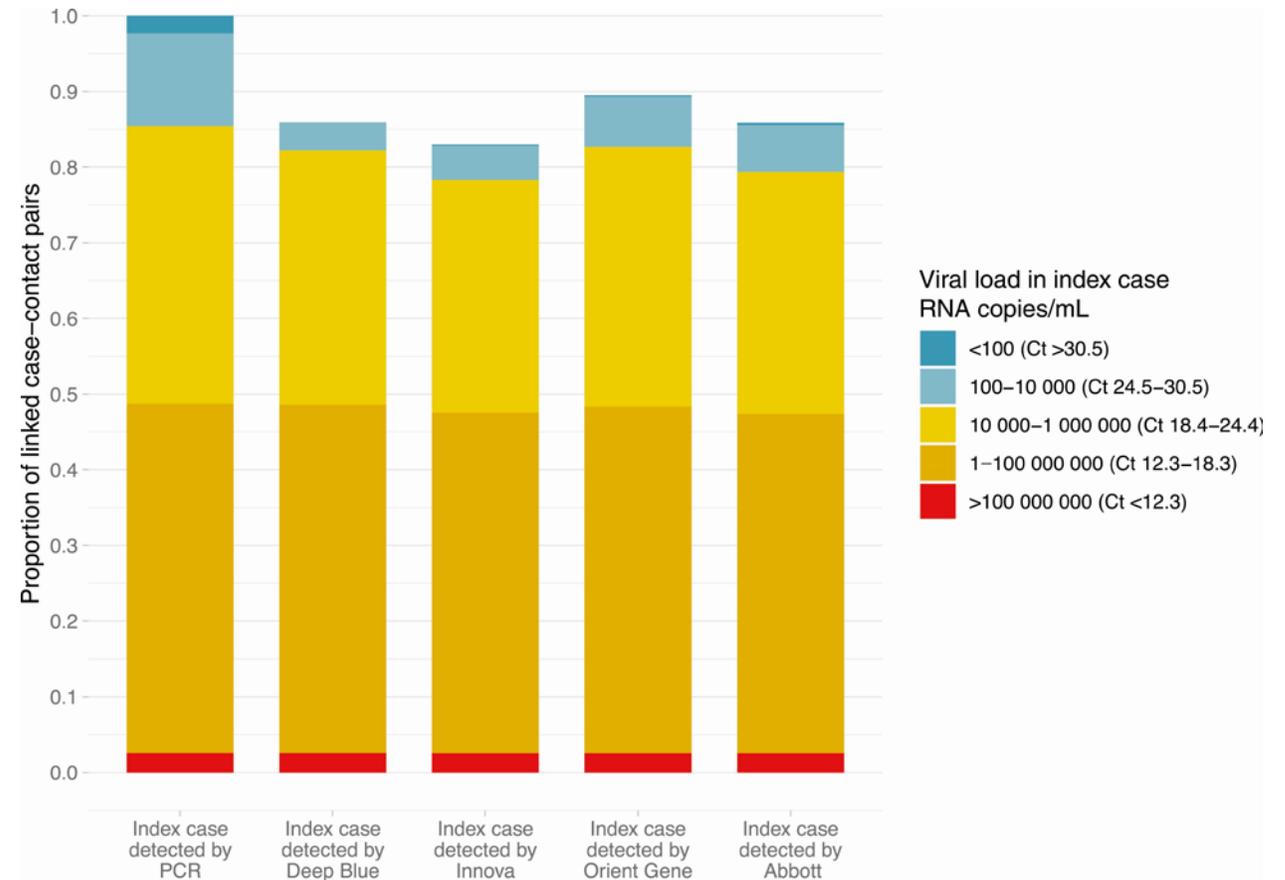
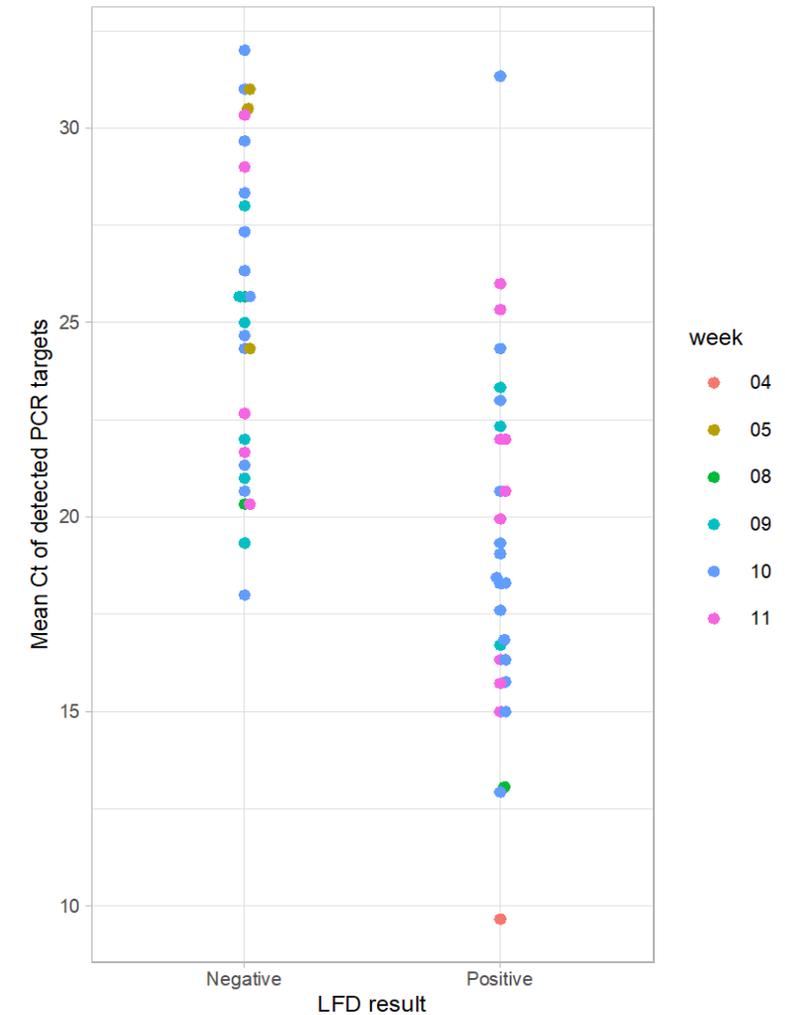


Figure from: Lee et al *Clin Infect Dis*, ciab421,  
<https://doi.org/10.1093/cid/ciab421>

# Performance of LFDs

	PCR detected SARS-CoV-2	PCR negative for SARS-CoV-2	Total	
LFD positive for SARS-CoV-2	32	2	34	PPV (95% CI) = 94% (80-99)
LFD negative for SARS-CoV-2	28	3164	3192	NPV (95% CI) = 99.12 (98.7-99.4)
Total	60	3166		
	Sensitivity 53% (95% CI 40-66)	Specificity 99.93% (95% CI 99.77-99.99)		



# “Test To Stay” Studies

**Ebony Thomas**  
CDC State, Tribal, Local, and Territorial Support Task Force



## CMS Update

**Felicidad Valcarcel**

Centers for Medicare and Medicaid Services (CMS)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# Centers for Medicare and Medicaid Services (CMS)

- **CLIA Laboratory Guidance During COVID-19 Memo and FAQs**

<https://www.cms.gov/medicareprovider-enrollment-and-certificationsurvey/certificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health>

- **FAQs Only**

<https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus>



## FDA Update

**Toby Lowe**

U.S. Food and Drug Administration (FDA)



U.S. Department of  
Health and Human Services  
Centers for Disease  
Control and Prevention

# U.S. Food and Drug Administration (FDA)

- **COVID-19 Emergency Use Authorization (EUA) Information for Medical Devices**

<https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

- **COVID-19 In Vitro Diagnostic EUAs**

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

- **COVID-19 Frequently Asked Questions**

<https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/coronavirus-disease-2019-covid-19-frequently-asked-questions>

- **COVID-19 Updates**

<https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

- **FDA Townhall Meetings**

<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-06032020>

- **Independent Evaluations of COVID-19 Serological Tests**

<https://open.fda.gov/apis/device/covid19serology/>

# U.S. Food and Drug Administration (FDA)

- **COVID-19 Diagnostic Development**

[CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov)

- **Spot Shortages of Testing Supplies: 24-Hour Support Available**

1. Call 1-888-INFO-FDA (1-888-463-6332)

2. Then press star (\*)

- **FDA MedWatch**

<https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program>

# CDC Social Media

<https://www.facebook.com/CDC>



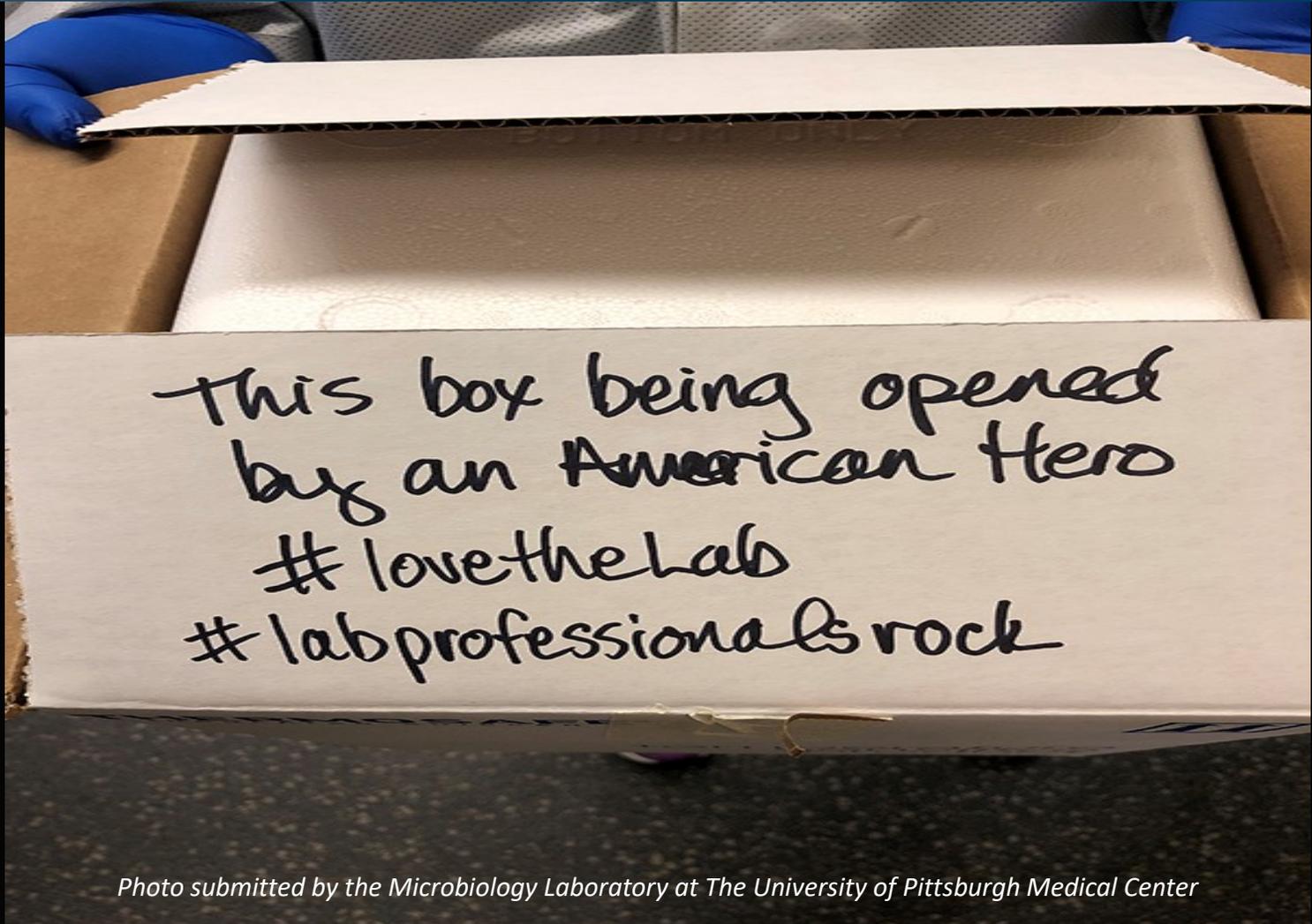
<https://twitter.com/cdcgov>

<https://www.instagram.com/cdcgov>



<https://www.linkedin.com/company/cdc>

# Thank You For Your Time!



This box being opened  
by an American Hero  
#lovethelab  
#labprofessionalsrock

*Photo submitted by the Microbiology Laboratory at The University of Pittsburgh Medical Center*