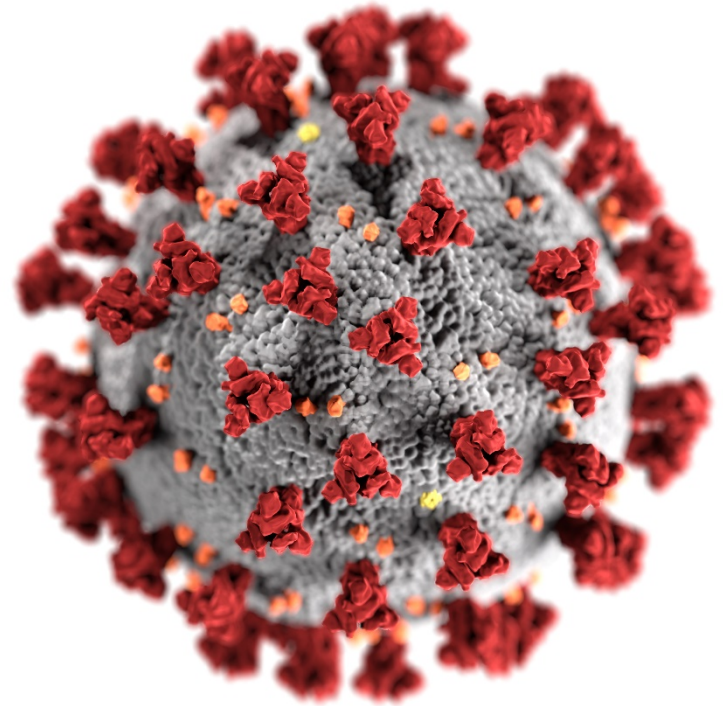


# CDC and FDA updates

**Temet McMichael, PhD**  
**Epidemic Intelligence Service Officer**  
Public Health – Seattle & King County

Indian Country COVID-19 teleECHO  
November 30, 2020



[cdc.gov/coronavirus](https://cdc.gov/coronavirus)

**FDA, COVID-19 page:** <https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19>

**CDC, what's new:** <https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html>

**WA DOH, literature reports:**  
<https://www.doh.wa.gov/Emergencies/COVID19/Resources>

# FDA Authorizes First COVID-19 Test for Self-Testing at Home

## EUA for first at home rapid COVID-19 test:

- Lucira COVID all-in-one test kit
  - Nasal swab (self collected)
  - 14 and older with suspected COVID-19
  - Can be done as point of care by HCP
  - Younger than 14 okay if HCP swabs
  - Rx use only (HCP required to report +’s)
  - Results available in 30 min or less



The graphic is a dark blue header with the 'LUCIRA HEALTH' logo on the left and a green 'REQUEST MORE INFO' button on the right. Below the header, four steps are illustrated with icons and text: 1. Swab Your Nose (hand holding a swab), 2. Stir Into Sample Vial (swab in a vial), 3. Get Results In 30 Minutes (a vial with a plus sign and a clock icon), and 4. Seek Treatment (a smartphone with a plus sign on the screen).

Accessed online, ABC news, 11/20/20: <https://www.nytimes.com/live/2020/11/17/world/covid-19-coronavirus>

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  - Rx use only (HCP required to report +'s)
  - Results available in 30 min or less
  - Limit of detection: 2700 genome copies/swab
  - Sensitivity 94%; Specificity 98%
  - Estimated cost \$50/test
  - Not expected to be available nationwide until spring 2021



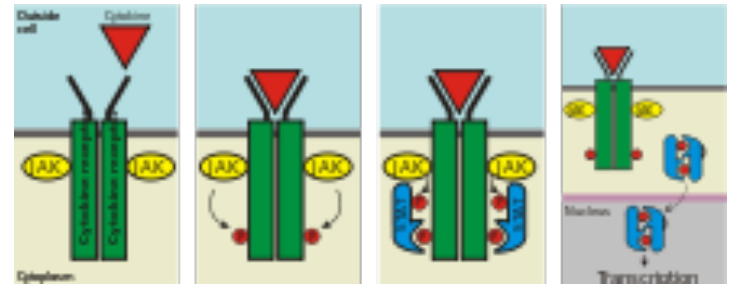
Accessed online, local 12 news, 11/20/20: <https://local12.com/health/health-updates/fda-approves-first-at-home-covid-19-test-cincinnati>



## FDA Authorizes Drug Combination for Treatment of COVID-19

### EUA for combination therapy: Baricitinib and Remdesivir

- Remdesivir (nucleoside analog)
- Baricitinib
  - Treatment of RA
  - Janus kinase inhibitor (JAK-STAT)
  - Oral tablet
  - Reduces inflammation
- Randomized, double-blind, placebo controlled trial
- Therapy reduced time to recovery in patients hospitalized w COVID-19
  - Combination therapy (recovery = 7 days)
  - Remdesivir + placebo (recovery = 8 days)
  - Odds of death or ventilation reduced in combination therapy



Accessed online, Wikipedia, 11/20/20: [https://en.wikipedia.org/wiki/Janus\\_kinase](https://en.wikipedia.org/wiki/Janus_kinase)

# Updates from CDC

## Updates:

- Cases and deaths update
- Toolkit for Healthcare Providers
- Contact Tracing Resources for Health Departments
- Testing and International Air Travel
- Holiday Celebrations and Small Gatherings

## MMWR:

- COVID-19 incidence by Urban-Rural classification
- COVID-19 in counties with and without mask mandates
- COVID-19 outbreak associated with motorcycle rally
- Pooled testing program for asymptomatic SARS-COV-2 infections on college campuses





## Coronavirus Disease 2019 (COVID-19)

# CDC COVID Data Tracker

Maps, charts, and data provided by the CDC

Case Trends ▾

County View

Laboratory ▾

Community Impact ▾

Unique Populations ▾

COVID-19 Home

Cases and Deaths by State

[US and State Trends](#)

[Compare State Trends](#)

[Demographics](#)

[Trends by Population Factors](#)

[Forecasting](#)

[Trends in ED Visits](#)

## United States COVID-19 Cases and Deaths by State

Reported to the CDC since January 21, 2020

TOTAL CASES

13,142,997

+143,333 New Cases

CASES IN LAST 7 DAYS PER 100K

48.7

TOTAL DEATHS

265,166

+1,210 New Deaths

CDC | Updated: Nov 29 2020 1:32PM

CDC in Action +

Global COVID-19 +

Science & Research +

Guidance Documents

**Communication Resources** -

**COVID-19 One-Stop Shop Toolkits** -

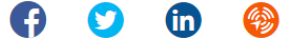
People 15 to 21

Childcare Programs & Summer Camps

Youth Sports

# Toolkit for Healthcare Providers

Updated Nov. 18, 2020 [Print](#)



Guidance and tools to help clinicians make decisions, protect patients and employees, and communicate with their communities.

## Guidance and Planning Documents

- [Clinical Care Guidance for Healthcare professionals about Coronavirus Disease 19 \(COVID-19\)](#)
- [Considerations for Wearing Masks](#)
- [Cleaning and Disinfection for Households](#)
- [COVID-19 Guidance for Shared or Congregate Housing](#)
- [Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for](#)

Contact Tracing Resources for Health Departments

COVIDTracer Tool

Case Investigation & Contact Tracing Guidance

Prioritizing Case Investigations and Contact Tracing in High Burden Jurisdictions +

Principles of Contact Tracing

Contact Tracing Training

Evaluating PUIs Residential

Contact Tracing Communications Toolkit

# Contact Tracing Resources for Health Departments



Resources for Conducting Contact Tracing to Stop the Spread of COVID-19

Updated Nov. 23, 2020

[Print](#)



## What's New

- [Prioritizing Case Investigations and Contact Tracing for COVID-19 in High Burden Jurisdictions](#)
- [Prioritizing COVID-19 Contact Tracing – Mathematical Modeling Methods and Findings](#)
- [Answer the Call – Contact Tracing Video](#)
- [Interim Guidance for Case Investigation and Contact Tracing in K-12 Schools](#)
- [Interim Guidance for Case Investigation and Contact Tracing in Institutions of Higher Education \(IHEs\)](#)
- [Contact Tracing: A Community Engagement Checklist for Health Departments](#)  [PDF - 3 pages] [Español](#) 

## On This Page

[Guidance documents](#)

[Contact tracing implementation](#)

[Communication resources](#)

[Digital tools for contact tracing](#)

[Federal and state resources](#)

[Private sector and other non-governmental resources](#)

🏠 Your Health

Things You Need to Know

Symptoms +

Testing +

Vaccines +

Prevent Getting Sick +

If You Are Sick +

People at Increased Risk +

Daily Activities & Going Out +

Travel -

Testing and International

YOUR HEALTH

# Testing and International Air Travel

Updated Nov. 21, 2020

Languages ▾

Print

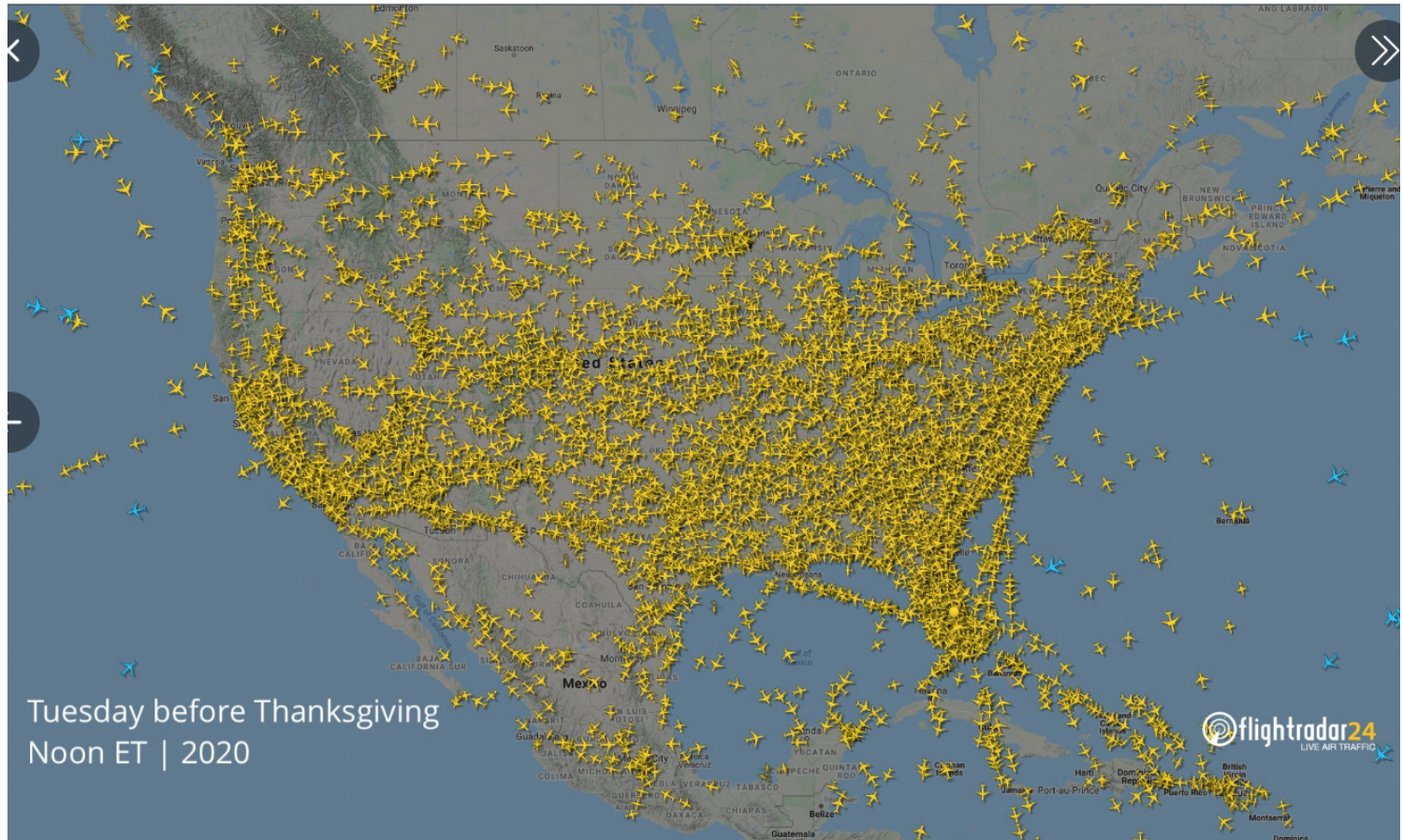


These CDC recommendations are based on the latest public health science to inform safer, more responsible international travel during the COVID-19 pandemic. These recommendations are not intended to be requirements for the travel industry. Follow all destination and airline recommendations or requirements.

Air travel requires spending time in security lines and airport terminals, which can bring you in close contact with other people and frequently touched surfaces. Social distancing is difficult in busy airports and on crowded flights, and sitting within 6 feet of others, sometimes for hours, may increase your risk of getting COVID-19. How you get to and from the airport, such as with [public transportation and ridesharing](#), can also increase your chances of being exposed to the virus.

Testing before and after travel can reduce the risk of spreading COVID-19. Testing does not eliminate all risk, but when paired with a period of staying at home and everyday precautions like [wearing masks](#) and [social distancing](#), it can make travel safer by reducing spread on planes, in airports, and at

Please visit CDC at: <https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html>



Flightradar online access 11/30/20: <https://www.flightradar24.com/35.17,-90.21/5>

Travel During COVID-19	+
Travel Health Notices	+
When to Delay Travel	
Know Your Travel Risk	
Travel Planner	+
After You Travel	
Cruise Ship Travel	+
Travel FAQs	
Travelers Prohibited from Entry to the US	
Communication Resources for Travelers	+
Children & Teens	+

Here's what to know:

- Get tested 1-3 days before your flight.
- Get tested 3-5 days after travel **AND** stay home for 7 days after travel.
  - Even if you test negative, stay home for the full 7 days.
  - If you don't get tested, it's safest to stay home for 14 days after travel.
- Always follow [state and local](#) recommendations or requirements related to travel.
- [Delay your](#) travel if you are waiting for test results.

Travelers with a known exposure to COVID-19 should [delay travel](#), [quarantine](#) themselves from other people for 14 days after their last known exposure, get [tested](#), and monitor their health.

## Get Tested Before Your Flight

Below is what you need to know about getting tested before your international flight.

- Get tested with a [viral test](#) 1-3 days before you depart and again 1-3 days before you return.
- Make sure you get your test results before you travel. If you are waiting for results, delay your travel.
- [Do not travel](#) if your test result is positive; immediately [isolate](#) yourself, and follow [public health](#)



Things You Need to Know

Symptoms +

Testing +

Vaccines +

Prevent Getting Sick +

If You Are Sick +

People at Increased Risk +

Daily Activities & Going Out -

Deciding to Go Out

Returning to Work

# Holiday Celebrations and Small Gatherings

Updated Nov. 19, 2020 Languages ▾ Print



Thanksgiving >

Coping with Holiday Stresses >

Hosting Gatherings >

Attending an Event or Gathering >

Travel >

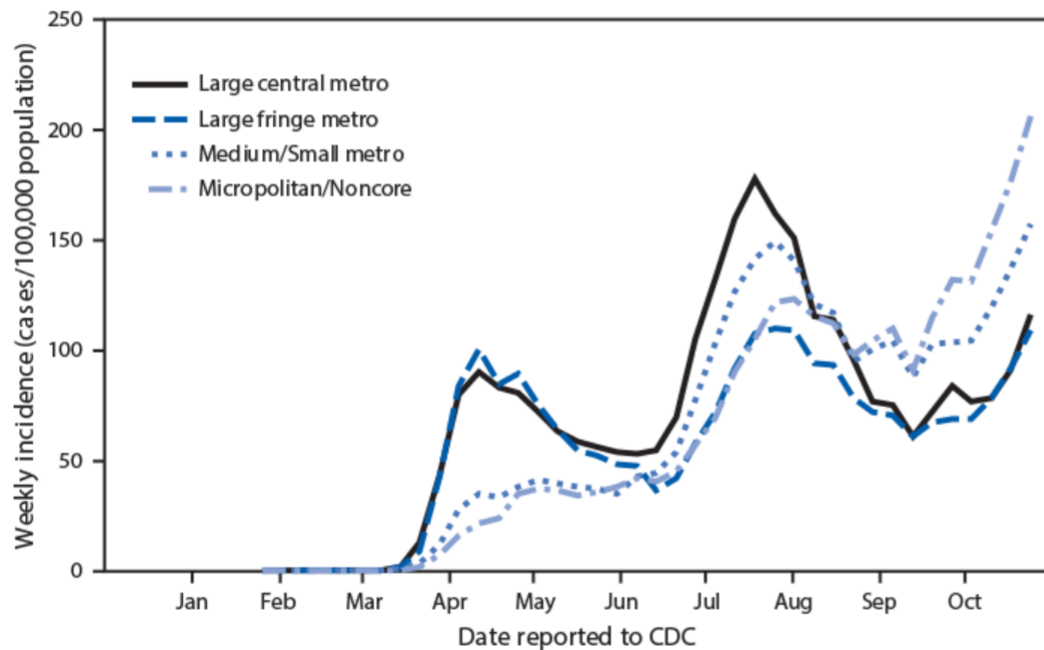
More than 1 million COVID-19 cases were reported in the United States over the last 7 days.



## COVID-19 Incidence, by Urban-Rural Classification – United States, January 22-October 31, 2020

### Summary:

- Incidence has gone up and down in metropolitan areas over time
- Mid-March to mid-May, COVID-19 incidence high in metropolitan areas, as compared with rural
- Rural areas saw steady increases over time
- Rural areas saw slight decrease in September; now seeing marked increases
- Weekly incidence increasing steadily for all areas





## Level COVID-19 Incidence in Counties With and Without a Mask Mandate – Kansas, June 1 – August 23, 2020

### Summary:

- Kansas governor issued executive order requiring masks in public spaces, effective July 3, 2020
- Counties were able to opt out
- 24 counties opted in; incidence decreased
- 81 opted out; incidence increased
- Mask mandates appear to mitigate COVID-19 transmission

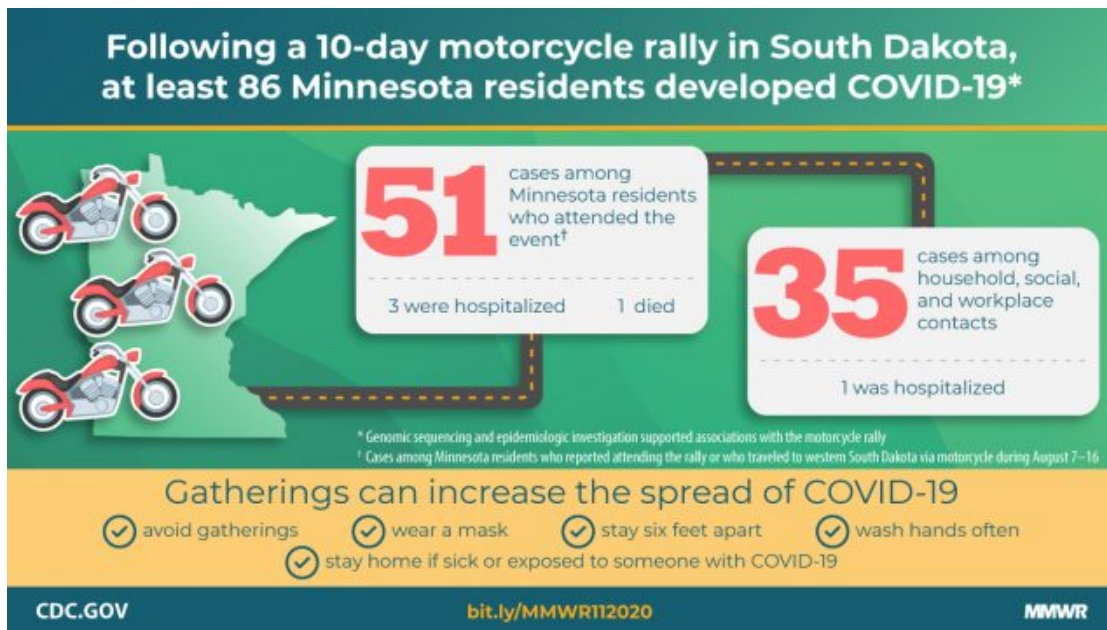




## COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State – Minnesota, August – September 2020

### Summary:

- 10-day motorcycle rally in South Dakota attended by 460,000 persons
- Many indoor and outdoor events
- 51 confirmed primary event cases; 21 secondary cases; 5 tertiary linked to rally via sequencing
- From all cases; 4 hospitalized and 1 died
- Gatherings can increase spread of COVID-19





# Implementation of a Pooled Surveillance Testing Program for Asymptomatic SARS-CoV-2 Infections on a College Campus – Duke University, Durham, North Carolina, August 2-October 11, 2020

## Summary:

- Duke University's COVID-19 prevention strategy included PCR testing using pooled samples
- 68,913 specimens from 10,265 students were tested
- Asymptomatic screening
- 84 positive results; approximately half were asymptomatic
- Undergraduate students tested 1-2 times/week
- Grad students tested once/week
- 8,012 faculty and staff also tested (data not included in report)

TABLE 2. Number of tests\* positive for SARS-CoV-2 among students, by test category — Duke University, Durham, North Carolina, August 2–October 11, 2020



Test category	No. of tests performed	No. of positive tests	No. (%) of persons <sup>†</sup> asymptomatic at testing
Entry testing	8,873	17	9 (53)
Pooled testing <sup>§</sup>	59,476	29	29 (100)
Contact tracing <sup>¶</sup>	379	23	5 (22)
Symptom monitoring <sup>¶</sup>	185	15	0 (0)
Total	68,913	84	43 (51)

# References

## Guidance documents

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-covid-19-test-self-testing-home> (FDA EUA for testing at home)

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-combination-treatment-covid-19> (combo treatment for COVID)

[https://covid.cdc.gov/covid-data-tracker/#cases\\_casesper100klast7days](https://covid.cdc.gov/covid-data-tracker/#cases_casesper100klast7days) (COVID tracker)

<https://www.cdc.gov/coronavirus/2019-ncov/communication/toolkits/clinicians.html> (Toolkit for HCP)

<https://www.cdc.gov/coronavirus/2019-ncov/php/open-america/contact-tracing-resources.html> (Contact tracing resources)

<https://www.cdc.gov/coronavirus/2019-ncov/travelers/testing-air-travel.html> (Testing and international Air Travel)

<https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/holidays.html> (Holiday celebrations)

## MMWRs

*COVID-19 Stats: COVID-19 Incidence, by Urban-Rural Classification — United States, January 22–October 31, 2020.* MMWR Morb Mortal Wkly Rep 2020;69:1753. DOI: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6946a6.htm?s\\_cid=mm6946a6\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6946a6.htm?s_cid=mm6946a6_w)

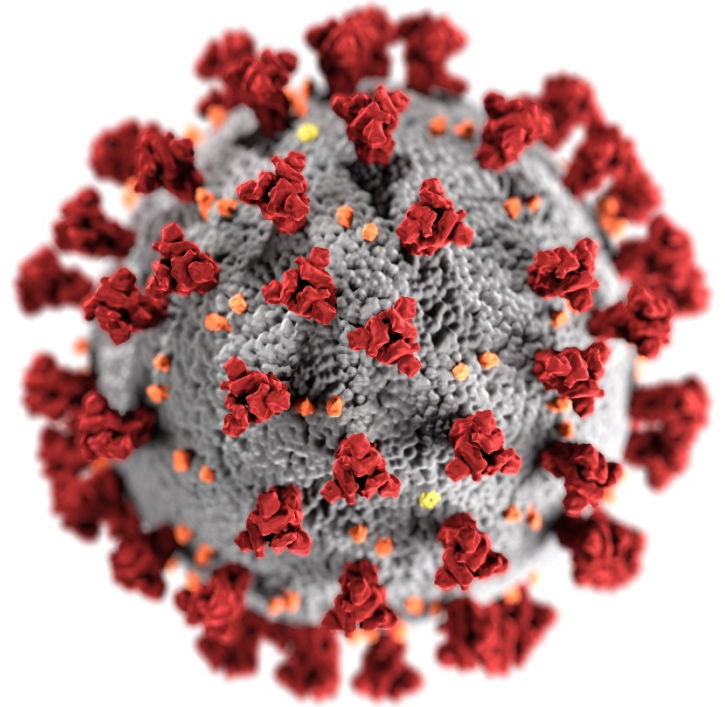
Van Dyke ME, Rogers TM, Pevzner E, et al. Trends in County-Level COVID-19 Incidence in Counties With and Without a Mask Mandate — Kansas, June 1–August 23, 2020. MMWR Morb Mortal Wkly Rep. ePub: 20 November 2020.

DOI: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e2.htm?s\\_cid=mm6947e2\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e2.htm?s_cid=mm6947e2_w)

Firestone MJ, Wienkes H, Garfin J, et al. COVID-19 Outbreak Associated with a 10-Day Motorcycle Rally in a Neighboring State — Minnesota, August–September 2020. MMWR Morb Mortal Wkly Rep. ePub: 20 November 2020.

DOI: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e1.htm?s\\_cid=mm6947e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6947e1.htm?s_cid=mm6947e1_w)

Denny TN, Andrews L, Bonsignori M, et al. Implementation of a Pooled Surveillance Testing Program for Asymptomatic SARS-CoV-2 Infections on a College Campus — Duke University, Durham, North Carolina, August 2–October 11, 2020. MMWR Morb Mortal Wkly Rep 2020;69:1743–1747. DOI: [https://www.cdc.gov/mmwr/volumes/69/wr/mm6946e1.htm?s\\_cid=mm6946e1\\_w](https://www.cdc.gov/mmwr/volumes/69/wr/mm6946e1.htm?s_cid=mm6946e1_w)



For more information, contact CDC  
1-800-CDC-INFO (232-4636)  
TTY: 1-888-232-6348 [www.cdc.gov](http://www.cdc.gov)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

