

# New and updated COVID-19 guidance of note

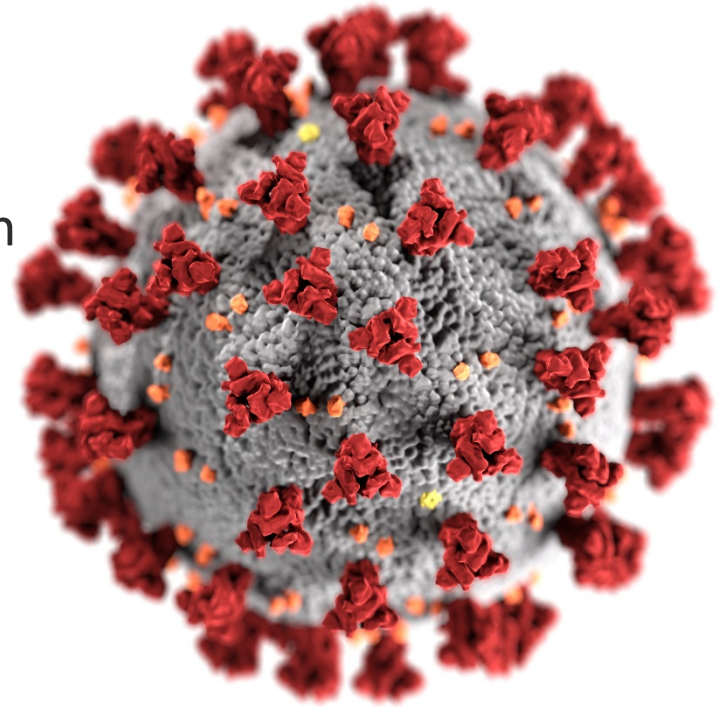
**Eileen Dunne, PhD**

**Epidemic Intelligence Service Officer**

assigned to Idaho Division of Public Health

Indian Country COVID-19 teleECHO

November 16, 2020



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



# Potential for False Positive Results with Antigen Tests for Rapid Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers

Issued 11/03/2020

## Alert to clinical laboratories and health care providers

- False positive results can occur with antigen tests
- Antigen tests indicated for use in individuals suspected of COVID-19 within a certain number of days of symptom onset (e.g. 7, depending on test)
- Typically, antigen tests are less sensitive than PCR
- Reports of false positive results with antigen tests used in nursing homes and other settings
- Some false positive results expected to occur even when very accurate tests are used

## Recommendations

- Be aware of Emergency Use Authorization conditions
- Follow instructions for storage, handling, and reading within appropriate time frame
- Reduce cross-contamination by cleaning workspaces and changing gloves
- Consider confirmatory RT-PCR test in low incidence settings
  - As disease prevalence ↓, % false positives ↑
- **Health care providers should always consider diagnostic test results in the context of all available clinical, diagnostic and epidemiological information**

# Coronavirus (COVID-19) Update: FDA Authorizes Monoclonal Antibody for Treatment of COVID-19

- Bamlanivimab – neutralizing monoclonal IgG1 antibody that binds to SARS-CoV-2 spike protein (single dose i.v.)
- Emergency Use Authorization granted based on interim clinical trial data showing a clinical benefit in COVID-19 patients with mild to moderate illness



Authorized for COVID-19 patients who:

- >12 years of age and weigh at least 40kg
- Have mild to moderate illness
- Are at high risk of progressing to severe disease (e.g. >65 years of age with certain underlying conditions)

**Not** authorized for COVID-19 patients who:

- Are hospitalized
- Require oxygen therapy due to COVID-19

# Updates from CDC

## Guidance:

- COVID-19 reinfection
- FAQ: Funerals and burial services
- Vaccines

## MMWR:

- Birth and infant outcomes
- COVID-19 in pregnancy
- COVID-19 outbreak — Hopi Tribe
- COVID-19 surveillance program — Hopi Tribe
- Readmission of hospitalized patients



# Common Investigation Protocol for Investigating Suspected SARS-CoV-2 Reinfection

- Reinfection can occur but data are limited
- SARS-CoV-2 reinfection can be differentiated from persistent viral carriage via laboratory evidence, symptomology, and epi links
- CDC protocol for confirming reinfection requires sequencing of paired respiratory specimens from the initial COVID-19 illness and the suspected reinfection
- Prioritize persons with SARS-CoV-2 RNA detected  $\geq 90$  days since first SARS-CoV-2 infection

# Frequently Asked Questions: Funeral and Burial Services for American Indians and Alaska Natives

Updated Nov. 2, 2020

Languages ▾ [Print](#)



At the request of tribal leaders, federal partners developed this Coronavirus Disease 2019 (COVID-19) fact sheet to help guide tribes with funeral and burial health and safety. This fact sheet also helps tribes plan for an increase in deaths within a community. Tribes and families practice unique traditions and refer to death in varying ways as they honor those who have passed on. We share this public health guidance with sincere respect for those traditions.

## COVID-19 and Funerals

How can communities plan for an increase in the number of deaths? +

Am I at risk if I go to a family gathering, traditional event, ceremony, or funeral for someone who died of COVID-19? +

What are the most important things to remember about COVID-19 and AI/AN funeral services or other gatherings? +



- Your Health
- Community, Work & School
- Healthcare Workers & Labs
- Health Depts
- Cases & Data
- More

Your Health

Things You Need to Know

Symptoms

Testing

**Vaccines**

8 Things to Know

About COVID-19 Vaccines

How CDC is Making Vaccine Recommendations

Ensuring the Safety of Vaccines

Frequently Asked Questions about Vaccination

YOUR HEALTH

# Vaccines

Updated Nov. 9, 2020 [Languages](#)



## Safety Is a Top Priority

The U.S. vaccine safety system ensures that all vaccines are as safe as possible. [Learn more.](#)

## Birth and Infant Outcomes Following Laboratory-Confirmed SARS-CoV-2 Infection in Pregnancy — SET-NET, 16 Jurisdictions, March 29–October 14, 2020

Weekly / November 6, 2020 / 69(44):1635–1640

- 3,912 live births to women with COVID-19
  - 12.9% preterm (< 37 weeks)
  - Higher than national estimate of 10.2%
- 610 infants tested for SARS-CoV-2
  - 2.6% positive, most born to women with COVID-19 infection diagnosed within a week of delivery
- Providers should counsel pregnant women on measures to prevent COVID-19



## Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020

Weekly / November 6, 2020 / 69(44);1641–1647

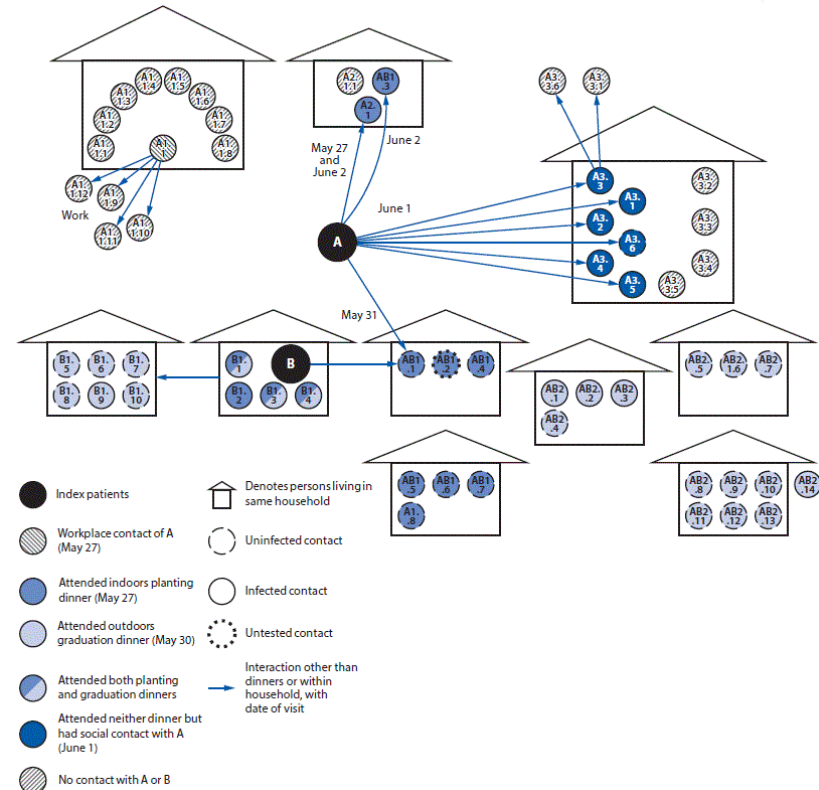
- Analysis of ~400,000 women aged 15–44y with symptomatic COVID-19
  - 5.7% pregnant
- Severe outcomes including ICU admission and death more likely in pregnant women vs nonpregnant women
- COVID-19 prevention measures should be emphasized for pregnant women and families

Outcome	% in pregnant women (n = 23,434)	% in nonpregnant women (n = 386,028)	Adjusted Risk Ratio (95%CI)
ICU admission	10.5	3.9	3.0 (2.6–3.4)
Invasive ventilation	2.9	1.1	2.9 (2.2–3.8)
ECMO	0.7	0.3	2.4 (1.5–4.0)
Death	1.5	1.2	1.7 (1.2–2.4)

# A SARS-CoV-2 Outbreak Illustrating the Challenges in Limiting the Spread of the Virus — Hopi Tribe, May–June 2020

Weekly / November 6, 2020 / 69(44);1654–1659

- Two elder siblings (patient A and B) developed symptoms 1 day apart
- 34 primary contacts (household, work, extended family, graduation party, planting dinner, visits)
- Among 58 primary and secondary contacts, 47% developed COVID-19
- Frequent interactions among extended family members and social gatherings contributed to transmission
- Consistent mask use, isolating when sick, frequent hand washing, and physical distancing can help prevent the spread of COVID-19



## *Notes from the Field*: Development of an Enhanced Community-Focused COVID-19 Surveillance Program — Hopi Tribe, June–July 2020

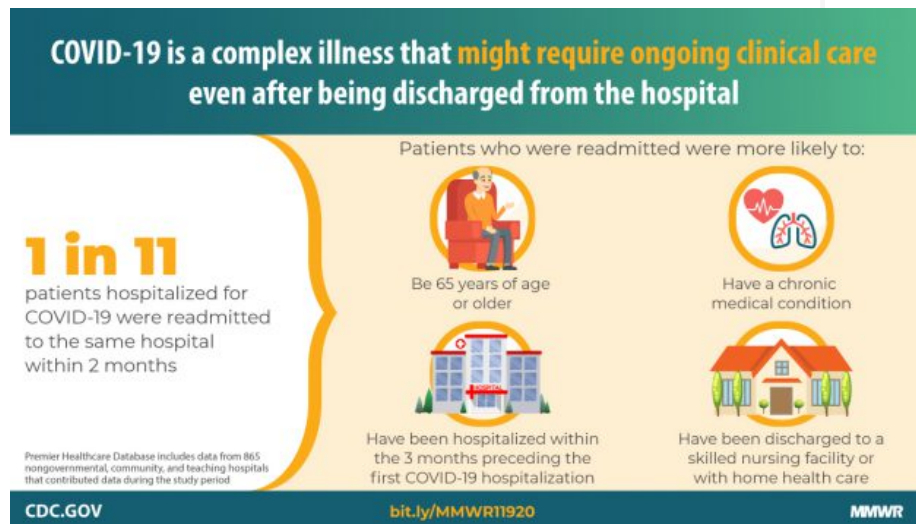
Weekly / November 6, 2020 / 69(44);1660–1661

- House-to-house community surveillance of COVID-19 piloted in two Hopi villages (populations 100 and 175)
- Community health workers visited every household, screened people for COVID-19-like signs, symptoms, and exposures, recommended testing where indicated, and provided education and public health guidance about COVID-19
  - Safety precautions in place (PPE, outdoor interviews, distancing)
- Good feasibility: 10 staff members screened 141 persons in < 10 hours
- Good community acceptance: 5% household refusal rate
- Plans to continue and expand the program and include mask distribution

## Characteristics of Hospitalized COVID-19 Patients Discharged and Experiencing Same-Hospital Readmission — United States, March–August 2020

Early Release / November 9, 2020 / 69

- Study on 126,137 patients with a COVID-19 admission during Mar–July 2020
  - 15% died during index hospitalization
  - Among survivors, 9% were readmitted within 2 months of discharge
- Ensuring adequate follow-up care of COVID-19 patients is critical
- Public health messaging and strategies to prevent COVID-19 among older people and those with underlying conditions remain important



# References

## Guidance documents

<https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory> (FDA alert about false positive results from antigen tests)

<https://www.fda.gov/media/143602/download> (FDA EUA for bamlanivimab)

<https://www.cdc.gov/coronavirus/2019-ncov/php/reinfection.html> (CDC protocol for investigating suspected SARS-CoV-2 reinfection)

<https://www.cdc.gov/coronavirus/2019-ncov/community/tribal/faq-burial-practice.html> (CDC FAQ: Funerals for AI/AN)

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html> (CDC COVID-19 vaccines webpage)

## MMWRs

Woodworth KR, et al. Birth and Infant Outcomes Following Laboratory-Confirmed SARS-CoV-2 Infection in Pregnancy — SET-NET, 16 Jurisdictions, March 29–October 14, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1635–1640.

DOI: <http://dx.doi.org/10.15585/mmwr.mm6944e2>

Zambrano LD, et al. Update: Characteristics of Symptomatic Women of Reproductive Age with Laboratory-Confirmed SARS-CoV-2 Infection by Pregnancy Status — United States, January 22–October 3, 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1641–1647.

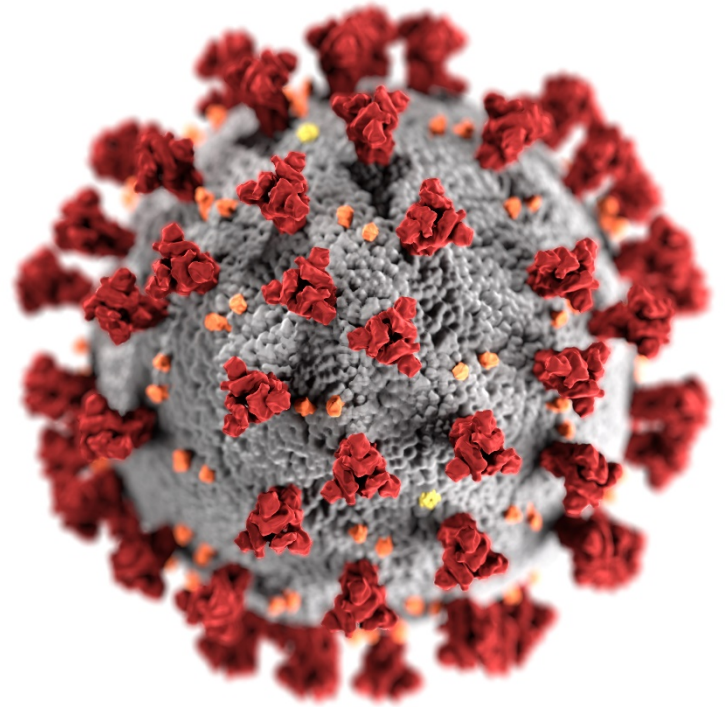
DOI: <http://dx.doi.org/10.15585/mmwr.mm6944e3>

Hirschman J, et al. A SARS-CoV-2 Outbreak Illustrating the Challenges in Limiting the Spread of the Virus — Hopi Tribe, May–June 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1654–1659. DOI: <http://dx.doi.org/10.15585/mmwr.mm6944a5>

Jenkins R, et al. *Notes from the Field*: Development of an Enhanced Community-Focused COVID-19 Surveillance Program — Hopi Tribe, June–July 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1660–1661. DOI: <http://dx.doi.org/10.15585/mmwr.mm6944a6>

Lavery AM, Preston LE, Ko JY, et al. Characteristics of Hospitalized COVID-19 Patients Discharged and Experiencing Same-Hospital Readmission — United States, March–August 2020. *MMWR Morb Mortal Wkly Rep*. ePub: 9 November 2020.

DOI: <http://dx.doi.org/10.15585/mmwr.mm6945e2>



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.

