## New and updated COVID-19 public health information

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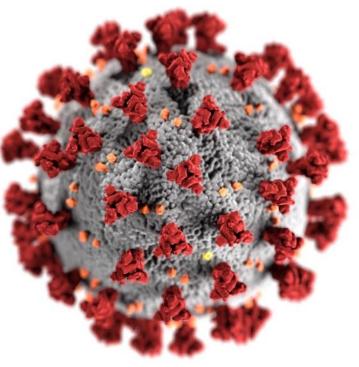
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Assigned to Idaho Division of Public Health

Indian Country COVID-19 teleECHO

March 22, 2021





cdc.gov/coronavirus

# Updates from FDA

- FDA issues Emergency Use Authorization (EUA) for Adaptive Biotechnologies T-Detect COVID Test (3/5/2021)
- For identifying individuals with an adaptive T cell immune response to SARS-CoV-2, indicating recent or prior infection
- PCR + sequencing to identify T-cell receptor beta gene sequences specific for SARS-CoV2
  - Authorized for use in patients 15 days or more post symptom onset
  - EUA: <u>https://www.fda.gov/media/146481/download</u>
- Clinical performance evaluated using blood samples from 175 COVID-19 patients (≥ 15 days from onset) and 99 negative controls
  - Sensitivity 96.0%
  - Specificity 99%



# Updates from FDA

- Why you should not use ivermectin to treat or prevent COVID-19 (3/5/2021)
- FDA has not approved ivermectin for use in treating or preventing COVID-19 in humans
- The FDA has received multiple reports of patients who required medical support and been hospitalized after self-medicating with ivermectin intended for horses
- Taking large doses of this drug is dangerous and can cause serious harm. Ivermectin preparations for animals are very different from those approved for humans.
- https://www.fda.gov/consumers/consumer-updates/why-you-should-not-useivermectin-treat-or-prevent-covid-19



www.fda.gov

# Updates from CMS

- CLIA SARS-CoV-2 variant testing frequently asked questions (3/10/2021)
- Does a facility that performs surveillance testing to identify SARS- CoV-2 genetic variants need a CLIA certificate?
  - Sequencing to identify SARS-CoV-2 variants can be performed in a facility that is <u>NOT</u> CLIA certified, provided that patient-specific results are <u>not</u> reported to (1) the individual who was tested or (2) their health care provider
    - Results can be reported to Public Health Departments for public health purposes
  - CLIA-certified laboratories can report patient-specific results to authorized persons (e.g. individual who was tested, their health care provider, or a Public Health Department) for SARS-CoV-2 genetic variant testing
    - If a CLIA certified laboratory decides to report patient-specific results to an individual or their healthcare provider, the laboratory must establish performance specifications for their assay
- CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 genetic variant testing
- https://www.cms.gov/files/document/clia-sars-cov-2-variant.pdf

# Updates from CMS

- Biden-Harris administration increases Medicare payment for life-saving COVID-19 vaccine (3/15/2021)
- Effective for COVID-19 vaccines administered on or after 3/15/2021, the average payment rate for physicians, hospitals, pharmacies and other immunizers will be \$40 to administer each dose of a COVID-19 vaccine
  - Increase from approximately \$28 to \$40 for the administration of single-dose vaccines, and an increase from approximately \$45 to \$80 for vaccines requiring two doses
- The exact payment rate will depend on the type of entity that furnishes the service and will be geographically adjusted based on where the service is furnished
- https://www.cms.gov/newsroom/press-releases/biden-harris-administration-increases-medicare-payment-lifesaving-covid-19-vaccine

# **Updates from HHS**

- Biden administration to expand COVID-19 vaccine program to 950 community health centers (3/11/2021)
- An additional 700 Health Resources and Services Administration (HRSA)-supported health centers will be invited to join the Health Center COVID-19 Vaccine Program
- 700 health centers invited to participate in this program include those that:
  - Serve high proportions of low income and minority patients
  - Provide services to rural/frontier populations
  - Operate Tribal/Urban Indian Health Programs
  - Utilize mobile vans to deliver services
- List of participating and invited health centers: <u>https://www.hrsa.gov/coronavirus/health-center-program/participants</u>

# Updates from CDC

**Guidance and Resources** 

- Public health recommendations for fully vaccinated people
- Updated healthcare recommendations in response to COVID-19 vaccination MMWR
- Racial and ethnic disparities in COVID-19 incidence
- COVID-19 vaccine second dose completion
- Effectiveness of COVID-19 vaccine in skilled nursing facility outbreaks

# Interim Public Health Recommendations for Fully Vaccinated People (3/8/2021)

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinatedguidance.html

Fully vaccinated people can:

- Gather indoors with other fully vaccinated people without wearing masks or physically distancing
- Gather indoors with unvaccinated people from one other household without masks, unless any of those people or anyone they live with has an increased risk for severe illness from COVID-19
- Refrain from quarantine and testing following a known exposure if asymptomatic

Fully vaccinated people should continue to:

- Take precautions in public (masks and distancing) and when visiting with people at increased risk for severe COVID-19
- Avoid medium or large gatherings





# Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination - updated 3/11/2021

https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-after-vaccination.html

- Fully vaccinated health care personnel (HCP) who are asymptomatic do not need to be restricted from work for 14 days following a COVID-19 exposure
  - Work restrictions should still be considered for HCP who have underlying immunocompromising conditions, which might impact vaccination
- HCP who have traveled should continue to follow CDC travel recommendations and requirements, including restriction from work
- Fully vaccinated inpatients and residents in healthcare settings should continue to quarantine following close contact with someone with SARS-CoV-2 infection
  - Although not preferred, healthcare facilities could consider waiving quarantine for fully vaccinated patients and residents following close contact as a strategy to address critical issues (e.g., lack of space, staff, or PPE to safely care for exposed patients or residents) when other options are unsuccessful or unavailable

#### CDC

Racial and Ethnic Disparities in COVID-19 Incidence by Age, Sex, and Period Among Persons Aged <25 Years — 16 U.S. Jurisdictions, January 1– December 31, 2020

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- Data from 16 jurisdictions with ≥ 70% race and ethnicity data complete
- Incidence higher in females and lowest in younger children
- Largest persistent disparities in incidence involved American Indian or Alaska Native and Hispanic persons
- Ensuring equitable and timely access to preventive measures, including testing, safe work and education settings, and vaccination is important to address racial/ethnic disparities

Race/ethnicity (n)	No. of cases	Cases per 100,000 pop. (95% Cl)	Rate Ratio (95% CI)
AI/AN	536	163 (150–177)	4.6 (4.2–5.1)
Asian	498	54 (49–59)	1.5 (1.4–1.7)
Black	2,461	87 (83–90)	2.5 (2.3–2.6)
NH/PI	73	88 (70–111)	2.5 (2.0–3.1)
White	4,947	35 (34–36)	Ref
Hispanic/Latino	6,129	137 (133–140)	3.9 (3.7–4.0)
Multiple, non- Hispanic	424	38 (35–42)	1.1 (1.0–1.2)

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COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020-February 14, 2021 Race/ethnicity Completed No 2<sup>nd</sup> dose Overdu

Early Release / March 15, 2021 / 70

- Data from 12,496,258 persons who received a first COVID-19 vaccine dose with sufficient time to receive the 2<sup>nd</sup> dose
- 88.0% completed the series; 8.6% awaiting 2<sup>nd</sup> dose; 3.4% overdue for the 2<sup>nd</sup> dose
- Lowest series completion and highest proportion overdue for 2<sup>nd</sup> dose was among AI/AN persons
- Providers can help people get the 2<sup>nd</sup> dose on time
  - Schedule 2<sup>nd</sup> dose appointments at 1<sup>st</sup> dose visits
  - Send reminders

Race/ethnicity (n)* (n=6,764,604)	Completed series (%)	No 2 <sup>nd</sup> dose but within window	Overdue 2 <sup>nd</sup> dose
AI/AN (145,449)	83.7	11.2	5.1
Asian (365,379)	90.2	7.0	2.8
Black (366,379)	88.8	8.6	2.6
NH/PI (17,755)	90.3	6.8	2.9
White (4,138,164)	90.2	7.4	2.3
Hispanic/Latino (718,384)	87.0	9.5	3.5
Multiple/other, non-Hispanic (1,013, 031)	86.1	10.7	3.2

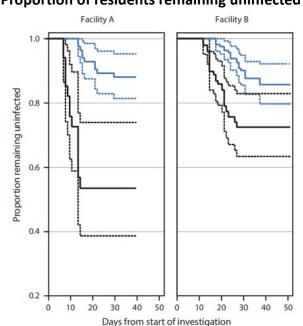
\*reported from 54.1% of persons

CDC

Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021 Proportion of residents remaining uninfected

Early Release / March 15, 2021 / 70

- Investigation of two skilled nursing facilities with COVID-19 outbreaks after each facility's first vaccination clinic
- Vaccine effectiveness (VE) estimated for partial vaccination (>day 14 after 1<sup>st</sup> dose through day 7 after 2<sup>nd</sup> dose)
- VE in preventing SARS-CoV-2 infection was 63% (33%–79%)
- While partial vaccination with Pfizer-BioNTech COVID-19 vaccine provided protection, high coverage with the complete 2-dose series is recommended to optimize vaccine impact among this population.



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Unvaccinated — Partially vaccinated ::: 95% confidence intervals

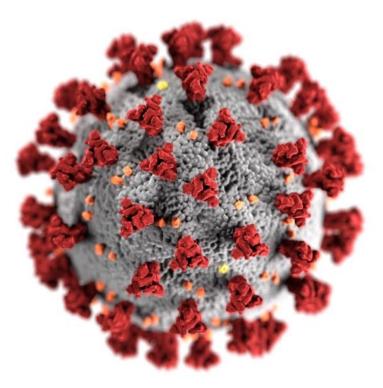
## References

## **Updates (additional references)**

- https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-adaptivebiotechnologies-t-detect-covid-test (FDA Authorizes Adaptive Biotechnologies T-Detect COVID Test)
- <u>https://www.hhs.gov/about/news/2021/03/11/biden-administration-expand-covid-19-vaccine-program-950-community-health-centers.html</u> (Biden Administration to Expand COVID-19 Vaccine Program to 950 Community Health Centers)

#### MMWRs

- Van Dyke ME, et al. Racial and Ethnic Disparities in COVID-19 Incidence by Age, Sex, and Period Among Persons Aged
  <25 Years 16 U.S. Jurisdictions, January 1–December 31, 2020. MMWR Morb Mortal Wkly Rep. ePub: 10 March</li>
  2021. DOI: <a href="http://dx.doi.org/10.15585/mmwr.mm7011e1">http://dx.doi.org/10.15585/mmwr.mm7011e1</a>
- Kriss JL, Reynolds LE, Wang A, et al. COVID-19 Vaccine Second-Dose Completion and Interval Between First and Second Doses Among Vaccinated Persons — United States, December 14, 2020–February 14, 2021. MMWR Morb Mortal Wkly Rep. ePub: 15 March 2021. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7011e2</u>
- Britton A, et al. Effectiveness of the Pfizer-BioNTech COVID-19 Vaccine Among Residents of Two Skilled Nursing Facilities Experiencing COVID-19 Outbreaks — Connecticut, December 2020–February 2021. MMWR Morb Mortal Wkly Rep. ePub: 15 March 2021. DOI: <u>http://dx.doi.org/10.15585/mmwr.mm7011e3</u>



For more information, contact CDC 1-800-CDC-INFO (232-4636) TTY: 1-888-232-6348 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.

