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Wednesday, June 2, 2021

FDA warns against using two COVID-19 antigen, antibody tests

The Food and Drug Administration is warning health care providers and the public not to use Lepu Medical Technology's SARS-CoV-2 Antigen Rapid Test Kit and the Leccurate SARS-CoV-2 Antibody Rapid Test Kit (Colloidal Gold Immunochromatography). The FDA has not approved the two tests for use in the US, but the agency is aware these tests were distributed to some pharmacies to be sold to consumers for at-home testing. Health care providers should consider retesting patients suspected to have had recent or prior COVID-19 infection and were tested with either of the two tests.

Reporting certain COVID-19 hospital data optional starting June 10

The Department of Health and Human Services has announced effective Thursday, June 10, hospitals will no longer need to report data for influenza and inventory and usage for bamlanivimab administered alone as part of their daily COVID-19 data reports. Reporting data for those fields will be optional after this date. HHS will update its web application early next week.

The Food and Drug Administration last month revoked its emergency-use authorization for bamlanivimab when administered alone, which prompted HHS to make those fields optional. The influenza data fields may become mandatory again after Friday, Oct. 1, when acute respiratory illnesses are likely to increase.

CDC recommends clinicians report certain heart conditions after COVID-19 vaccination

The Centers for Disease Control and Prevention has recommended clinicians report cases of myocarditis and pericarditis after COVID-19 vaccination to the Vaccine Adverse Event Reporting System. Since April, an increase in cases has been reported after vaccination with the Pfizer or Moderna mRNA vaccines. These conditions have particularly affected adolescents and young adults. The CDC continues to recommend COVID-19 vaccination for everyone 12 and older given the risks associated with COVID-19.

Peer review of Pfizer COVID-19 vaccine data confirms effectiveness in adolescents

A new study published in the New England Journal of Medicine confirms Pfizer's claims of high levels of effectiveness among adolescents for its COVID-19 vaccine. The study, which looked at 2,260 adolescents between 12 and 15, observed 100% efficacy in the group, with a favorable safety and side effect profile. The authors concluded the Pfizer vaccine produces a greater immune

response for adolescents than it does in young adults.

CMS issues information bulletin about COVID-19 vaccines for adolescents

CMS has issued a new informational bulletin about COVID-19 vaccines for adolescents 12 and older. The bulletin addresses access, eligibility, patient outreach and education. The bulletin includes a fact sheet to help states identify Medicaid, Children's Health Insurance Program and Basic Health Program requirements for COVID-19 vaccine administration coverage, cost-sharing and reimbursement.

FDA authorizes new monoclonal antibody therapy

The Food and Drug Administration has authorized for emergency use a new monoclonal antibody therapy, sotrovimab, for outpatients at risk for progressing to severe COVID-19 disease. The authorization of this monoclonal antibody treatment provides another option to help keep high-risk patients with COVID-19 out of the hospital and is an addition to the arsenal for use against future variants.

FDA recommends transitioning to only NIOSH-approved respirators

The Food and Drug Administration has recommended health care providers transition away from using disposable respirators not approved by the National Institute for Occupational Safety and Health, including imported respirators such as KN95s, based on the increased domestic supply of new NIOSH-approved respirators. The agency also had previously recommended providers transition away from using decontamination or bioburden reduction to extend the use of N95s and other similar disposable respirators because of increased domestic supply of NIOSH-approved respirators.

Moderna seeks full FDA approval

Moderna has asked the FDA for full approval of its coronavirus vaccine in people 18 and older. Its vaccine is approved under an emergency-use authorization. Full approval would allow the company to market the vaccine directly to consumers.

FDA updates information about thawing, packaging Pfizer vaccine

The FDA recently updated its Pfizer COVID-19 emergency-use authorization for storage, handling and packaging. The vaccine now can be thawed and stored in undiluted vials in the refrigerator (2ºC to 8ºC [35ºF to 46ºF]) for up to one month. This is a change from the previous 120 hours. And besides packages of 195 six-dose vials (1,170 doses), the Pfizer COVID-19 vaccine also will be available in packages of 75 six-dose vials (450 doses).

NIH declares blood donations safe from COVID-19

New research by the National Institutes of Health has confirmed the safety of blood donation and transfusions from COVID-19. NIH concluded the likelihood of infection transmission by transfusion is 0.001%. Based on these findings, blood donor screening guidelines that do not require blood testing for the SARS-CoV-2 virus are safe and pose no threat to the US blood supply. This includes guidelines used by the Food and Drug Administration. Guidelines require donor screenings of physical symptoms of COVID-19 that occurred within 14 days of donation, and blood of donors with recent infections or who develop COVID-19 infections cannot be used.

Reminders about funding opportunities

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- **COVID Tech Connect Smart Device Donation Program:** This smart device donation program for hospitals, care facilities and hospice centers is designed to allow critically ill COVID-19 patients to connect with their loved ones. Priority is given to those in greatest need, including facilities in rural areas. **Applications ongoing.**
- **Local Community-based Workforce to Increase COVID-19 Vaccine Access:** Grants are available to address COVID-19-related health disparities and advance health equity by mobilizing community outreach workers to educate and help people in medically underserved areas get the COVID-19 vaccination. **Application deadline: Wednesday, June 9.**
- **Telehealth Technology-enabled Learning Program:** This **program** will support up to nine public or private, non-profit or for-profit, entities to connect specialists at academic medical centers with primary care providers in rural areas to improve patient care in their communities. Recipients are encouraged to implement quality improvement activities that measure value by outcomes. **Application deadline: Friday, June 25.**
- **The Rural Health Clinic Vaccine Confidence Program:** The Health Resources and Services Administration's Federal Office of Rural Health Policy will award all eligible rural health clinics that apply to expand the response to COVID-19 in rural communities. Clinics may use this funding to increase vaccine confidence, improve rural health care, and reinforce key messages about the prevention and treatment of COVID-19 and other infectious diseases. Interested clinics should review the Notice of Funding Opportunity and start the process to register to apply for an HRSA grant. For questions about the program, email RHCVaxConfidence@hrsa.gov. **Application deadline: Wednesday, June 23.**

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