U.S. FOOD & DRUG ADMINISTRATION

Coronavirus Q&As for Consumers

The FDA is working to address the coronavirus disease (COVID-19) outbreak and keep you and your family informed on the latest developments. Here are answers to some frequently asked questions from consumers about possible treatments and testing:

Q. Is remdesivir approved by the FDA to treat COVID-19?

A. No. While there are no FDA-approved therapeutics or drugs to treat, cure or prevent COVID-19, there are several FDA-approved treatments that may help ease the symptoms from a supportive care perspective. Remdesivir is an investigational antiviral drug. It is not currently FDA-approved to treat or prevent any diseases, including COVID-19.

Q. Are there data showing remdesivir might benefit patients with COVID-19?

A. In vitro (laboratory) testing of remdesivir demonstrated it is active against SARS-CoV-2 (the virus causing COVID-19). Preliminary results from a placebo-controlled clinical trial of remdesivir by the National Institute for Allergy and Infectious Diseases suggested that patients taking remdesivir experienced faster time to recovery as compared to patients taking a placebo. Preliminary results from a Phase 3 trial evaluating 5-day and 10-day dosing durations of remdesivir in hospitalized patients with severe COVID-19 disease, but most of whom were not receiving mechanical ventilation or extracorporeal membrane oxygenation (ECMO) at baseline, reported that patients receiving a 10-day treatment course achieved similar improvement as those taking a 5-day treatment course. The safety and efficacy of remdesivir for the treatment of COVID-19 are being evaluated in multiple ongoing clinical trials.

Because remdesivir may possibly help very sick patients, the FDA is allowing this drug to be provided to hospitalized patients with severe COVID-19 under an Emergency Use Authorization (EUA) issued May 1, 2020. Under the EUA, health care providers and patients are provided with information about the risks of remdesivir. However, final data from clinical trials included in an FDA application are necessary for us to determine whether the drug is safe and effective in treating or preventing COVID-19.

Q: What is the difference between the types of tests available for SARS-CoV-2?

A: There are currently two types of tests available for SARS-CoV-2, the virus that causes COVID-19. Molecular tests detect the virus and can be used to directly diagnose COVID-19, and antibody tests detect the body's immune response to the infection caused by the virus but cannot be used to definitively diagnose or exclude COVID-19.

Molecular Tests: "Nucleic acid amplification tests," or "NAAT" tests are molecular tests that detect the virus's genetic material. The FDA has issued Emergency Use Authorizations (EUA) for dozens of molecular tests. Based on current data, we believe these EUA-authorized tests are highly accurate tests.
Antibody Tests: Antibody (or serology) tests detect antibodies in the blood when the body is fighting or has fought an infection. The test does not detect the actual virus; rather, it detects the body's immune response to the virus. In the early days of an infection, antibodies may not be detected, limiting the effectiveness of an antibody test. This type of test may also be falsely positive if antibodies to a coronavirus other than the pandemic novel strain are present. Because of this potential for false negative and false positive results, an antibody test should not be used alone to diagnose COVID-19. The FDA has also issued EUAs for serology tests to detect SARS-CoV-2 antibodies.

Q: If antibody tests are not used for diagnosis or exclusion of SARS-CoV-2 infection, what is their purpose?

A: Antibody tests cannot be used alone to rule out COVID-19. However, they can serve an important role. Using antibody tests on many patients may help the medical community better understand how the immune response develops in patients over time and how many people may have been infected. In the future, it is also possible that they may also be used to help determine, together with other clinical data, that some individuals are no longer susceptible to infection. In addition, these test results can aid in determining who may be eligible to donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

To learn more about these and other coronavirus topics, visit: Frequently Asked Questions

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