

**Mission:**

To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.



**Ron DeSantis**  
Governor

**Scott A. Rivkees, MD**  
State Surgeon General

**Vision:** To be the **Healthiest State** in the Nation

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## **Important Updates Regarding Electronic Registering and Reporting COVID-19 Results, FDA Alert on Potential False Positive Results for Antigen Tests, and Authorizations for Bamlanivimab for the Treatment of Coronavirus Disease 2019 (COVID-19)**

November 17, 2020

### **Emergency Rule 64DER20-34 for Electronic Reporting COVID-19 Results**

Health care practitioners, facilities and laboratories are subject to mandatory electronic reporting to the Florida Department of Health under section 381.0031, Florida Statutes, and Chapter 64D-3, Florida Administrative Code (FAC). All health care practitioners, laboratories and facilities, including long-term care facilities, must report both negative and positive COVID-19 test results, including point-of-care rapid test results within 24 hours. Effective November 12, 2020, [Emergency Rule 64DER20-34](#) requires special electronic reporting requirements for COVID-19. There are three options for health care practitioners, facilities and laboratories to report test results electronically:

- (1) By electronic laboratory reporting through the generation of an electronic comma-separated value (CSV) or Health Level 7 (HL7) formatted message;
- (2) By reporting through the National Healthcare Safety Network COVID-19 module for CMS-certified long-term care facilities; or
- (3) By reporting through a web portal – called the COVID-19 Reporting Portal – which is for entities that are unable to generate an electronic CSV or HL7 formatted message (e.g., long-term care facilities, assisted living facilities, nursing homes, etc.).

Registration in one of these methods, must be completed within 7 days of the effective date of the Emergency Rule 64DER20-34 (11/12/2020), or within 7 days of obtaining the ability to conduct testing. Until laboratory reporting has been established, test results must be submitted by facsimile to the Florida Department of Health's Bureau of Epidemiology confidential fax line, 850-414-6894, or to the patient's local county health department. For a list of county health department contact information, please visit [www.FLhealth.gov/chdepcontact](http://www.FLhealth.gov/chdepcontact).

### **Suspected or Confirmed Outbreak Reporting**

Regardless of the method by which entities choose to electronically report COVID-19 test results to the Florida Department of Health, suspected or confirmed outbreaks of COVID-19 in long-term care facilities, or similar group settings such as assisted living facilities, must be reported immediately to the local county health department.

### **Instructional PowerPoint on Registering for the COVID-19 Reporting Portal**

The Florida Department of Health has created an [instructional PowerPoint](#) about how health care providers and facilities that are providing COVID-19 testing, including point-of-care rapid tests, can report their test results electronically to the Department using the COVID-19 Reporting Portal. The purpose of this presentation is to provide guidance to facilities that are conducting in-house COVID-19 testing on how to report results electronically to the Florida Department of Health. To establish electronic reporting through a web portal, please begin the enrollment process by emailing the COVID-19 Reporting Portal team at [COVID19PortalEnrollment@flhealth.gov](mailto:COVID19PortalEnrollment@flhealth.gov).

## Alert Regarding Potential False Positive Results with Antigen Tests

The U.S. Food and Drug Administration (FDA) is alerting clinical laboratory staff and health care providers that false positive results can occur with antigen tests, including when users do not follow the instructions for use of antigen tests for the rapid detection of COVID-19. The FDA has provided recommendations for clinical laboratories and health care providers which includes considerations for performing confirmatory RT-PCR tests within 48 hours. For more information on the alert and recommendations, please go to: [https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory?utm\\_medium=email&utm\\_source=govdelivery](https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-antigen-tests-rapid-detection-sars-cov-2-letter-clinical-laboratory?utm_medium=email&utm_source=govdelivery).

Additionally, while antigen tests produce more timely results than laboratory-based PCR tests, they also have lower sensitivity and specificity than RT-PCR assays. When comparing the results of antigen tests to RT-PCR tests, it is important to consider the pre-test probability of infection and the likelihood that an antigen test result may be falsely positive or falsely negative. When the probability of infection is high (e.g., symptomatic, known exposure, part of an outbreak, high community COVID-19 activity, or county positivity rate is greater than five percent), guidance is as follows:

- If an antigen test result is positive, a confirmatory RT-PCR test is unnecessary.
- If a RT-PCR test is also performed and the result is negative, facilities should base their infection prevention and control actions on the positive antigen test result.
- If antigen test result is negative, perform confirmatory RT-PCR test within 48 hours.

Please refer to the following table for guidance based on recommendations from the Centers for Disease Control and Prevention:

Pre-test probability of infection	Considerations	Guidance
Probability of infection is low	<ul style="list-style-type: none"> <li>• Asymptomatic</li> <li>• No known exposure</li> <li>• Not part of an outbreak</li> <li>• Low community COVID-19 activity</li> <li>• County positivity rate is less than five percent</li> </ul>	<ul style="list-style-type: none"> <li>• If an antigen test result is negative, it may not be necessary to perform a confirmatory PCR test<sup>1</sup>.</li> <li>• If an antigen test result is positive, perform confirmatory PCR test within 48 hours. If the PCR test result is negative, treat as a negative result.</li> </ul>
Probability of infection is high	<ul style="list-style-type: none"> <li>• Symptomatic</li> <li>• Known exposure</li> <li>• Part of an outbreak</li> <li>• High community COVID-19 activity</li> <li>• County positivity rate is greater than five percent</li> </ul>	<ul style="list-style-type: none"> <li>• If antigen result is negative, perform a confirmatory PCR test within 48 hours.</li> <li>• If an antigen test result is positive, a confirmatory PCR test is unnecessary.</li> <li>• If a PCR test is also performed and the result is negative, facilities should base their infection prevention and control actions on the</li> </ul>

		positive antigen test result.
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<sup>1</sup>PCR confirmatory testing is also considered presumptive when screening asymptomatic persons, thus the potential benefits of confirmatory testing should be carefully considered in the context of the person's clinical presentation.

### **Emergency Use Authorization of Bamlanivimab**

The FDA has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product bamlanivimab for the treatment of mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Please note, this product is only for non-hospitalized patients who are diagnosed with COVID-19, and it must be administered by intravenous infusion. For more information regarding the use of bamlanivimab, please see the below resources:

- FDA's [Letter of Authorization](#) for bamlanivimab (LY-CoV555)
- [Fact Sheet for Healthcare Providers](#)
- [Fact Sheet for Patients and Caregivers](#)
- [FDA Frequently Asked Questions](#)
- [U.S. Government OWS Post-EUA Outpatient Administration Playbook](#)
- [Lilly Bamlanivimab Antibody Playbook](#)