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MONOCLONAL ANTIBODY SITES STATEWIDE WILL BE CLOSED AFTER FDA REMOVES TREATMENT AUTHORIZATION



Contact: Communications Office <u>NewsMedia@flhealth.gov</u> (850) 245-4111

Tallahassee, Fla. — This evening, without any advanced notice, the U.S. Food and Drug Administration (FDA) revised the Emergency Use Authorizations (EUA) for <u>bamlanivimab/etesevimab</u> and <u>REGEN-COV</u>. The revised EUAs do not allow providers to administer these treatments within the United States.

<u>Unfortunately, as a result of this abrupt decision made by the federal government, all monoclonal antibody state sites will be closed until further notice.</u>

Individuals with appointments have been directly contacted regarding cancellations. If you have tested positive for COVID-19, please contact your health care provider for more information and resources on treatment options. Resources for emerging treatments can be found at <u>www.HealthierYouFL.org</u>. Pharmacies that have received allocations of anti-viral treatments can be found at <u>www.FloridaHealthCOVID-19.gov</u>.

Florida disagrees with the decision that blocks access to any available treatments in the absence of clinical evidence. To date, such clinical evidence has not been provided by the United States Food and Drug Administration (FDA).

As stated in one of the <u>pre-print studies</u> cited on the <u>NIH website</u>, "despite observing differences in neutralizing activity with certain mAbs, it remains to be determined how this finding translates into effects on clinical protection against B.1.1.529."

For more information on why this decision was made, please contact the FDA at 1-888-463-6332.

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