

Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
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COVID-19 Update on Testing, Sequencing and Non-hospitalized Patient Treatment

As a result of surging COVID-19 numbers and the predominance of the more transmissible delta variant within Alabama and nationally, the ADPH is making sure that providers have access to the information needed to hopefully deal with the increases in cases and hospitalizations.

Testing for SARS-CoV-2 Virus

All persons with symptoms consistent with COVID-19 infection should be tested for the SARS-CoV-2 virus. This includes persons with a history of prior COVID-19 infection regardless of how long ago they were infected and persons who are vaccinated

Identifying and investigating hospitalized or fatal post-vaccination cases

Some COVID-19 infections post vaccination are expected. However, post-vaccination hospitalizations and deaths are of utmost concern because this could represent changes or mutations in the SARS-CoV-2 virus.

For the purpose of reporting to ADPH, a post-vaccination (also referred to as a vaccine breakthrough) infection is defined as the detection of SARS-CoV-2 in a respiratory specimen collected from a person ≥ 14 days after they have completed all recommended doses of a U.S. Food and Drug Administration (FDA)-authorized COVID-19 vaccine.

Requesting Genomic Sequencing of Specimens

As a result of the need to prioritize cases for surveillance purposes, specimens for the purpose of sequencing should be limited to those persons with the detection of SARS-CoV-2 who are hospitalized or deceased.

Monoclonal Antibody COVID-19 Treatment for Non-hospitalized Patients

There are currently three monoclonal antibody products under Emergency Use Authorization (EUA) for the treatment of mild to moderate COVID-19. None of these products are authorized for use in persons who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19 or who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity. Treatment should be given as soon as possible after a positive COVID-19 test and within 10 days of symptom onset to patients who have tested positive **and** who are at “high risk” for disease progression to severe COVID-19. The definition of high risk is product and EUA specific. Please visit the following links for complete requirements, and EUA Fact Sheets.

1. BAMLANIVIMAB/ETESEVIMAB

Distribution of bamlanivimab/etesevimab (Lilly product) has been paused due to its lack of activity against the Beta and Gamma variants of the COVID-19 virus.

2. CASIRIVIMAB/IMDEVIMAB (REGEN-COV)

Dose: 600 mg of casirivimab and 600 mg of imdevimab as a one-time dose.

Approved for intravenous infusion and subcutaneous injection when intravenous administration is not feasible and would lead to delay in treatment.

Minimum infusion times for intravenous administration are 20 to 50 minutes, depending on the size of Sodium Chloride bag used.

When giving by subcutaneous injection, four syringes containing 2.5 ml each should be given at four different injection sites into the thigh, back of upper arm, or abdomen, except for 2 inches around the navel, using different quadrants. The waistline should be avoided.

New and existing providers can order REGEN-COV via the AmerisourceBergen C19 Therapies Direct Order Request at no charge:

<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>

3. SOTROVIMAB

Dose: 500 mg by intravenous infusion over 30 minutes

Sotrovimab is available **for purchase** directly with AmerisourceBergen using existing AmerisourceBergen accounts or by calling Customer Service (1-800-746-6273) or emailing c19therapies@amerisourcebergen.com. More information can be found on the sotrovimab website: <https://www.sotrovimab.com/>

Please visit the following links for additional information on the above monoclonal antibodies including patient requirements, EUA FACT Sheets for each product, and CMS reimbursement information:

Direct link on ADPH webpage to monoclonal antibody COVID-19 treatment document at: <https://www.alabamapublichealth.gov/covid19/assets/cov-antibody-treatment.pdf>

CMS reimbursement rates for monoclonal antibody administration can be found at: <https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies>

More information about COVID-19 treatment options, including EUA Fact Sheets, can be found at: <https://combatcovid.hhs.gov/i-have-covid-19-now/available-covid-19-treatment-options>

Providers of monoclonal antibodies for COVID-19 treatment can be found at: <https://covid.infusioncenter.org/>