

COVID-19 EUA Testing Requirement Change - Drug Information Update

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COVID-19 EUA Testing Requirement Change

Today, FDA revised the Letters of Authorization for two EUAs, Paxlovid and Lagevrio, to remove the requirement for positive test results to prescribe these products. The agency continues to recommend that providers use direct SARS-CoV-2 viral testing to help diagnose COVID-19.

However, we recognize that, in rare instances, individuals with a recent known exposure (e.g., a household contact) who develop signs and symptoms consistent with COVID-19 may be diagnosed by their health care provider as having COVID-19 even if they have a negative direct SARS-CoV-2 viral test result. In such instances, their health care provider may determine that treatment with authorized therapeutics may be appropriate if the patient reports mild-to-moderate symptoms of COVID-19 and is at high risk for progression to severe COVID-19, including hospitalization or death, and the terms and conditions of the product's authorization are met.

The latest information about COVID-19 therapeutics can be found on [FDA's EUA webpage](#).

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