

Clinical Brief #39 | COVID-19

Developed Thursday, August 6, 2020

INFORMATION FOR ALL CLINICIANS

Clinical leaders are providing frequent updates to all clinicians in an effort to keep you current about AdventHealth's response to COVID-19. The following topics are included in this brief:

- **Visitation Policy Updates: Pediatric and OB**
- **COVID-19 Antigen Testing**

Visitation Policy Updates: Pediatric and OB

The [visitation policy](#) has been updated to allow in-person visitor support for COVID-19-positive patients in pediatric and obstetric settings.

Pediatric Visitation - Patients under the age of 18, regardless of their COVID-19 status, may be accompanied by two (2) adult visitors at a time per day.

OB Visitation - Obstetric patients, including those that are asymptomatic COVID-19-positive, may be accompanied by one (1) adult visitor per day and (1) doula. Symptomatic COVID-19-positive obstetric patients are restricted to telephone/virtual visits only.

Cesarean Delivery - Support person of COVID-19-positive patient will not be in attendance in the operating room suite.

COVID-19 Antigen Testing

On May 9, 2020, the U.S. Food and Drug Administration (FDA) issued the first Emergency Use Authorization (EUA) for COVID-19 rapid antigen testing to **Quidel** Corporation, with an update on July 17, 2020. The intended use of the Quidel antigen test (using the Sofia-2 analyzer) is an anterior nare nasal swab or nasopharyngeal swab on "fresh symptomatic patients, within five days of onset of symptoms." For this symptomatic patient group, the reported study sensitivity was 96.7 percent and specificity of 100 percent. A positive result is a positive result. For a negative result, if the test was within five days of onset of symptoms, a PCR test is not needed. If the test was taken more than five days from onset of symptoms, a negative result is "presumptive" and a PCR test is recommended.

On July 6, 2020, the FDA issued the second EUA for COVID-19 rapid antigen testing to **BD Veritor** System. The intended use is for patients within the first five days of onset of symptoms with freshly collected, immediately processed, directly dispensed

specimens onto assay test device using the Veritor Plus Analyzer Instrument at the point-of-care. BD Veritor instructs nasal swab of both nostrils. For the study group, the sensitivity was 84 percent and specificity of 100 percent. For a negative result, a PCR is recommended if clinical suspicion remains.

Antigen testing has been in many media reports and part of the national testing debate for COVID-19. Recently, the federal government (Department of Health and Human Services) purchased 2,000 Sofia-2 analyzers and 750,000 tests. The state of Florida (Agency for Health Care Administration) issued guidance that hospitalized patients can be cleared to return to skilled nursing facilities with two negative COVID-19 tests and the "second test can be antigen." The governor of Florida also announced this week a "shift in rapid antigen testing for the community testing." The reports do not have guidance for use at this time. AdventHealth Clinical is proactively monitoring the evolving plans.

FDA "off label use" is a common health care practice and is solely at the discretion of the individual ordering physician with the expectation they understand the authorization, intended use and limitations of the test they order. Examples of "off label use" of antigen testing include asymptomatic individuals (post-exposure, pre-procedure, return to work, clearance for work, travel planning, visitation, or screening of groups or populations).

AdventHealth Clinical recommends:

1. FDA Emergency Use Authorization antigen tests can be used at AdventHealth for COVID-19 **symptomatic** patients **within five days** of onset of symptoms, following the manufacturer's directions.
2. For negative results in **symptomatic** patients who the physician has **clinical suspicion** for COVID-19, they should do a PCR test, having the patient isolate until result available.

[Clinical Briefs](#) | [Hospitalist Briefs](#)

We encourage you to take care of yourself, your families and each other as we move through this ongoing response to COVID-19.

GREATER AS A WHOLE | RESOURCES

Online

[Novel Coronavirus Information Site](#)

[AdventHealth Coronavirus Website | Videos | Blog](#)

[Centers for Disease Control and Prevention \(CDC\)](#)

Department of Health: [Florida, Georgia, North Carolina, Kansas, Kentucky, Texas, Wisconsin](#)

Worldwide Coronavirus Data: [Johns Hopkins' global cases webpage](#)

By Email:

coronavirusquestions@adventhealth.com

By Phone:

COVID-19 Hotline: 1-877-847-8747