Yale Medicine | Yale NewHaven Health

'At Home' Testing for SARS-CoV-2 and COVID-19

Recommendations:

The following recommendations are provided from the Yale Medicine/Yale New Haven Health Testing Stewardship Committee based on current information, CDC guidelines, and FDA regulatory authorizations:

- Home testing can be an important strategy to reduce risk associated with social gatherings and facilitate personal decision making by allowing positive individuals to isolate from situations where viral spread may occur and/or identifying infected individuals more rapidly than laboratory-based NAAT which may experience delays.
- **Home testing requires advance planning**. Testing supplies should be ordered and on-hand so that they are available when needed.
- Appropriately authorized home antigen tests can be used to reduce risk associated with in person social gatherings by testing twice over 48 to 72 hours (See Figure 1).
- Home testing strategies for asymptomatic risk assessment can be used in place of NAAT when there are high demands placed on testing services.
- At home NAAT testing, including PCR, is available through mail order, and these tests may meet travel or pre-arrival testing requirements. These tests should be considered if there is sufficient advance notice.
- At home NAAT devices are now available, and some are authorized for the same repeat testing algorithm as at home antigen tests.
- There is no current role for at home antibody testing.
- **Symptomatic patients who test positive by an at home test should be considered to have COVID-19, adhere to applicable institutional or CDC recommendations for quarantine/isolation, and seek assessment for treatment as needed. Repeat or confirmatory NAAT/PCR is not necessary (Figure 2). The clinical scenario (type and date of symptoms, test result, type and date of test) should be recorded in the medical record.**

Situation:

Guidance is needed on 1) the role of at home testing as a risk mitigation strategy for gatherings, and 2) the general role for at home testing including at home antigen tests.

Background and Definitions:

- The US FDA maintains websites for all currently authorized tests, and tests authorized for home testing are indicated.
- On the FDA website, tests are listed with an *Authorized Setting* of "Home" and/or an *Attribute* of "Serial Screening."
- There are three general approaches to home testing: 1) at home antigen testing, 2) at home amplified RNA testing, and 3) mail in testing with at home collection.
- All tests for at home use have been specifically evaluated for ease of use, and they are available for adults and specimens collected from children by adults.

Assessment:

- *General Considerations:*
  - All test results represent the moment in time during which the sample was collected. They cannot predict infection or infectiousness in the future. More sensitive methods may detect

infections earlier than less sensitive methods, but they may remain positive longer. There are no widely available tests or test results that reliably relate to infectivity or infectiousness.
  - Many factors including sample type, sample collection quality, and timing of sample collection in relation to symptoms all combine to affect the amount of virus present in a sample, and tests differ in their abilities to detect virus. The sum of all of these factors will affect test clinical performance.

- *Antigen Methods:*
  - There is not a robust literature comparing antigen methods, and we cannot determine the "best" method. We do not recommend one manufacturer over another.
  - Antigen methods are less analytically sensitive than methods that amplify and detect viral RNA and are more susceptible to falsely-negative results especially in asymptomatic or pre-symptomatic patients.
  - Antigen methods can be used for serial screening as described in the instructions for use. One example of a serial screening plan is presented (See Figure 1).
  - If home antigen tests are used to increase the safety of a social gathering, testing should be performed as close in time as possible to a gathering to provide the most temporally relevant information. ***Exposure risk should be minimized between tests for maximum efficacy***.
  - Examples include, but are not limited to: BinaxNOW, QuickVue at Home, CareStart, Flowflex, BD Veritor at Home, Ellume, et al.

- *Home Collected, Mail In Testing*
  - Tests are available that allow at-home self-collection of nasal swabs or saliva. After collection, samples are mailed to a centralized laboratory for conventional amplified viral RNA testing. Some tests require remote observation.
  - The test methods used are often the same or similar to methods used in YNHHS laboratories including PCR testing with comparable performance characteristics.
  - Some mail-in testing is offered by national reference laboratories, and those results may be available in Epic. All results from these tests will generate a record of testing in some form.
  - Examples include, but are not limited to: LapCorp Pixel, Amazon, Wren Labs, et al.

- *Home RNA Testing*
  - A limited number of at home NAAT available, but more be available in the future.
  - These tests have indications for use similar to at home antigen tests.
  - Direct comparisons of at home NAAT and at home antigen methods are lacking.
  - Examples include: Detect, Lucira, and Cue.

Recommendations:

Recommendations are listed at the box at the beginning of the document.

References:

CDC Home Testing Guidance: https://www.cdc.gov/coronavirus/2019-ncov/testing/self-testing.html

FDA Authorized Antigen Tests: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2

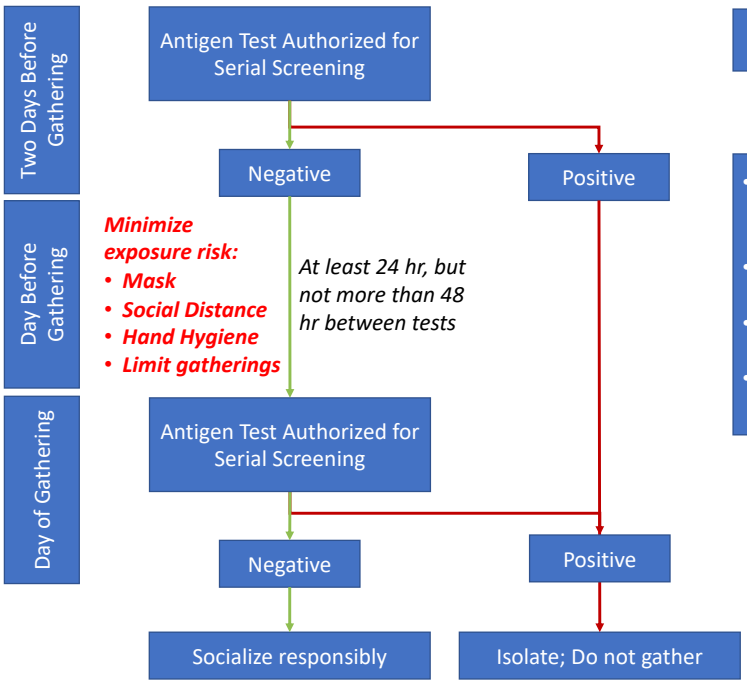

Figure 1: Potential home testing plan for **asymptomatic** individuals testing prior to social gatherings.

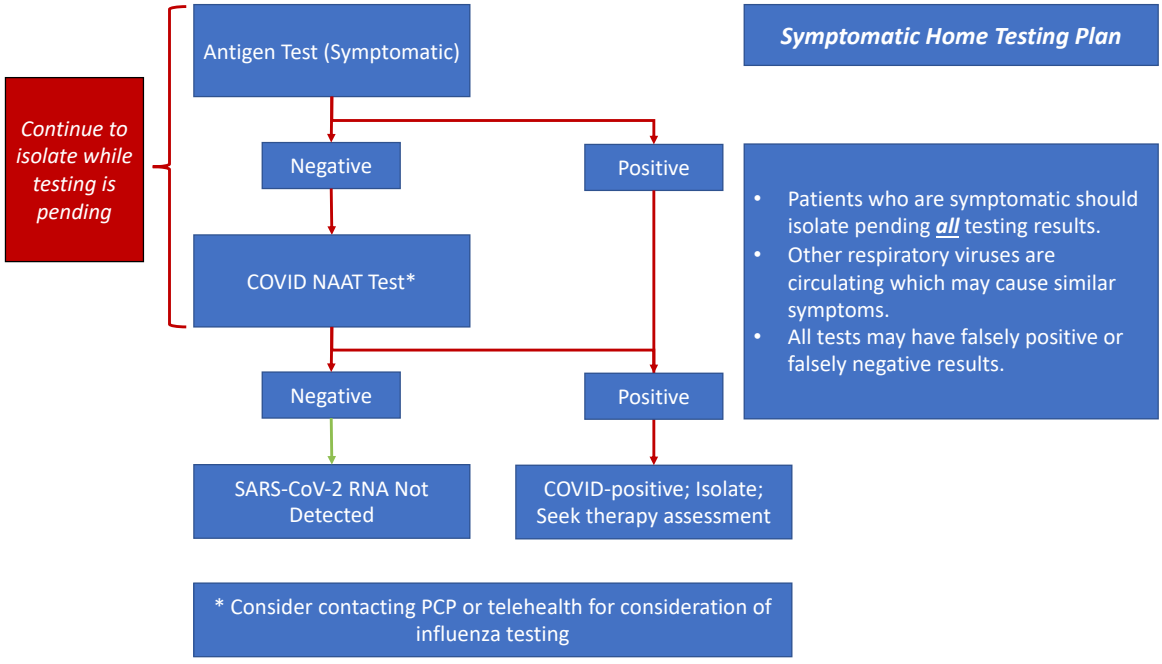

Figure 2: Approach to home antigen testing for ***symptomatic*** patients.