

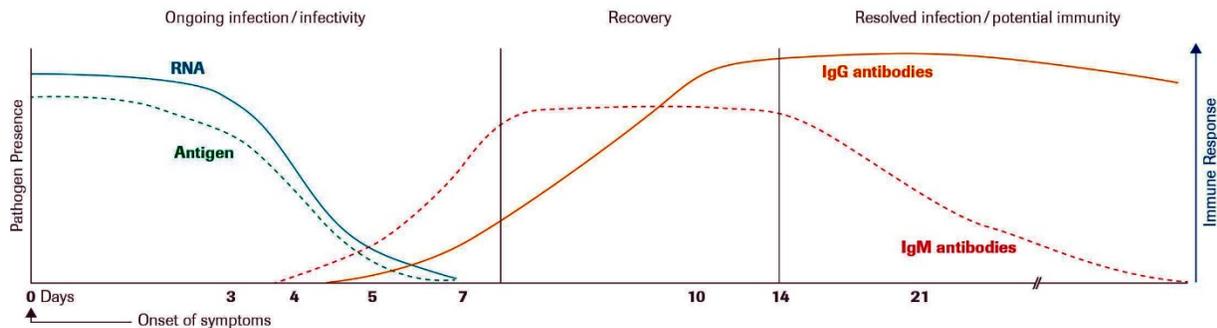
## Currently Recommended Use of SARS-COV-2 Serology Testing

Lifespan Clinical Immunology Lab

May 14, 2020

At the request of a number of physicians who use Lifespan Laboratories, we are providing answers to frequently-asked questions about SARS-COV-2 Total Antibody (IgG and IgM) and SARS-COV-2 IgG Antibody testing which became available in our menu as of May 6, 2020.

1. What is the time course of antibodies and other markers in SARS-CoV-2 infection?



2. During which phase of the disease will the antibody testing be most useful?

Fourteen days after the onset of symptoms. When Lifespan inpatients were tested on or after 14 days of symptom onset, the sensitivity was  $\geq 98\%$  [95% CI: 89.9%-100%] for both tests. The specificity was  $>99\%$  [95% CI: 97.7%-99.9%] for Total Antibodies and  $>98\%$  [95% CI: 95.8%-99.4%] for IgG Antibodies.

3. How to interpret the results?

A positive result indicates that the patient could have had a recent (within weeks) or prior infection with SARS-CoV-2. The diagnosis of acute infection cannot be made based on this test and should not be used for this indication. False positive results may occur infrequently due to cross-reaction with non-COVID coronaviruses or due to technical limitations of the test. It is not yet known whether positive serology indicates resolution of infection and non-contagious state, or immunity from future infection.

A negative result indicates that SARS-CoV-2 antibody is not detected. Negative results may occur in serum collected too early following infection, in immunosuppressed patients, or in some individuals with prior mild or asymptomatic illnesses. The test cannot be used solely to exclude COVID-19. There is no data at this time on duration of antibody response.

4. Is there a limited supply of test reagents and restrictions on ordering antibody testing?

Although there is an adequate supply to perform testing at this time, excessive utilization could compromise our supply and restrictions may become necessary.

5. Who should be tested only after Infectious Diseases consultation (ID approval)?

- A. Complicated cases requiring nuanced evaluation and expertise in test interpretation.
- B. Suspected respiratory COVID-19 patients with repeat negative PCR testing, but with symptoms lasting less than 2 weeks.
- C. Any suspected COVID-19 patients with non-respiratory presentations, including “COVID toe”, “Kawasaki disease-like” presentations, and other atypical COVID-19 presentations.

6. Who can be tested without Infectious Diseases consultation (ID approval)?

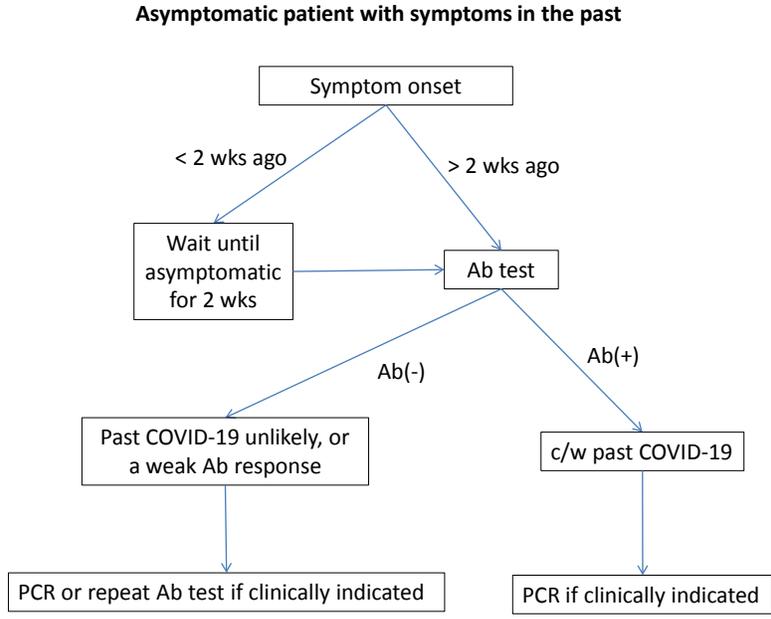
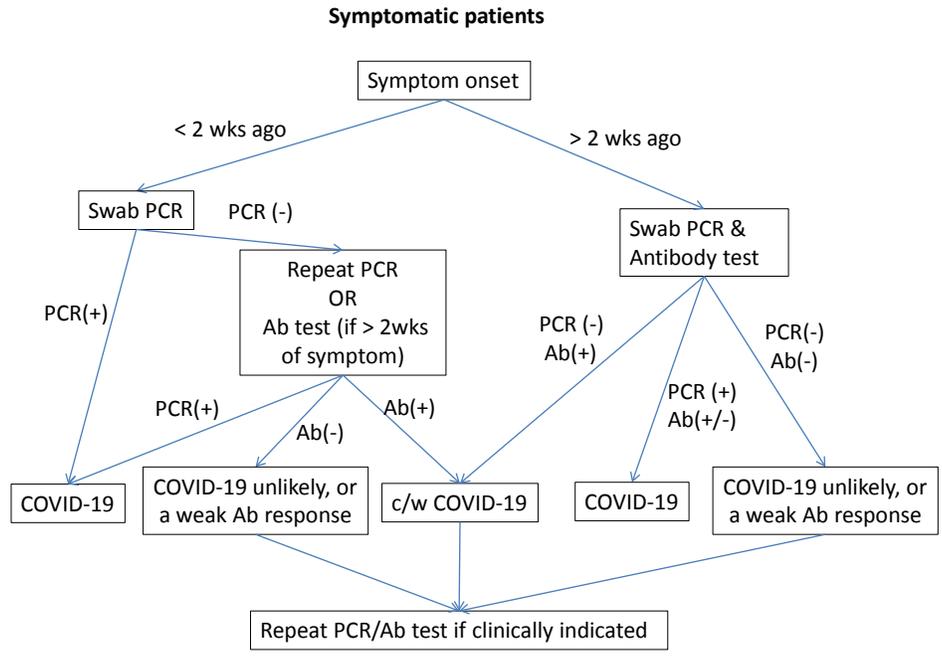
Any of the following individuals who had a symptom onset date earlier than 14 days ago may be tested (the individual may be asymptomatic now), including but not limited to:

- A. Healthcare workers with confirmed or highly suspected prior infection with mild or severe symptoms:
  - a. Health care providers and caregivers in health facilities (hospital, nursing home, etc.) who worked directly with a COVID-19 patient, or directly with a potentially infectious specimen from a COVID-19 patient.
  - b. Any other health care worker whose job may not involve direct disease exposure, but in whom COVID-19 is highly suspected.
  - c. Any health care worker approved by Employee Health.
- B. Selected patients under special clinical circumstances, such as:
  - a. Suspected respiratory COVID-19 patients with repeated negative PCR testing
  - b. Co-habiting family member or other close contact (of established COVID patient) who had mild or no symptoms and was not tested or was negative by PCR.

7. Who should not be tested?

- A. Anyone who has never been symptomatic for COVID-19, except when required by Rhode Island Department of Health, their employer, or other specifically mandated testing.
- B. Any patient with new COVID-19 symptoms lasting less than 2 weeks. These patients should be tested by PCR.

**Appendix:** Recommended flowcharts for symptomatic and asymptomatic patients with suspected COVID-19.



Ab: Antibody; wks: weeks.