



Back to Life program

Helping patients and providers get back to daily routines

Knowing what comes next

Quest Diagnostics understands that the COVID-19 pandemic has had a significant impact on virtually every aspect of daily life.





That's why we have created the **Back to Life program**—a solution to help people who are thinking about resuming daily routines—such as work, care, school, dining out, sports, etc—by providing key insights about COVID-19 status.

Our **Back to Life** testing protocols and solutions can help you make clear, actionable suggestions for your patients' return to work and a return to daily life.

Developing a guideline-driven model for getting back to life

Reopening communities across the country requires a sound, strategic approach to help people who are thinking about transitioning back to work and daily routines.

The model developed was based on:

-  Evaluation of CDC guidelines
-  External benchmarks for safety
-  Metrics to keep office environment up to standards
-  State directives



For more information on COVID-19, please visit
QuestDiagnostics.com/COVID19

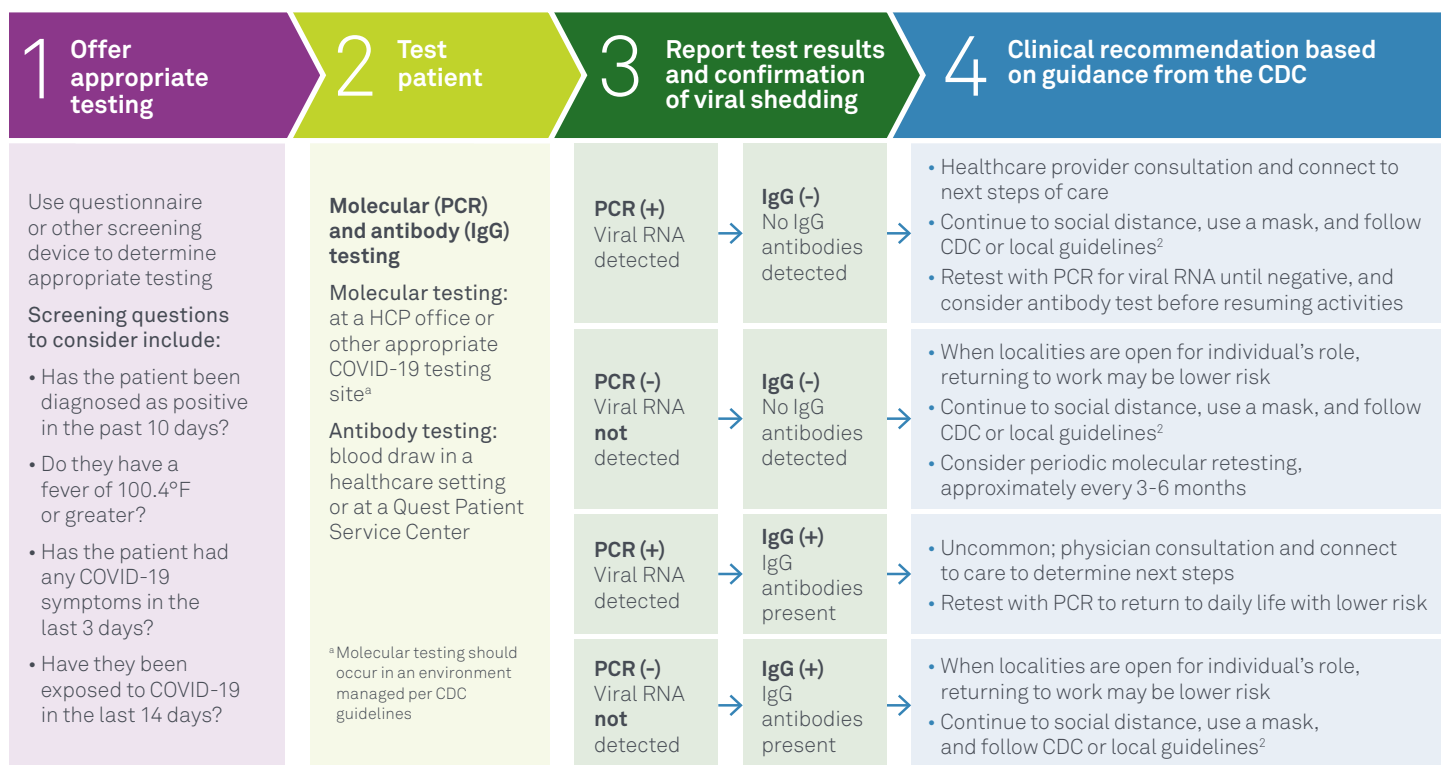
Current FDA recommendations for antibody testing

An April 17, 2020 letter from the FDA outlines information and guidance for HCPs regarding the use of antibody testing for COVID-19¹:

- The FDA recommends that healthcare providers continue to use serological tests intended to detect antibodies to SARS-CoV-2 to help identify people who may have been exposed to the SARS-CoV-2 virus or have recovered from the COVID-19 infection
- Serological tests can play a critical role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have been exposed to SARS-CoV-2 virus and may have developed an immune response
- Experience with other viruses suggests that individuals whose blood contains antibodies associated with SARS-CoV-2 infection—provided they are recovered and not currently infected with the virus—may be able to resume work and other daily activities in society
- Individuals whose blood contains antibodies may also be eligible to serve as potential donors of convalescent plasma
- The FDA is not aware of an antibody test that has been validated for diagnosis of SARS-CoV-2 infection. While the FDA remains open to receiving submissions for these tests for such uses, based on the underlying scientific principles of antibody tests, the FDA does not expect that an antibody test can be shown to definitively diagnose or exclude SARS-CoV-2 infection

Getting back to life

Here is one example of a **Back to Life** testing model, developed based on CDC guidelines and in partnership with infectious disease experts, local employers, and civic officials. Local and state requirements may vary and HCPs will need to adjust their protocols accordingly. This model may change as CDC guidelines and FDA recommendations are updated.



Meeting your patients' testing needs

Antibody testing is available at our 2,250 nationwide Patient Service Centers (PSCs). All PSCs have implemented the **Peace of Mind program** with enhanced safety features consistent throughout the day for all patients.

Test info

SARS-CoV-2 RNA (COVID-19), Qualitative NAAT

Test code: 39448

CPT code*: 87635 (HCPs:U0003)

SARS-CoV-2 Serology (COVID-19) Antibody (IgG), Immunoassay

Test code: 39504

CPT code*: 86769

*CPT codes are based on American Medical Association guidelines and are for informational purposes only. CPT coding is the sole responsibility of the billing party. Please direct any questions regarding coding to the payer being billed.



For more information or to talk to your Quest sales representative, call **1.866.MYQUEST (1.866.697.8378)**.

The antibody tests (sometimes known as the serology tests or IgG tests) are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. Individuals may have detectable virus present for several weeks following seroconversion. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, molecular testing for SARS-CoV-2 is necessary. The antibody test should not be used to diagnose acute SARS-CoV-2 infection. False positive results for the antibody test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

- The antibody tests and the molecular tests (together "All tests") have not been FDA cleared or approved;
- All tests have been authorized by FDA under EUAs for use by authorized laboratories;
- The antibody tests have been authorized only for the detection of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens;
- The molecular tests have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,
- All tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

References

- US Food & Drug Administration (FDA). Important information on the use of serological (antibody) tests for COVID-19—letter to health care providers. April 17, 2020. <https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers>. Accessed May 5, 2020.
- Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Prevent getting sick. Updated May 7, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/index.html>. Accessed May 5, 2020.

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