Back to School program

Helping you and your students get back to campus

Quest Diagnostics **Back to School solution** can help you keep students, faculty, and staff aware of their risk of exposure to COVID-19 while getting your students the education they deserve.

Returning to Campus

The following approach to help students and faculty understand their risk of COVID-19 exposure was built using guidance from the Centers for Disease Control and Prevention (CDC),[1] and should be adjusted as appropriate to reflect university policy and civic, regional, state, and federal guidance.

1 Offer appropriate testing	2 Test staff and students	3 Report test results and confirmation of active infection	4 Clinical recommendation based on CDC guidance[1]
Use screening questionnaire at home to determine which is more appropriate: • Antibody testing[a] for asymptomatic students or staff • Molecular testing[b] for symptomatic, exposed, or high-risk students or staff	**Antibody testing:** blood draw at a Patient Service Center or in the home	**IgG (+)** IgG antibodies present	• May be cleared for return when campus is open • Continue to social distance and use mask following university and community guidelines
		IgG (-) **No** IgG antibodies detected	• May be cleared for return when campus is open • Continue to social distance and use mask following university and community guidelines • Consider dedicated dorm floors, single occupancy dorm rooms, and special dining hall hours for unexposed students • Consider regular antibody retesting every few months
	Molecular testing: offered via home self-collection kit, at a physician's office, or other appropriate COVID-19 testing site	**PCR (+)** Viral RNA detected	• Healthcare provider consultation and connect to next steps of care • Retest with molecular prior to returning to campus
		PCR (-) Viral RNA **not** detected	• May be cleared for return when campus is open • Continue to social distance and use mask following university and community guidelines • Consider dedicated dorm floors, single occupancy dorm rooms, and special dining hall hours for unexposed students

a. Antibody testing is a blood test to detect antibodies that show a person may have an immune response to COVID-19
b. Molecular testing is a swab test to diagnose active COVID-19 infection

The value of antibody testing according to current FDA recommendations

An April 17, 2020 letter from the FDA outlines information and guidance for HCPs regarding the use of antibody testing for COVID-19[2]:

- 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. 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

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

Staying on Campus

The following approach to help students and faculty understand and manage their risk of COVID-19 exposure while on campus was built using guidance from the CDC,[1] and should be adjusted as appropriate to reflect university policy and civic, regional, state, and federal guidance.

1 Identification	2 Test staff and students	3 Report test results and confirmation of active infection		4 Clinical recommendation based on CDC guidance[1]
Molecular and antibody testing offered to exposed or symptomatic students	Swab collection for molecular testing Blood collection for antibody testing	**PCR (+)** Viral RNA detected	**IgG (-)** No IgG antibodies detected	• Connect student with medical care • On-campus student into isolation dorm • Contact tracing immediately implemented • Close contacts test and quarantine per policy
		PCR (-) Viral RNA **not** detected	**IgG (-)** No IgG antibodies detected	• PPE mandatory • Attend classes from home if possible • Consider follow-up testing for flu and other conditions • Consider housing student in single dorm room
		PCR (+) Viral RNA detected	**IgG (+)** IgG antibodies present	• Uncommon; Physician consultation to determine next steps • Retest with molecular
		PCR (-) Viral RNA **not** detected	**IgG (+)** IgG antibodies present	• May be cleared to resume on-campus activities after two consecutive negative molecular tests • PPE must be worn until data confirms IgG + people are non-infectious • Student may be cleared for shared dorm room

Our Back to School solution can help you:

- Help your faculty, staff, students, and their parents understand their risk of exposure
- Make informed decisions about the risk to your faculty and staff
- Develop and implement return-to-campus scenarios
- Lessen the risk of exposure in your classrooms
- Help your students get the education and support they need to excel

To learn more about our Back to School program, contact your Quest Diagnostics sales representative or visit **health.questdiagnostics.com/backtoschool**

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.

Reference

1. Centers for Disease Control and Prevention (CDC). Coronavirus Disease 2019 (COVID-19). Considerations for institutes of higher education. Updated May 21, 2020. Accessed May 26, 2020. https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/considerations.html
2. 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. Accessed May 5, 2020. https://www.fda.gov/medical-devices/letters-health-care-providers/important-information-use-serological-antibody-tests-covid-19-letter-health-care-providers

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