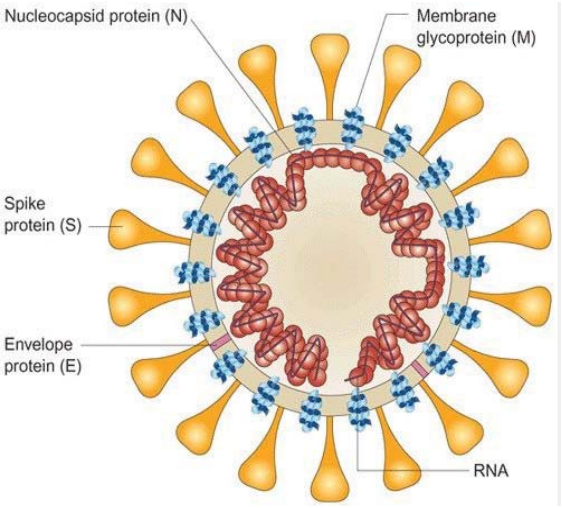
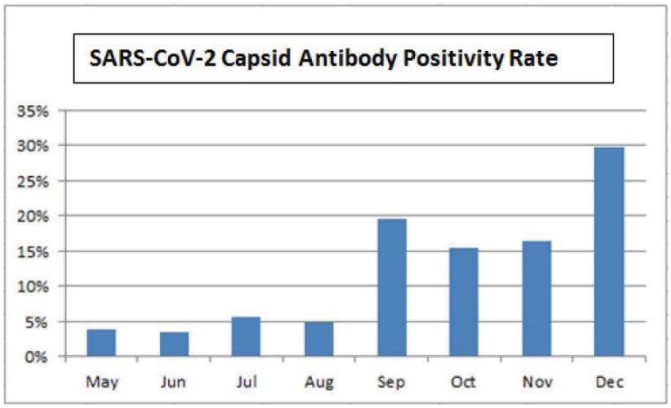
LabWire
Laboratory News and Analysis for Clinicians February 2021

New Serology Panel for SARS-CoV-2 (COVID-19) Antibodies

Effective: February 23, 2021

Since May of 2020, Bronson Laboratory has offered a test for total antibodies (IgM, IgG and IgA) to the nucleocapsid (capsid) protein of the SARS-CoV-2 virus. All SARS-CoV-2 viruses contain the capsid antigen and people who are infected or recovered from infection have antibodies to this antigen. The antibodies are not present in people who have never been infected or in those who have received the COVID-19 vaccine. The current and forthcoming COVID-19 vaccines all consist of the spike protein only, and none contain the capsid protein. The test is qualitative and reported as either positive or negative. Additional details on this test were published in the May 2020 LabWire.





Monthly test positivity rate over the past year is displayed at left and shows that providers are using the test to detect current and previously infected patients.

Recently a new test has been authorized by the FDA (under an Emergency Use Authorization) for antibodies specific to the spike protein of this virus. Some features of this test include:

- This test is positive in individuals who have either been infected by or vaccinated for COVID-19
- The test detects total antibodies (IgG, IgM and IgA) to the SARS-CoV-2 spike protein
- Nearly 100% of individuals have detectable spike antibody within 14 days of infection or immunization
- Samples collected sooner than 14 days may give false negative results
- The analytical specificity when tested against 1,100 pre-pandemic samples positive for other coronavirus antibodies was 100% [1] (the test did not cross-react with other Coronaviruses)
- This test gives a numeric result in U/mL. Because there is no international standard for quantifying coronavirus antibodies, the FDA has classified the test as semi-quantitative but a higher number denotes a higher level of antibodies
- Validation studies determined that a value greater or equal to 0.80 U/mL is a positive result (spike protein antibodies were detected)
- The upper range of the reported results will be 250 U/mL; specimens above that level will be reported as >250 U/mL
- Internal dilution studies have shown that many individuals have values in excess of 2,500 U/mL after their 2nd dose of mRNA vaccine

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SARS-CoV-2 Antibodies (cont.)

Bronson Laboratory will offer the two SARS-CoV-2 virus serology tests as a panel called "COVID-19 Ab Panel" Epic LAB3778 or Sunquest C19ABP.

Combining the two tests into a panel allows for better determination of a patient's serological picture:

Capsid Antibody	Spike Antibody	Status
Negative	Negative	Indicates neither vaccination nor infection
Negative	Positive	Indicates vaccination; no evidence of infection
Positive	Negative	Indeterminate. Could be early post infection or possible non-specific false positive
Positive	Positive	Indicates infection with or without vaccination

Limitations of the test continue to be our lack of knowledge of how long detectable antibodies persist in the patient following either infection or immunization. We do not know what levels of antibodies indicate immunity or protection from infection, but preliminary studies suggest that the presence of anti-spike or anti-nucleocapsid IgG antibodies is associated with a substantially reduced risk of SARS-CoV-2 reinfection in the ensuing 6 months. [2]

The current applications and clinical utility for COVID-19 serology testing include:

- Seroprevalence and epidemiological studies
- Diagnosis of individuals who may have been infected more than 14 days before testing, after the virus may no longer be detectable by PCR or antigen tests
- Distinguishing whether a patient's positive SARS-CoV-2 PCR test represents current infection (serology test should be negative) or past infection (serology test should be positive)
- Identification of individuals who may serve as potential convalescent plasma donors.

References

1) Elecsys Anti-SARS-CoV-2 S Emergency Use Authorization package insert, Roche Diagnostics, Indianapolis, IN
2) Lumley, SF, Antibody Status and Incidence of SARS-CoV-2 Infection in Health Care Workers, The New England Journal of Medicine, Dec 23, 2020