LabWire
Laboratory News and Analysis for Clinicians May 2020

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

Effective May 18, 2020

- The test is intended to detect antibodies to the virus, not to diagnose active infection.
- This is a total antibody test and may detect IGG, IGM or IGA.
- The result is reported as Positive or Negative. Titers are not an option.
- A positive result indicates previous infection with COVID-19. Patients need to be counseled that the test does not confer immunity. Studies to determine immunity are ongoing.
- The test was validated by the vendor Roche on over 5000 specimens and the specificity was 99.81%. The FDA granted Emergency Use Authorization.
- The sensitivity at 14 days post PCR diagnosis was reported as 100%. Internal validation at BMH showed 21/21 patients positive at 14+ days, 11/11 at 7-13 days and 10/12 at 0-6 days. 32 PCR negative patients were all negative by serology.
- False positives are possible. With a hypothetical disease incidence of 5%, the positive predictive value would be 96%.

How should serologic testing be used?

Serologic testing is recommended at least 10-14 days post symptom onset or exposure to someone with known COVID-19. The following are current applications for serology testing:

- Seroprevalence and epidemiologic studies
- Identification of an individual who has been infected in the past
- Identification of individuals with prior COVID-19 infection who may serve as potential convalescent plasma donors
- Monitoring immune response during vaccine clinical trials

TEST NAME	SARS-Cov-2 Antibody		
SPECIMEN	SERUM preferred (gold top tube), PLASMA acceptable (mint top)		
TRANSPORT CONDITIONS	Refrigerated		
STABILITY	Serum samples are stable: 3 days at 15-25 °C, 7 days at 2-8 °C, 28 days at -20 °C (± 5 °C). Plasma samples are less stable, and not suitable for add-on testing.		
EXPECTED TURNAROUND	8 hours from receipt of sample in laboratory.		
TEST ORDER CODE	Sunquest: COV2AB	EPIC: LAB3778	Cost: $68.00

BRONSON

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Update COVID-19 Molecular Diagnostic Test

1. Bronson is performing testing with real-time polymerase chain reaction (PCR), a molecular assay that is considered the standard test for diagnosing COVID-19 infection.
2. This test detects SARS-CoV-2 RNA from nasopharyngeal swab or bronchioalveolar lavage (BAL).
3. A positive test by PCR is diagnostic of COVID-19.
4. A negative result does not necessarily mean that the patient does not have COVID-19. False negative results can occur due to low level of virus early or late in the clinical course or due to suboptimal collection. Negative results that become positive upon retesting have been infrequent in our experience.
5. SARS-CoV-2 is likely to be at the highest concentrations in the nasopharynx during the first 0-3 days of symptomatic illness. There is evidence that in a patient with pneumonia, a BAL may be superior to a NP swab.