

Allermetrix Introduces Quantitative COVID-19 Serology

What is a COVID-19 serology blood test?

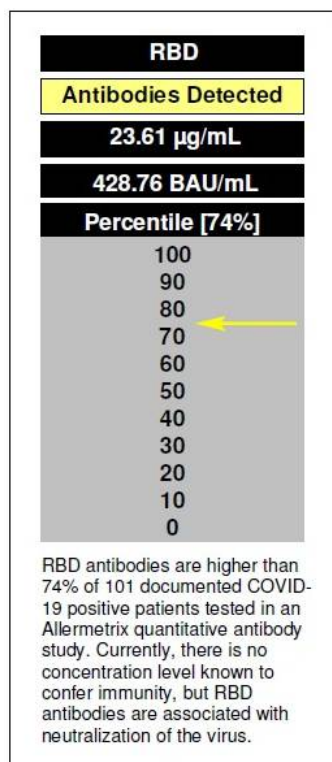
A serology blood test is used to determine if there are certain antibodies, IgG or IgM, in your blood that react with certain substances called COVID-19 antigens. At this time, it is not known what proportion of the population has antibodies to COVID-19. When antibodies are found in your blood it is part of a picture that your physician can use to aid in determining whether you have had a COVID-19 infection. Testing is done on a blood sample.

What do the results of a serology blood test mean?

COVID serology tests can help identify if you have had the disease, and if you responded to a vaccine. If you have had the disease or received a vaccination, it will tell you if you produced antibodies.

What does the Allermetrix test tell you and how is it different?

- The Allermetrix test is an LDT (laboratory developed test) and, validation documents have been submitted to the FDA and are available at www.allermetrix.com.
- Other current COVID-19 serology tests are qualitative which only tell you if you have antibodies or not and many only one antigen. Allermetrix serology tells you how much antibody you have directed to three important COVID antigens.
 - Receptor binding domain (RBD) which targets what cells get infected
 - S1 subunit of the spike protein (S1) which aids in the infection process
 - Nucleocapsid (N protein) which protects the viral RNA
- Allermetrix can show you how your results compare to samples with verified COVID-19 disease that we have tested. This is called benchmarking and an example of it is shown below.



* BAU/mL is an Antibody Binding Unit established by the World Health Organization (WHO)

Why a quantitative assay?

- As future studies are performed, it may be possible to determine when antibodies are high enough to confer immunity and for how long.
- A WHO consensus standard is available for quantitative values and is valuable when comparing results between laboratories.

Why test more than one protein?

- To avoid false positive tests, the CDC recommends testing 2 different antigens to better avoid the possibility that you incorrectly think you have had the disease.

Why offer both IgG and IgM?

- Depending on when the patient has been infected, it is possible to have detectable IgM levels and negative IgG levels. This pattern may suggest the patient was recently infected and may still be contagious

How much blood is needed for testing?

- Testing can be done with 0.5 mL of serum or plasma

Allermetrix tests for COVID-19.

Allermetrix has validated the assays using one hundred sixty-five COVID-19 negative patients and seventy COVID-19 positive convalescent plasmas. When testing one antigen, RBD and S1 protein have excellent sensitivity and specificity, and N protein has excellent sensitivity but relatively poor specificity.

Individual IgG tests	RBD	S1	N Protein
Sensitivity ¹	97.14%	97.14%	100%
Specificity ²	96.36%	95.76%	82.42%

¹Sensitivity is the probability that if your test is positive you had or may have COVID-19

²Specificity is the probability that if your test is negative you have not had COVID-19

When RBD and S1 protein are both positive or both negative in panel testing, the sensitivity is 97.14% and the specificity is 98.79%. When disease prevalence is 5%, the negative predictive value of the panel is 99.8% and the positive predictive value is 97.0%.

Panel IgG tests	RBD and S1
Sensitivity	97.14%
Specificity	98.79%



www.allermetrix.com/covid.html

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