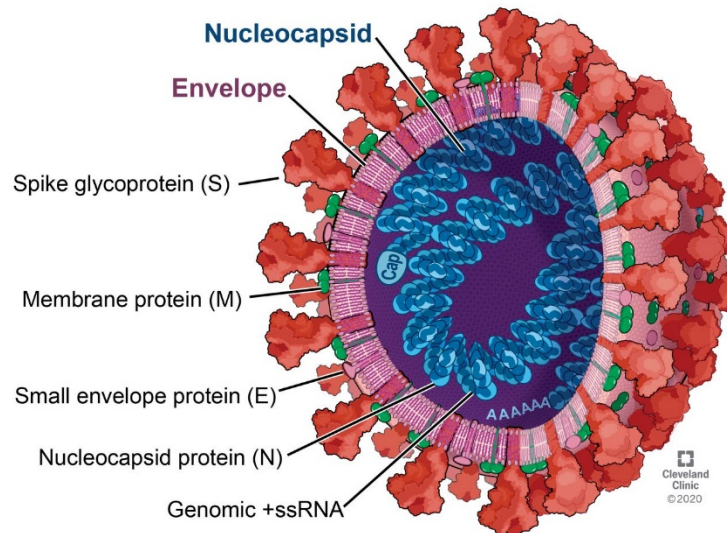


So You Have Questions About the New COVID Antibody Test?



BACKGROUND:

- ◆ In June of 2020, The Blood Center started testing all donations for COVID Antibodies using an antibody test by Roche Diagnostics to detect COVID Antibodies against the Nucleocapsid protein, also known as the N-capsid protein or “N-protein” (see illustration above).
- ◆ The only way a person would develop COVID Antibodies to the N-protein is if:
 - They were exposed to the COVID-19 virus.
 - They developed an immune response against virus.
 - Their immune system “ripped open” the virus, exposing the N-protein from inside the virus, and allowing their immune system to “see” the N-protein so it could develop antibodies against it.
- ◆ Testing for COVID Antibodies against the N-protein allowed two things:
 - If a donor tested positive, then it could tell them that they may have been exposed to the COVID-19 virus, even if they never experienced symptoms.
 - This testing allowed The Blood Center to identify donors who may have been exposed to COVID-19. and recruit these donors for COVID Convalescent Plasma or “CCP”.
 - CCP was the first treatment available for severe COVID-19 infections.,
 - CCP contains COVID Antibodies against the various proteins found on the COVID-19 virus that were produced by the donor during their COVID exposure.
 - Saints Coach Sean Payton and local celebrities such as Morris Bart were among our first CCP donors.
 - For more information about CCP, go to: <https://www.thebloodcenter.org/covid-19>.



WHAT CHANGED?

- ◆ With the advent of the COVID vaccines, our donor’s interest switched from “Was I exposed?” to “I wonder if my vaccine worked?”
- ◆ Typically, if someone was never exposed, but received a COVID vaccine, they would test Negative for the COVID Antibody N-protein test, but would test Low or High for the COVID Antibody S-protein test.
 - COVID Antibodies against the S-protein are produced when an individual has had either an exposure to the COVID virus, AND/OR received one of the COVID vaccines. Here is a chart of some possible scenarios:

Exposed to COVID Virus	Received COVID Vaccine	Typical COVID Antibody to N-Protein Result	Typical COVID Antibody to S-Protein Result
No	No	Negative	Negative
Yes	No	Positive	Low or High
No	Yes	Negative	Low or High
Yes	Yes	Positive	Low or High

- ◆ **IN RESPONSE TO OUR DONORS’ INTERESTS, WE STARTED TESTING ALL DONATIONS STARTING WITH DONATIONS MADE ON MAY 19, 2021, USING AN ANTIBODY TEST BY ROCHE DIAGNOSTICS TO DETECT THE S-PROTEIN**

QUESTIONS WE HAVE RECEIVED FROM OUR DONORS

- ◆ **“Why is the new COVID Antibody test reported as Negative, Low, or High and not a number?”**

The instrumentation that we perform the COVID Antibody test on does give a number in Units per Milliliter (U/mL), but our computer system, which is specifically designed and FDA cleared for blood banks cannot accept a numerical value for any type of viral antibody testing including COVID Antibody.

We knew our donors would be interested in seeing what their “level” of COVID Antibody was, so we decided to share the Negative, Low, and High result from our computer system, along with a chart to show how those values equate to a range of numerical values.

The Negative, Low, and High results were based upon “cutoff” ranges dictated by the FDA for the labeling of CCP. Those cutoff ranges very roughly equate to the “titer” or concentration of COVID Antibodies in the CCP itself.



PLEASE NOTE: YOU SHOULD NOT INTERPRET THE RESULTS OF THIS TEST AS AN INDICATION OR DEGREE OF IMMUNITY OR PROTECTION FROM INFECTION.

- A result of High or Low simply means that COVID Antibodies against the S-protein have been detected in your blood.
- A High result does NOT mean that you have “better immunity” than someone with a Low result or vice versa.

We strongly urge you to review the “Fact Sheet for Recipients” that can be accessed via a link on the “My Test Results” page on our website when you access your COVID Antibody results. You can also share the “Fact Sheet for Healthcare Providers” with your personal healthcare provider who can discuss your personal health status and answer any questions you may have.

◆ **“I know I had COVID (or) I received a full course of one of the COVID vaccines. Why is my result Negative?”**

There are many factors that determine an individual’s immunity:

- Age.
- Underlying health conditions that can affect the immune system like diabetes, immunosuppressive therapy, autoimmune conditions, etc.
- The avidity or strength of the antibodies produced in response to an exposure or vaccination.
- The amount of protein (also known as “antigen”) the individual was exposed to.
- The length of time since exposure or vaccination.
- The degree of development of “Memory Cells” by the immune system. Here’s a good link on information about Memory Cells: <https://askabiologist.asu.edu/memory-b-cell>.

Over time, the detectable levels of antibodies (not just COVID, but all antibodies) start decreasing if it has been a while since your body has seen the antigen that caused the antibody to be produced.

This is why sometimes, “booster” vaccines are recommended after certain lengths of time. Tetanus boosters are an example of this.

Having a Negative COVID Antibody results does NOT necessarily mean that you do not have COVID Antibodies. It just means that they may be below the detectable limits of the Roche Diagnostics test that we use. The Roche test is one of the most sensitive and specific tests available.



We strongly urge you to review the “Fact Sheet for Recipients” that can be accessed via a link on the “My Test Results” page on our website when you access your COVID Antibody results. You can also share the “Fact Sheet for Healthcare Providers” with your personal healthcare provider who can discuss your personal health status and answer any questions you may have.

◆ **“I donated on May 18, 2021. Why can I not see my COVID Antibody result from that donation date on your website?”**

We truly apologize for that inconvenience. We experienced some technical difficulties uploading COVID Antibody results from that date to the www.TBCdonors.org website.

Unfortunately, due to the change over to the new COVID Antibody S-protein test, we cannot go back and upload those results.

We have identified those donors who did not have their COVID Antibody results uploaded and are in the process of sending out letters to those affected. Be on the lookout for any correspondence from The Blood Center over the next couple of weeks.

◆ **I donated on May 26, 2021 and watched my COVID Antibody result change. What’s going on?**

Again, we apologize for the confusion. As mentioned above, we experienced technical difficulties uploading the new COVID Antibody test results to the www.TBCdonors.org website.

What was being uploaded after May 19, 2021 were the results for the old COVID Antibody N-protein test.

If you refer to the table below, if you were someone who fell into the category of not being exposed, but being vaccinated (3rd scenario), then your results may have initially been Negative, but changed to Low or High.

Exposed to COVID Virus	Received COVID Vaccine	Possible COVID Antibody to N-Protein Result	Possible COVID Antibody to S-Protein Result
No	No	Negative	Negative
Yes	No	Positive	Low or High
No	Yes	Negative	Low or High
Yes	Yes	Positive	Low or High

THE TECHNICAL DIFFICULTIES WERE FIXED ON JUNE 1, 2021. ANYONE WHO DONATED ON OR AFTER MAY 19, 2021, AND VIEWS THEIR COVID ANTIBODY RESULTS AFTER JUNE 1, 2021 WILL NOW SEE THEIR CORRECT RESULT.

We hope the information above have answered any questions you may have had. If you have any additional questions, please free to contact us at (800)- 86-BLOOD or by e-mail at info@thebloodcenter.org.