FAQs for Blood Donors COVID-19 Antibody Testing

Will the antibody test tell me if I have COVID-19? If you are wondering if you have COVID-19 right now, this test will not help you. The test only shows whether you have been exposed to the virus in the past, not whether you have it now. If you are feeling sick, or if you have been exposed to someone with COVID-19 and you want to know if you are infected, please do NOT donate blood! See your healthcare provider to get a test that will determine if you are infected. We are providing this antibody test to help identify future, potential donors who can give convalescent plasma to help patients currently battling COVID-19.

What COVID-19 antibody test is LifeStream using? LifeStream uses the Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack ("Ortho test") as our main screening test for antibodies against the virus that causes COVID-19 (this testing began in early June 2020). Please visit https://www.fda.gov/media/137362/download to read more about this test. Beginning 9/4/2020, per FDA guidance, LifeStream began using a second antibody test, the Roche Elecsys Anti-SARS-CoV-2 ("Roche test") to further qualify all donors who tested positively on the Ortho test as eligible to give convalescent plasma. The Roche test helps distinguish COVID-19 antibodies from unrelated antibodies the first test may have identified. Please visit https://www.fda.gov/media/137604/download to read more about the Roche test.

How are test results displayed?

- **Positive:** The individual very likely has antibodies to SARS-CoV-2 that resulted from a previous COVID-19 exposure. Please discuss with your healthcare provider if you do not believe you had COVID-19.
- **Negative:** Antibodies to SARS-CoV-2 were not found in the blood. False-negative results may occur. Please discuss with your healthcare provider if you believe you had COVID-19.
- **Blank (no results posted):** Test results are pending.
- **Not Tested:** The blood could not be tested due to an issue with the sample.

How and when will I learn about my COVID-19 antibody test results? Confidential test results will be available in your private, online donor account approximately 2 weeks after your donation. Visit LStream.org/profile/ to view step-by-step instructions.

Is the COVID-19 antibody test the same as the COVID-19 diagnostic test? No. This is not a test that tells a person whether or not they have a current COVID-19 infection. The antibody test determines whether the blood contains antibodies against the SARS-CoV-2 coronavirus, which causes COVID-19. The test does not check for the presence of an active COVID-19 infection. If you’re concerned you might have COVID-19, do not donate. Check with your healthcare provider about getting a diagnostic test.
Can I opt out of antibody testing? No. The COVID-19 antibody test is included in the full panel of tests LifeStream’s laboratory performs on every donation. Their lab is not set up to offer a choice for donors to opt out of this antibody test.

My blood test shows that I have COVID-19 antibodies. Is this something I should be concerned about? For questions about your current state of health, please contact your healthcare provider, who can help you understand the meaning of a positive result for antibodies against the virus that causes COVID-19. In general, having COVID-19 antibodies suggests that you may have been exposed to the virus or that you had COVID-19 at some point. Please see https://www.fda.gov/media/137362/download for info about what a positive result may mean.

If I have a positive antibody test, am I protected from getting COVID-19 again? It is unclear if these antibodies provide long-lasting protection (immunity) against getting infected again. The Centers for Disease Control and Prevention have stated that they do not yet know if antibodies make people immune to the virus. Please discuss this issue with your healthcare provider for more information.

On a previous donation, my blood was “positive” for COVID-19 antibodies, but now, with my most recent donation, my result is “negative.” Why? Once an immune response is no longer needed, over time, the body’s antibody-producing cells often make fewer antibodies (this decrease in antibody production is well-known in COVID-19). As a result, some donors who test positive for antibodies may test negative at a later donation. It is also possible that the earlier result was a “false positive,” meaning that the donor was not in fact positive for antibodies (this is possible especially in donors who had no clear symptoms of COVID-19 or a positive “swab test” for the virus). In addition, the most recent result could be a “false negative,” as this can occur in those who truly carry antibodies (see https://www.fda.gov/media/137362/download for more details).

The best course of action if you want confirmation of your current antibody status is to follow up with your health care provider. You remain eligible to donate blood and we encourage you to do so to ensure that blood is always available in the community.

Do I have to complete a blood donation to get the COVID-19 antibody test? Yes. This test is available only to donors who successfully complete a whole blood, platelet, double red cell or plasma donation, because the antibody test is part of the full panel of tests performed on each complete blood donation. Testing is not performed on incomplete donations.

Do I need to have a donation appointment to receive the COVID-19 antibody test? No. You need to give a complete blood donation to receive the antibody test. While we strongly recommend that donors schedule an appointment, it is not required.
If I cannot donate blood, will I be able to get COVID-19 antibody test results? No. We are offering antibody testing only for complete donations that will be used for patient transfusion. The antibody test is only performed as part of the many tests we conduct on successful blood donations.

I got a positive COVID-19 antibody test result from LifeStream (or another source). Why can’t I give convalescent plasma right away? We greatly appreciate your willingness and desire to help patients battling COVID-19. Even if you have antibodies, you must meet all FDA eligibility criteria before donating convalescent plasma. Our staff will work with you to complete this pre-screening. Please visit LStream.org/covidplasma to complete the online questionnaire and begin the process.

I tested positively for COVID-19 antibodies and want to become a convalescent plasma donor. What should I do? Having a positive result means that you may be eligible to donate what is known as “convalescent plasma” that can be given directly to patients currently battling COVID-19. However, you must be pre-qualified to donate this product. Please go to LStream.org/covidplasma or call 909-386-6837 to start the process.

Are all donation procedures tested for COVID-19 antibodies? Effective November 16, 2020, all platelet donations will receive the COVID-19 antibody test only if 56 or more days have passed since last tested for antibodies by LifeStream. In addition to volunteer whole blood and platelet donors, donors donating for themselves (“Autologous” donors), for a specific patient (“Directed” donors), and those with hereditary hemochromatosis (HH) and testosterone therapy (TT) whose blood may be used for transfusion will also be tested. Those who are donating for therapeutic reasons whose blood is not used for transfusion will not receive the antibody test.

Is LifeStream sharing COVID-19 antibody test results with public health departments, including for the purposes of contact tracing? As standard practice and consistent with other routine infectious disease testing, test results are only released as required by law. Most often data are supplied in aggregate, unless donor identifying information is required.

ADDITIONAL RESOURCES

- LStream.org/COVIDPlasma
- LStream.org/COVID-19/AntibodyTesting
- CDC: Using Antibody Tests
- FDA: EUA Authorized Serology Test Performance
  - Ortho-Clinical Diagnostics VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack.
    - Information for Test Recipients
    - Information for Health Care Providers
  - Roche Elecsys Anti-SARS-CoV-2
    - Information for Test Recipients

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Information for Health Care Providers