



SEVERE ACUTE RESPIRATORY SYNDROME

FORM

Consent Form (SARS Laboratory Testing Public Health Response): Coronavirus Antibody Testing

Information regarding SARS laboratory testing may change. For the most current information and up-to-date version of this document, see www.cdc.gov/ncidod/sars/diagnosis.htm.

Background

Severe Acute Respiratory Syndrome, or SARS, is a respiratory illness caused by a virus. It can start as fever and cough. It may go on to pneumonia in some people and can be serious. SARS may spread easily from person to person. The Centers for Disease Control and Prevention (CDC) and state and public health laboratories are using an experimental laboratory test to help detect people who have been infected with the SARS virus. This test is one tool in a public health response to the SARS outbreak to try to limit spread of this illness. The Food and Drug Administration (FDA) has not approved this test. We don't know for sure if this test can detect all people who may get sick with SARS. There are no proven tests that quickly find the virus.

Who Is Being Tested?

We are asking you (or your child) to be tested for the SARS-related virus because you (or your child):

- Have symptoms that are like the symptoms of SARS, and/or
- Had traveled 10 days before start of symptoms to an area that had reported SARS cases, and/or
- Have cared for, lived with, or had direct contact with a patient with suspected SARS.

Procedures

To do this test, we need a minimum of ¼ teaspoon of blood from children and 1 to 2 teaspoons of blood from adults. This blood may be taken using a needle put into a vein in your (or your child's) arm. This test may also be done on blood that is left over after other tests for your (your child's) care are done.

We may also ask for a second blood sample more than 21 days after you (your child) became sick. We may ask for this second sample in order to test for SARS. This is because this test looks for evidence that the body is fighting the infection (antibodies), and sometimes it takes time for the body to make antibodies to fight the virus.

Are There Any Benefits?

There may be no direct benefits to you (or your child) from having this test done. This test may help to show whether you (your child) have SARS. If people with the SARS virus limit contact with other people, this can prevent others from getting sick. By having this test done, you could lower the chance of spreading the virus from you (your child) to your family or others. It could also help us learn more about this virus to help stop the spread of illness.

Are There Any Risks?

When we take you (your child's) blood, the needle poke may pinch or sting or cause a bruise.

There is a small chance that this test may give a positive result for the SARS virus when the virus is not present (false positive). If your (your child's) result from this test is positive:

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1. You (your child) could be asked to limit contact outside the home by not going to work, school, out-of-home childcare, church, or other public areas. You may also be asked to use a mask at home to limit the risk of spread of the virus. If you (your child) have had symptoms of SARS, you might be asked to follow these limits because of these symptoms and not because of the test results. However, if your (your child's) samples tested positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) has no symptoms.
2. Based on the testing results, your (or your child's) doctor may choose to change how your care will be managed.

This test may give a negative result when you (or your child) actually have the virus (false negative). A false negative result should not have an effect on your (or your child's) care. CDC has told doctors that a negative test does not prove that a person does or does not have the SARS virus. No changes in your medical care or how you interact with people around you should be based on a negative result.

Your (or your child's) doctor will use other information along with this test to decide what is best for you (your child).

Are There Other Choices?

You may refuse to be tested or to have your child tested. There are several other tests for the SARS virus, but they are all experimental and we don't know which tests work the best.

What About Privacy?

We will keep all facts about you (your child) as private as the law allows. CDC, FDA the Local/State Health Department staff, and the person(s) who ordered your test (such as your doctor) may see your/your child's results. When we present or publish papers about these tests, neither you (nor your child) will be identified.

What Are the Costs?

The test will be done by CDC or your health department at no cost. You, your insurer, Medicare or Medicaid will need to pay for other costs related to the testing, such as doctor's visits.

What Happens If You (Your Child) Are Harmed?

If you (your child) are harmed as a result of taking the samples, CDC will not pay the costs for hospital and medical care. You, your insurer, Medicare or Medicaid will need to pay those costs. You (or your child) do not give up any legal rights that otherwise would be available to you (or your child).

Right to Refuse

This testing is voluntary. It is your choice to have this testing done on you (your child). If you refuse to have the testing done, then you (or your child) will not lose the right to get health care because of not having results from these tests. Your doctor will take care of you (your child) in the same way they would take care of you (your child) if this test were not available.

Whom to Call If You Have Questions

Please call your doctor if you have any questions about this testing. If you have questions about your (or your child's) rights as a participant in this testing program or if you feel you have been harmed or injured by taking part in the program, please call the CDC Associate Director for Science at 1-800-584-8814.

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Leave a message including your (or your child's) name, phone number and that the protocol # is 3918. Someone will call you back as soon as possible.

Consent Statement

I agree that this investigational laboratory testing can be done on samples collected from me (my child).

I have read the above and have had my questions answered by _____.

Print Patient's Name: _____

Patient's/Parent's Signature: _____ Date: _____

Witness to signature: _____ Date: _____

Physician witness to signature: _____ Date: _____

Consent for Sample Storage

Thank you for agreeing for you (or your child) to be in this program. We are asking for your consent to store any remainders of your (your child's) samples used for SARS virus testing at CDC for future SARS-related research. If the results of any future tests are important for your medical care we will make every effort to notify your physician.

We will not do human genetic testing or HIV testing unless we contact you and ask for your consent. If you agree to storage and change your mind later please fax Suzette Bartley at 404-639-0590.

- Yes, I agree to long-term storage of my (my child's) samples for future testing
- No, I do not agree to long-term storage of my (my child's) samples for future testing

Print Patient's Name: _____

Patient's/Parent's Signature: _____ Date: _____

NOTE: PLEASE RETURN OR FAX A SIGNED COPY OF THIS FORM TO

Suzette Bartley
Centers for Disease Control and Prevention
1600 Clifton Rd. Mailstop L02
Atlanta, Ga. 30333
FAX: 404-639-0590

For more information, visit www.cdc.gov/ncidod/sars or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)