NOTICE

Since 2004, there have not been any known cases of SARS reported anywhere in the world. The content in this PDF was developed for the 2003 SARS epidemic. But, some guidelines are still being used. Any new SARS updates will be posted on this Web site.

CONSENT FORM (SARS-CoV EIA Laboratory Testing)

[Please send a signed copy of this form with the specimen]

The Centers for Disease Control and Prevention (CDC) and public health laboratories are using an investigational laboratory test to test for the virus that causes "severe acute respiratory syndrome" or (SARS). The Food and Drug Administration (FDA) has not licensed this test. The FDA has agreed that we can use this test as part of the public health response to SARS. We do not know for sure if this test can find all people who may get sick with SARS. There are no FDA approved tests that quickly find the virus.

Your State or Local Health Department and CDC are using the results of this test as one piece of information to help us find out if people are sick with SARS and to limit the spread of this illness. Your (or your child's) doctor will use other information along with this test result to decide what is best for you (your child).

BACKGROUND

SARS is a respiratory illness that can start as fever and cough. It may go on to pneumonia in some people. SARS seems to be spread by close person to person contact. This can occur when a person who is sick with SARS coughs or sneezes onto themselves, other people, or nearby surfaces. Droplets from the cough or sneeze can travel a short distance through the air and land on the mouth, nose, or eyes of persons who are nearby. The virus also can spread when a person touches a surface or object with infectious droplets and then touches his or her mouth, nose, or eye(s). It also is possible that SARS can be spread through the air or by other ways that we don't yet know about.

WHY SHOULD MY (MY CHILD'S) SAMPLE BE TESTED?

You (or your child) may be asked to have SARS testing done when there are no reported cases of SARS in the world or when and if SARS returns. It is important to test for SARS when there are no reported SARS cases so that public health efforts could quickly identify a case and limit its spread. The results of this test, along with other information, may also help your (your child's) doctor take better care of you (your child). You (or your child) may be asked to be tested for the SARS virus because:

1. You (or your child) are being hospitalized for symptoms like pneumonia **and** within 10 days of the start of symptoms you (or your child):
   a. Have traveled to an area that had reported SARS cases in the past, **or**
   b. Had close contact with an ill person who just came back from these areas, **or**
   c. Had close contact with person(s) who have pneumonia like symptoms and have not been diagnosed, **or**
   d. Are employed in a job that may put you at risk for SARS, such as a healthcare worker with direct patient contact or a worker in a laboratory that has live SARS virus.

OR

2. There are reported cases of SARS in the world and you (or your child) have symptoms which may be early symptoms of SARS, such as fever or lower respiratory symptoms or other symptoms your doctor feels might be SARS **and**:
   a. Recent close contact with persons thought to have SARS, **or**
   b. Recent exposure to areas (in the U.S. or outside the U.S.) with confirmed or suspected SARS (or close contact with ill persons with a history of these exposures)

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CENTERS FOR DISEASE CONTROL AND PREVENTION
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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 find the virus in people who do not yet have all the signs of 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 may lower the chance of spreading the virus from you (your child) to your family or others. Use of this test could also help us to know more about this virus to help stop the spread of this illness. The results of this test, along with other information, may help your (your child's) doctor take better care of you (your child).

IF THIS TEST IS POSITIVE, DOES THAT MEAN I (MY CHILD) HAVE SARS AND WHAT ARE THE RISKS OF A POSITIVE RESULT?
There is a small chance that this test may give a positive result for the SARS virus when the virus is not there (false positive). If your (your child's) result from this test is positive:

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. If your (your child's) tests are positive, there is a small chance that you (your child) may be asked to follow these limits even if you (your child) do not seem sick.

2. There is no proven treatment for SARS at this time. If you (your child) your child is very ill, in rare cases, you (your child) may be advised to take an antiviral drug. If this happens, your (your child's) doctor will discuss the risks and benefits and obtain your consent.

3. Your (or your child's) doctor may decide how to care for you based on the test results along with other factors.

IF THIS TEST IS NEGATIVE, DOES THAT MEAN I (MY CHILD) DO NOT HAVE SARS?
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.

ARE THERE ANY RISKS FROM TAKING MY (MY CHILD'S) SAMPLES?
To do this test, extra blood samples may be taken that are like samples that are normally taken for testing when you are sick. Your (your child's) doctor may also ask to take more blood samples in the future.

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 by putting a needle 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 28 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.

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

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ARE THERE OTHER CHOICES?
There are no rapid laboratory tests approved by FDA that can be used to tell if you (or your child) have the virus believed to be causing SARS.

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 named.

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
It is your choice to have this testing done on you (your child). If you refuse to have the testing done, you (or your child) will not lose the right to get health care because of not having results from these tests.

WHO 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. 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 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 Patients Name:_____

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

Legally Authorized Representative Signature :_____ Date :_____

Witness to signature:_____ Date:_____
(required by FDA)

CONSENT FORM (SARS-CoV EIA Laboratory Testing)
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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 doctor.

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 call Dr. Lia Haynes at 404-639-4004.

☐ 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:_____
_____

Legally Authorized Representative
Signature :_____

Date:_____

NOTE: PLEASE INCLUDE A SIGNED COPY OF THIS FORM WITH THE SPECIMEN AND PROVIDE A COPY TO THE PATIENT.

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)

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