

## **PATIENT INFORMATION (SARS Laboratory Testing)**

The Centers for Disease Control and Prevention (CDC) and public health laboratories are using an experimental laboratory test as one tool in a public health response to the “severe acute respiratory syndrome” (SARS) outbreak. 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.

Your State Health Department and/or CDC are using this test as one tool to help us find out if people are infected. We are using this test to respond to the SARS outbreak and limit spread of this illness.

Because SARS can be a serious illness, your State Health Dept and/or CDC have used this test on samples from 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. SARS may also spread by touching the skin of other people or objects with infected droplets and then touching your eye(s), nose, or mouth. This can occur when someone who is sick with SARS coughs or sneezes droplets onto themselves, other people, or nearby surfaces. It also is possible that SARS can be spread through the air or by other ways that we don’t yet know about.

### **WHY WAS I (MY CHILD) TESTED?**

You (your child) were tested for the SARS-related virus because you (your child):

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

The samples used to do this laboratory test may have come from extra nasal swab or aspirate, or throat swab samples, taken from you (or your child) to do this test. These samples may have been taken as part of your routine care to find out what illness you (or your child) have.

### **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 was 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) were 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).

## **ARE THERE ANY RISKS?**

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:

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) have no symptoms.
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. You can refuse such treatments, but if you take them, they might cause side effects.
3. 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 this other information along with this test to decide what is best for you (your child).

Your (or your child's) doctor will use other information along with this test to decide what is best for you (your child). You and your doctor should discuss the result of this test and decisions about your (your child's) care.

## **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, 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 3911. Someone will call you back as soon as possible.

**CONSENT FOR SAMPLE STORAGE:**

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 call Suzette Bartley, Phone: 770 488 7837 (FAX: 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

**SIGNATURE**

I have been provided with the above information about my (my child's) test results.

I have stated whether or not I agree to long term specimen storage.

I have read the above and have had my questions answered by \_\_\_\_\_

Print Patient's Name: \_\_\_\_\_

Patient's/Parent's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Physician's witness to 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  
Phone: 770 488 7837