Fact Sheet for Patients: Understanding Results from the Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR)

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Dear Patient:

If you have received this Fact Sheet, your respiratory and/or blood sample(s) were tested to help determine whether you may be infected with enterovirus D68 (EV-D68), specifically those virus strains detected in North America in 2014. The test that was used on your respiratory and/or blood sample(s) is called the Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR).

The EV-D68 2014 rRT-PCR is a laboratory test designed to help detect EV-D68 in certain individuals. The test has not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, in 2014, the United States experienced a nationwide outbreak of EV-D68 resulting in a substantial increase of specimens requiring lab testing and remains a concern. Therefore, FDA has authorized the emergency use of this test under an Emergency Use Authorization (EUA).

This Fact Sheet contains the minimum information necessary to help you understand the significant known and potential risks and benefits of the emergency use of the CDC's EV-D68 2014 rRT-PCR. If possible, you may want to discuss with your health care professional the benefits and risks described in this Fact Sheet.

What is EV-D68?

EV-D68 is one of more than 100 non-polio enteroviruses. This virus may cause mild to severe respiratory illness or cause no symptoms in some people. Mild symptoms may include runny nose, sneezing, cough, and body and muscle aches. Severe symptoms may include wheezing and difficulty breathing. Since EV-D68 causes respiratory illness, the virus can be found in an infected person's respiratory secretions, such as saliva, nasal mucus, or sputum. The virus has been detected in blood in a small number of individuals and therefore blood may be collected in addition to upper respiratory specimens. EV-D68 likely spreads from person to person when an infected person coughs, sneezes, or touches a surface that is then touched by others.

Why was my sample tested using the EV-D68 2014 rRT-PCR?

Your respiratory and/or blood sample(s) were tested using the EV-D68 2014 rRT-PCR to help determine whether you are infected with EV-D68. The results of this test, along with other information, may help your health care provider take better care of you. The test results could also help public health officials identify and limit the spread of this virus in your community.

What are the known risks and benefits of the EV-D68 2014 rRT-PCR?

Besides minimal potential discomfort during sample collection, there is a very small risk that the test result is incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider take better care of you. Also, knowing your test results may help you take precautions to prevent the spread of the virus to your family or others.

If this test is positive, does it mean that I have EV-D68?

If you have a positive test, it is very likely that you are infected with the EV-D68 virus. Although unlikely, there is a very small chance that this test can give a positive result that is wrong; this is called a "false positive." If your result from this test is positive, your health care provider will determine how to care for you.

If this test is negative, does it mean that I do not have EV-D68?

If you have a negative test, you probably are not infected with EV-D68 and are most likely sick with something else. There is a small chance that this test can give a negative result that is wrong (called a "false negative"), meaning you could possibly still be infected with EV-D68 even though the test is negative. A false positive or a false negative has the potential to delay a correct diagnosis. While a negative test most likely means you do not have EV-D68, your health care provider must consider the test result together with all other aspects of your illness (such as symptoms and possible exposures) in deciding how to treat you.

What is an Emergency Use Authorization (EUA)?

An EUA is a tool that FDA can use to allow the use of certain medical products for emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of *in vitro* diagnostics, such as the EV-D68 2014 rRT-PCR. At this time, there are no FDA-approved/cleared alternative tests available that can detect EV-D68.

FDA has authorized the emergency use of the EV-D68 2014 rRT-PCR to test for the presence of EV-D68 in respiratory and/or blood specimens. Use of this test is authorized only for the duration of the threat of the emergency, unless it is revoked by FDA sooner.

The information in this Fact Sheet is the minimum necessary to inform you of the significant known and potential risks and benefits of the use of the EV-D68 2014 rRT-PCR. You may want to discuss with your health care provider the benefits and risks described in this Fact Sheet.

How can I learn more?

Information about EV-D68 and any significant new findings observed during the course of the emergency use of the EV-D68 2014 rRT-PCR will be made available at http://www.cdc.gov/non-polio-enterovirus/about/EV-D68.html.

Please also contact your health care provider if you have any questions.