

## CONSENT FOR COVID-19 TESTING OF MINOR CHILD

We at Cleveland Metropolitan School District want to offer your minor child free COVID-19 testing to help keep our community safe.

The COVID-19 worldwide pandemic is still a national emergency. To help protect people in our local community, CMSD will follow recommendations from the U.S. Centers for Disease Control and Prevention (CDC) and other state and local public health authorities for COVID-19 testing.

Knowing if your minor child has COVID-19 can help you make decisions to protect your child, yourself, and other people in your family or community.

We hope that you will agree to allow your minor child to take a COVID-19 test. This test is free for you. The test does not include any medical processes that should pose a major risk for your child.

### WHAT YOU NEED TO KNOW

- **How is the sample collected?** The testing involves collecting one or more nasal swabs. We will tell or show your minor child the safe way to collect the swab. We will give your child a swab kit and watch your child gently swab the inside of their nose to collect the swab.

We use nasal swabs because the COVID-19 virus infects the areas in your body that help you breathe.

Most people do not have problems with nasal swabs, but some people may bleed slightly or become faint or feel sick. If this happens to your child, we will want your child to stay with us for a few minutes to be sure that the bleeding has stopped or that your child feels better.

- **Testing the swab for SARS-CoV-2.** We will take your child's swab and send it to a qualified lab that will test it for SARS-CoV-2. The lab will use a test called a "molecular amplification assay" to see if the swab contains evidence of SARS-CoV-2, the virus which causes COVID-19.
- **What constitutes evidence of virus?** If a person is infected with SARS-CoV-2, the virus makes copies of itself in the body. These are markers of the virus. The lab test quickly identifies the presence of SARS-CoV-2, the virus that causes COVID-19.
- **How will I be told about my child's testing results?** The testing results will usually be ready within 2-3 business days from the time the test was taken. If you signed up for the Guardian/Participant portal, you will be able to view your child's test results in the portal. Otherwise, the Health Provider who ordered the test will tell you if your child's test result is positive for presence of the virus. The Health Provider will not contact you if your child's test result is negative.
- **What are the possible risks and benefits of the test?** As with any test, sometimes there may be a false positive or false negative result. Your child's test result itself is not a clinical diagnosis of SARS-CoV-2 infection. A formal diagnosis can only be made by your healthcare provider after they look at all clinical and lab findings. This testing is for you to be aware and to help protect your child, you, your family, and community.

- **Will the test result be kept confidential?** Test results will be kept as private as possible but will be known to the Midwest Coordination Center, the qualified lab and to the CMSD. Federal and state public health agencies and/or local Department(s) of Public Health may require that the Midwest Coordination Center or the qualified lab report any positive test results. If your child's test is positive, your child could be identified through this required reporting.
- **What will be done with my child's nasal swab?** After all testing is done and your child's results have been given to you, your child's nasal swab and information will be kept by the Midwest Coordination Center.

FOR MORE INFORMATION

- For more information about the swab collection and "assay" testing process, please see the attached fact sheets (Patients), Fact Sheet (Health Care Providers).
- If you have questions about the testing processes or this consent form for your child, please contact the School Nurse at Lincoln-West 216-838-7107.

**CONSENT OF PARENT OR GUARDIAN**

I have read and understood the information in this Consent form about COVID-19 testing. I have had the chance to ask questions and have been given the answers I needed.

I have been provided a copy of the Midwest Coordination Center HIPAA Notice of Privacy Practices.

I authorize CMSD to:

- show or help my minor child to collect their nasal swab,
- have my child's swab tested through an approved SARS-CoV-2 test process, and
- communicate about the test results with the approved testing lab, Midwest Coordination Center, or any required federal, state, or local agencies that have the legal authority to obtain testing results that may identify my child.

Student Name: \_\_\_\_\_

(Parent/Guardian)/Signature: \_\_\_\_\_

Parent/Guardian Printed Name: \_\_\_\_\_

Parent/Guardian Phone Number: \_\_\_\_\_

Parent email: \_\_\_\_\_

Date: \_\_\_\_\_ Witness: \_\_\_\_\_

## HIPAA AUTHORIZATION FOR RELEASE OF TEST RESULTS

I have given my consent for my child to take part in COVID-19 testing managed by “Cleveland Metropolitan School District”. By signing this authorization, I also consent to the following uses and sharing of my test results and related personal information:

- The testing laboratory may provide my child’s COVID-19 test result, including health information that could be linked to my child personally, to the Midwest Coordination Center.
- The Midwest Coordination Center may maintain a record of and release my child’s COVID-19 test result, including health information that could be linked to my child personally, to the “CMSD”.
- The “CMSD” may maintain a record of my child’s test result.
- The Midwest Coordination Center, the testing laboratory and the “CMSD” may communicate with each other about my test result and related personal information to manage my child’s test result.

I understand that if my child’s test result or related personal information is shared as I am permitting here, persons authorized to receive the information may not be restricted by federal or state privacy law from further sharing with others.

I understand that I have the right to cancel this authorization at any time, by sending written notice of my cancellation to the Midwest Coordination Center at [Support@testedandprotected.org](mailto:Support@testedandprotected.org).

If I cancel this authorization, I understand it will not affect any previous use or disclosure of my child’s test result before the date that Midwest Coordination Center receives the notice of cancellation.

I understand that I do not need to sign this authorization in order for my child to receive health care treatment (including COVID-19 testing NOT managed by “(CMSD)”) or health insurance benefits.

Unless I cancel this authorization, I understand that it will remain in effect for two years after the date of my signature below, or such earlier date as state law may require.

I understand that I have a right to receive a copy of the authorization once it is signed.

_____ [Name of Child]	_____ Age of child	_____ Date of birth
_____ *[Name of Parent, Guardian, or Legal representative] of [name of Child]	_____ Required Signature	_____ Date

Relationship to Child:

\*This signature is required for this form. This form can be signed by the child's parent, legal representative, court-appointed guardian, or other description.

The signer's relationship to the child must be written on this form. Relationship could be "parent", legal representative, or other description.

# FACT SHEET FOR PATIENTS

Thermo Fisher Scientific, Inc.

Updated: October 9, 2020

TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced

Coronavirus  
Disease 2019  
(COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the TaqPath COVID-19 Combo Kit or the TaqPath COVID-19 Combo Kit Advanced.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

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## What is COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: <https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html>.

## What is the TaqPath COVID-19 Combo Kit and TaqPath COVID-19 Combo Kit Advanced?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

## Why was my sample tested?

You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

Testing of the samples will help find out if you may have COVID-19.

## What are the known and potential risks and benefits of the test?

### Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

### Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

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- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.
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Updated: October 9, 2020

TaqPath™ COVID-19 Combo Kit and TaqPath™ COVID-19 Combo Kit Advanced

Coronavirus  
Disease 2019  
(COVID-19)

## What does it mean if I have a positive test result?

If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms

## What does it mean if I have a negative test result?

A negative test result means that the virus that causes COVID-19 was not found in your sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

## Is this test FDA-approved or cleared?

No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

## What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.