TEST REQUISITION FORM

DOCTOR'S DATA INC.
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inquiries@doctorsdata.com – www.doctorsdata.com

Note: *This form must be completed and signed by both the physician and the financially responsible party in order to avoid processing delays.*

1 Bill to (select one):

- ❑ Physician Account (N/A in NY, NJ or RI) – Complete 1,2,3,4
  (If nothing is selected physician account will be billed)
- ❑ Patient Insurance – Complete Sections 1,2,3,4,6
- ❑ Medicare – Complete Sections 1,2,3,4,6 & ABN on back
- ❑ Payment Enclosed – Complete Sections 1,2,3,4,5

2 Physician Information

Account #:
Name:
Clinic:
Address:.
City/State/Zip:
Country:
Phone #:

Physician Signature:

X *(Required)* _____ Date Ordered:_____

NPI # _____

Medicare will pay only for tests that meet the Medicare coverage criteria and are reasonable and necessary to create or diagnose an individual patient. Medicare does not pay for tests for which documentation, including the patient record, does not support that the tests were reasonable and necessary. Medicare generally does not cover routine screening tests even if the physician or other authorized test orderer considers the tests appropriate for the patient. Your ordering of the test(s) means that you believe the test(s) is medically necessary unless you indicate that it is for screening purposes.

3 Test(s) Ordered *Medicare patients see reverse side for important information.*

❑ SARS-CoV-2 RT-PCR

Collection Information:

→ Date sample was collected: ____/____/____

→ Collection Type ❑ Saliva
❑ Nasopharyngeal swab
❑ Other _____

HCPCS: ICD-10 Diagnosis Codes (required for insurance/Medicare)

U0003 _____ _____ _____ _____ _____

For in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization (EUA) for detection and/or diagnosis of the novel coronavirus (2019-nCoV).

All SARS-CoV-2 results must be reported to Public Health Authorities. Full patient demographics including address and phone number must be provided for specimen processing.

E04.20

Client Reference:

4 Patient Information *Patient / responsible party is financially responsible for any portion of the claim not covered by insurance within 30 days.*

Patient Name: _____ Patient Date of Birth: ____/ ____/ ____ Sex: ❑ Male ❑ Female

Mailing Address: _____

City: _____ State: _____ County (required for NY): _____ Zip: _____

Daytime Phone: (_____) _____ Evening Phone: (_____) _____ Patient Social Security #: _____ - _____ - _____

Responsible Party Name: _____ Responsible Party Social Security #: _____ - _____ - _____

Responsible Party Date of Birth: _____/ _____/ _____ Relationship to Patient: ❑ Self ❑ Spouse ❑ Parent ❑ Other _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Patient/Responsible Party Signature: I authorize and request payment of medical benefits be made directly to Doctor's Data, Inc. I authorize the release of any medical information necessary to process this claim. I agree to be personally and fully responsible for any portion of the claim not covered by my insurance carrier and agree to make such payment within 30 days. A service charge of 1.5% per month may be charged on balances over 30 days.

X (*Required*) _____ Date: _____ ***Medicare Patients read and sign ABN on back of form.***

5 Check or Credit Card Information *Checks may be presented electronically. A NSF fee of $25 will be assessed for returned checks.*

Payment Amount:

$ _____ **USD**

Please do not send cash. A receipt will be provided which can be used to file your own insurance claim.

Credit card from: ❑ Patient ❑ Physician

Select one: ❑ Visa ❑ Mastercard ❑ American Express ❑ Discover

Credit Card #: _____ Expires: _____/ _____

Check from: ❑ Patient ❑ Physician

Cardholder Signature: **X** _____ Printed Name: _____

Check #: _____

Cardholder Address: _____

Make checks payable in U.S. dollars to:
Doctor's Data, Inc.

City: _____ State: _____ Zip: _____

6 Insurance Information *Medicare patients see reverse side for important information*

Fill out **only** if you intend for Doctor's Data to file a claim on your behalf. It is your responsibility to verify insurance coverage. DDI does not guarantee insurance coverage. Please attach a copy of both sides of your insurance card. You are financially responsible for any portion of the claim not covered by insurance.

	Primary	**Secondary**
Insurance Carrier Name:		
Claims Address:		
City/State/Zip:		
Carrier Phone #:	(_____) _____	(_____) _____
Insured's Name:		
Insured's Policy ID # /Medicare #:		
Group #:		
Relationship to Patient:	❑ Self ❑ Spouse ❑ Parent ❑ Other _____	❑ Self ❑ Spouse ❑ Parent ❑ Other _____
Insured's Date of Birth:	____/ ____/ ____	____/ ____/ ____

THIS SPACE FOR LAB USE ONLY

V01.12

No Medicare ABN or signature is required for this test type.

Please take a moment to verify that you have filled out all of the required sections on the front of this form before shipping.

FACT SHEET FOR HEALTHCARE PROVIDERS

Coronavirus Disease 2019 (COVID-19)

PerkinElmer Inc.

July 15, 2021

PerkinElmer® New Coronavirus Nucleic Acid Detection Kit

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the PerkinElmer New Coronavirus Nucleic Acid Detection Kit.

The PerkinElmer New Coronavirus Nucleic Acid Detection Kit is authorized for use with respiratory specimens collected from any individual, including individuals without symptoms or other reasons to suspect COVID-19. The test is also for use with saliva specimens from individuals suspected of COVID-19.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: PerkinElmer, Inc. - PerkinElmer New Coronavirus Nucleic Acid Detection Kit.

What are the symptoms of COVID-19?

Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?

Current information on COVID-19 for healthcare providers is available at CDC's webpage, Information for Healthcare Professionals (see links provided in "*Where can I go for updates and more information?*" section).

- The PerkinElmer New Coronavirus Nucleic Acid Detection Kit can be used to test oropharyngeal swab and nasopharyngeal swab specimens collected by a healthcare provider (HCP), and anterior nasal swab specimens collected by an HCP or self-collected under the supervision of an HCP from any individual, including individuals without symptoms or other reasons to suspect COVID-19.
- The PerkinElmer New Coronavirus Nucleic Acid Detection Kit can also be used to test saliva specimens collected using the SalivaSecure Saliva Collection Kit either by a HCP or self-collected under the supervision of a HCP in a healthcare setting from individuals suspected of COVID-19.
- The PerkinElmer New Coronavirus Nucleic Acid Detection Kit can also be used to test up to five pooled upper respiratory swab specimens (i.e., oropharyngeal swab and nasopharyngeal swab specimens collected by an HCP and anterior nasal swab specimens collected by an HCP or self- collected under the supervision of an HCP) using individual vials containing transport media.
- The PerkinElmer New Coronavirus Nucleic Acid Detection Kit is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19).* For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)* (see links provided in "*Where can I go for updates and more information?*" section).

This test is to be performed only using respiratory specimens collected from any individual, including individuals without symptoms or other reasons to suspect COVID-19. This test can also be performed on saliva specimens from individuals suspected of COVID-19.

What does it mean if the specimen tests positive for the virus that causes COVID-19?

A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088

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FACT SHEET FOR HEALTHCARE PROVIDERS

Coronavirus Disease 2019 (COVID-19)

PerkinElmer Inc.

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with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The PerkinElmer New Coronavirus Nucleic Acid Detection Kit has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that SARS- CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via PerkinElmer New Coronavirus Nucleic Acid Detection Kit.

In addition, asymptomatic people infected with COVID- 19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result. In the absence of symptoms, it is difficult to determine if asymptomatic people have been tested too late or too early. Therefore, negative results in asymptomatic individuals may include individuals who were tested too early and may become positive later, individuals who were tested too late and may have serological evidence of infection, or individuals who were never infected.

Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. Your interpretation of negative results should take into account clinical and epidemiological risk factors. When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative.

If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing using a new sample with a sensitive method or without pooling should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

If a negative result is obtained with a saliva specimen and COVID-19 is still suspected based on exposure history together with other clinical findings, testing an alternative specimen type should be considered by healthcare providers in consultation with public health authorities. Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

The performance of this test was established based on the evaluation of a limited number of clinical specimens. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARSCoV-2 and their prevalence, which change over time.

What is an EUA?

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA 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 (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when

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certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19. The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device- advice-comprehensive-regulatory-assistance/medical- device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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?

CDC webpages:
General: https://www.cdc.gov/coronavirus/2019-ncov/index.html
Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019- nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019- nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019- ncov/php/infection-control.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: (includes links to fact sheet for individuals and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

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FACT SHEET FOR PATIENTS

Coronavirus Disease 2019 (COVID-19)

July 15, 2021

PerkinElmer Inc.

PerkinElmer® New Coronavirus Nucleic Acid Detection Kit

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the PerkinElmer New Coronavirus Nucleic Acid Detection Kit.

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.

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

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 PerkinElmer New Coronavirus Nucleic Acid Detection Kit?

The test is designed to detect the virus that causes COVID-19 in respiratory specimens (for example oropharyngeal, nasopharyngeal, anterior nasal swabs) or saliva.

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.
- You and your healthcare provider believe there is another reason to investigate your COVID-19 infection status.

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.

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. 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

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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FACT SHEET FOR PATIENTS

PerkinElmer Inc.
PerkinElmer® New Coronavirus Nucleic Acid Detection Kit

Coronavirus Disease 2019 (COVID-19)
July 15, 2021

early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected. In particular, people infected with COVID-19 but who have no symptoms may not shed enough virus to trigger a positive test. 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. If you have no symptoms but have been tested because your doctor thought you may have been exposed to COVID-19, you should continue to monitor your health and let your healthcare provider know if you develop any symptoms of COVID-19.

If you develop symptoms you may need another test to determine if you have contracted the virus causing COVID-19. Laboratories may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing. If your test result indicates your specimen was pooled and you have a negative test result there a small chance that your result is incorrect. You should talk with your healthcare provider if you are concerned. 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. FDA may issue an Emergency Use Authorization (EUA) when certain criteria are met, which includes that there are no adequate, approved, available alternatives. 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?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice- comprehensive-regulatory-assistance/medical-device- databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. 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.

If you develop symptoms or your symptoms get worse you should seek medical care. If you have the following symptoms you should seek immediate medical care at the closest emergency room:

- **Trouble breathing**
- **Persistent pain or pressure in the chest**
- **New confusion**
- **Inability to wake up or stay awake**
- **Bluish lips or face**

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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