# FACT SHEET FOR HEALTHCARE PROVIDERS

**Diazyme Laboratories, Inc.** **August 17, 2020**

**Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit**

**Coronavirus Disease 2019 (COVID-19)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit.

**You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection.**

The Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit is authorized for the detection of antibodies to SARS-CoV-2 in human serum or plasma (potassium EDTA, disodium EDTA and lithium heparin).

**All individuals whose specimens are tested with this test will receive the Fact Sheet for Recipients: Diazyme Laboratories, Inc. - Diazyme DZ-Lite SARS-CoV-2 IgM CLIA 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 infection 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.

**This test detects human SARS-CoV-2 antibodies that are generated as part of the human adaptive immune response to the COVID-19 virus and is to be performed on only serum or plasma (potassium EDTA, disodium EDTA and lithium heparin) specimens.**

**What do I need to know about COVID-19 antibody 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 Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit can be ordered by healthcare providers to test human serum or plasma (potassium EDTA, disodium EDTA and lithium heparin) to detect if there has been an adaptive immune response to COVID-19, indicating recent or prior infection.
- The Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit should not be used to diagnose or exclude acute infection and should not be used as the sole basis for treatment or patient management decisions. Direct testing for SARS-CoV-2 should be performed if acute infection is suspected.
- The Diazyme DZ-Lite SARS-CoV-2 IgM CLIA 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 moderate or high complexity tests.
- Please refer to the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit instructions for use for additional information.

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).

**What does it mean if the specimen tests positive for antibodies against the virus that causes COVID-19?**
A positive test result with the SARS-CoV-2 antibody test indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

Antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection. Individuals may have detectable virus present for several weeks following seroconversion. If IgG antibodies are present, it often indicates a past infection but does not exclude recently infected patients who are still contagious.

***It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and it is not known if they confer immunity to infection.***

***Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public.***

***Regardless of the test result, individuals should continue to follow CDC guidelines to reduce the risk of infection, including social distancing and wearing masks.***

False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

The Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to the patient include the following: risk of infection by exposure to persons with active COVID-19. If a recent infection is suspected a false positive result may lead to 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-infected patients, limits in the ability to work, or other unintended adverse effects.

***Due to the risk of false positive results, confirmation of positive results should be considered – using a second, different antibody assay that detects the same type of antibodies.***

Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

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 antibodies against virus that causes COVID-19?**
A negative test result with this test means that SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection. ***However, patients tested early after infection may not have detectable antibodies despite active infection; in addition, it is not certain that all infected patients will develop a detectable antibody response to SARS-CoV-2 infection. A negative result should not be used to rule out infection. Direct testing of SARS-CoV-2 should be performed if acute infection is suspected.***

The absolute sensitivity of the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit is unknown.

Risks to a patient of a false negative result include: restriction of activities potentially deemed acceptable for patients with evidence of an antibody response to SARS-CoV-2, 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

# FACT SHEET FOR HEALTHCARE PROVIDERS

**Diazyme Laboratories, Inc.** **August 17, 2020**

**Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit**

**Coronavirus Disease 2019 (COVID-19)**

**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 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 at diagnosing recent or prior infection with SARSCoV-2 by identifying individuals with an adaptive immune response to the virus that causes 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?**
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?

### CDC webpages:

**General:** https://www.cdc.gov/COVID19
**Symptoms:**
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
**Healthcare Professionals:**
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
**Information for Laboratories:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
**Laboratory Biosafety:** https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
**Isolation Precautions in Healthcare Settings:**
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
**Specimen Collection:** https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
**Infection Control:** https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

### FDA webpages:

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

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**Website:**
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**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**

# FACT SHEET FOR HEALTHCARE PROVIDERS

## P23 LABS TAQPATH SARS-COV-2 ASSAY

**P23 Labs, LLC** **July 10, 2020**

**Coronavirus Disease 2019 (COVID-19)**

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the P23 Labs TaqPath SARS-CoV-2 Assay.

The P23 Labs TaqPath SARS-CoV-2 Assay is authorized for use with respiratory and/or saliva specimens collected from individuals suspected of COVID-19 by their healthcare provider or self-collected using a home collection kit specified in the test's instructions for use.

**All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: P23 Labs TaqPath SARS-CoV-2 Assay.**

**What are the symptoms of COVID-19?**
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage 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 P23 Labs TaqPath SARS-CoV-2 Assay can be used to test oropharyngeal (throat) swabs, nasopharyngeal swabs, anterior nasal and mid-turbinate nasal swabs, nasopharyngeal washes/aspirates or nasal aspirates, bronchoalveolar lavage (BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider.
- The P23 Labs TaqPath SARS-CoV-2 Assay is also for use with saliva specimens that are self-collected at home or in a healthcare setting, with or without the supervision and/or assistance of a HCP, by individuals using the P23 At-Home COVID-19 Test Collection Kit when determined to be appropriate by a HCP based on the results of a COVID-19 medical questionnaire.
- The P23 Labs TaqPath SARS-CoV-2 Assay can also be used with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home-collection kit, when determined to be appropriate by a HCP.
- The P23 Labs TaqPath SARS-CoV-2 Assay is only authorized for use at P23 Labs, LLC, located at 500 S. University Ave., Suite 504, Little Rock, AZ 72205 or other laboratories designated by P23 Labs, LLC that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

**This test is to be performed only using respiratory and/or saliva specimens collected from individuals suspected of COVID-19 by their healthcare provider or self-collected using a home collection kit specified in the test's instructions for use.**

Specimens should be collected with appropriate infection control precautions. Current guidance for COVID-19 infection control precautions are available at the CDC's website (see links provided in "Where can I go for updates and more information" section).

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of having COVID-19 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).

**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 the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.

The P23 Labs TaqPath SARS-CoV-2 Assay has been designed to minimize the likelihood of false positive test results. However, 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, the 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. A negative result does not exclude the possibility of COVID-19.

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 with an alternative method should be considered by healthcare providers in consultation with public health authorities. 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 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.

**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 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?**
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?

### CDC webpages:

**General:** https://www.cdc.gov/COVID19
**Healthcare Professionals:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
**Information for Laboratories:** https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
**Laboratory Biosafety:** https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
**Isolation Precautions in Healthcare Settings:** https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
**Specimen Collection:** https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
**Infection Control:** https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

### FDA webpages:

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

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