FACT SHEET FOR HEALTHCARE PROVIDERS

LIAISON® SARS CoV-2 S1/S2 IgG assay– DiaSorin Inc. **April 24, 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 LIAISON®SARS-CoVs S1/S2 IgG assay.

The LIAISON®SARS-CoVs S1/S2 IgG assay is authorized for the detection of IgG antibodies to SARS-CoV-2 in human serum or plasma specimens

This test measures human SARS-CoV-2 IgG antibodies, that are generated as part of the human adaptive immune response to the virus and is to be performed only using serum or plasma specimens.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Recipients: LIAISON®SARS-CoV-2 S1/S2 IgG assay.

What are the symptoms of COVID-19?
Many individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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 poses risks to 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 LIAISON®SARS-CoVs S1/S2 IgG assay can be used to test human serum or plasma (sodium heparin, lithium heparin, and potassium EDTA) specimens.
- The LIAISON®SARS-CoVs S1/S2 IgG assay can be ordered by a healthcare provider to detect if there has been an adaptive immune response to COVID-19, indicating a recent or prior infection.
- The LIAISON®SARS-CoVs S1/S2 IgG assay is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests.

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 IgG antibodies against virus that causes COVID-19?
A positive test result with the LIAISON®SARS-CoVs S1/S2 IgG assay indicates that antibodies to SARS-CoV-2 were detected, and the individual has potentially been exposed to COVID-19.

IgG antibodies are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

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**

When IgG antibodies are present it often indicates a past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long IgG antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive result for IgG may not mean that an individual's current or past symptoms were due to COVID-19 infection. 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.

The LIAISON®SARS-CoV-2 S1/S2 IgG assay has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks to individuals could 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 individual, monitoring of household or other close contacts for symptoms, isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19-infected individuals, limits in the ability to work, or other unintended adverse effects.

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

What does it mean if the specimen tests negative for IgG 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, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment, patient management decisions, or to rule out active infection.

Individuals tested early after infection may not have detectable IgG antibody despite active infection; in addition, not all individuals will develop a detectable IgG response to SARS-CoV-2 infection. The absolute sensitivity of the LIAISON®SARS-CoVs S1/S2 IgG assay is unknown.

When testing is negative, the possibility of a false negative result should be considered in the context of an individual'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 individual's recent exposure or clinical presentation indicate that COVID- 19 is likely and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any individual suspected of COVID-19, regardless of the LIAISON®SARS-CoV-2 S1/S2 IgG assay result.

Risks to an individual of a false negative result include: restriction of activities deemed acceptable for individuals with evidence of an IgG response to SARS-CoV-2, 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 the detection of IgG antibodies 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).

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 recipient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

DiaSorin S.p.A:

Via Crescentino snc
13040 Saluggia (VC) Italy

Website: www.diasorin.com

For Customer Service in the U.S. call toll free: 1-800-328-1482.

FACT SHEET FOR HEALTHCARE PROVIDERS

Elecsys Anti-SARS-CoV-2 **May 2, 2020**

Roche Diagnostics

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 Elecsys Anti-SARS-CoV-2 immunoassay.

The Elecsys Anti-SARS-CoV-2 immunoassay is authorized for on the detection of antibodies to SARS-CoV-2 in human serum or plasma.

All individuals whose specimens are tested with this assay will receive the Fact Sheet for Patients: Elecsys Anti-SARS-CoV-2.

What are the symptoms of COVID-19?
Most individuals with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. 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 4-5 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 poses 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, including case definitions and infection control, 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 Elecsys Anti-SARS-CoV-2 immunoassay can be used to test human serum or plasma (Heparin, EDTA).
- The Elecsys Anti-SARS-CoV-2 immunoassay should be ordered by a healthcare provider to detect if there has been an adaptive immune response to COVID-19, indicating a recent or prior infection.

This test measures human SARS-CoV-2 antibodies that are generated as part of the adaptive human immune response to the virus and is to be performed only using serum or plasma specimens.

- The Elecsys Anti-SARS-CoV-2 immunoassay is only authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) 42 U.S.C. §263a, to perform moderate or high complexity tests.
- The Elecsys Anti-SARS-CoV-2 immunoassay 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.

Specimens should be collected with appropriate infection control precautions following CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.*

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)*. These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. 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 for this test indicates that antibodies against SARS-CoV-2 were detected, and the individual has potentially been exposed to SARS-CoV-2.

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**

Antibodies are generally detectable several days following infection. A positive result can indicate recent or past infection but does not exclude recently infected individuals who are still contagious. It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection.

A positive antibody result may not mean that an individual's current symptoms are due to COVID-19 infection. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making patient management decisions.

The Elecsys Anti-SARS-CoV-2 immunoassay 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 confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for antibodies against the virus that causes COVID-19?
A negative test result for this test means that anti-SARS-CoV-2 specific antibodies were not present in the specimen above the limit of detection of the assay. 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 .

Individuals tested early after infection may not have detectable antibody response despite active infection; in addition, not all patients will develop a detectable antibody response to SARS-CoV-2 infection. The absolute sensitivity of the Elecsys Anti-SARS-CoV-2 immunoassay is unknown.

When testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. This is especially important if the individual has had recent exposure to COVID-19, or clinical presentation suggestive of COVID-19, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. Direct testing for virus (e.g., PCR testing) should always be performed in any patient suspected of COVID-19 regardless of Elecsys Anti-SARS-CoV-2 Immunoassay results.

Risks to a patient resulting from a false negative 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.

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 the detection of 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).

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/emergency-situations-medical-devices/emergency-use-authorizations

Roche Diagnostics GmbH
Sandhofer Strasse 116, D-68305 Mannheim, Germany

Roche HCP Support: 1-866-987-6243
diagnostics.roche.com