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MEMORANDUM **NOTE DE SERVICE**

TO Rosslynn Miller-Lee
Executive Director,
Medical Device Evaluation Bureau
MDD

FROM Emily Hollink
DE MDD

SUBJECT Recommendation for Authorization under the COVID-19 Interim Order
OBJET Manufacturer: DiaSorin Inc.

Device: DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG assay and the LIAISON® Control SARS-CoV-2 S1/S2 IgG
Application: 314838

Background

The application for the DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG assay and the LIAISON® Control SARS-CoV-2 S1/S2 IgG was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order will allow the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

The information submitted was evaluated based on the Health Canada Guidance: Requirements for Serological Antibody Tests Submitted under the COVID-19 Interim Order.

The DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG assay received a US FDA Emergency Use Authorization (EUA) on April 24, 2020.

Intended Use

The LIAISON® SARS-CoV-2 S1/S2 IgG is a chemiluminescent immunoassay (CLIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, and plasma (sodium heparin, lithium heparin, and potassium EDTA). The LIAISON® SARS-CoV-2 S1/S2 IgG is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The LIAISON® SARS-CoV-2 S1/S2 IgG should not be used to diagnose acute SARS-CoV-2 infection.

The LIAISON® SARS-CoV-2 S1/S2 IgG is to be used on the LIAISON® XL Analyzer.

Results are for the detection of SARS CoV-2 antibodies. IgG antibodies to SARS-CoV-2 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.

Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARSCoV-2 is necessary.

False positive results for LIAISON® SARS-CoV-2 S1/S2 IgG may occur due to cross-reactivity from pre-existing antibodies or other possible causes.

[*IFU 200/007-798, 03 – 2020-05*]

Discussion: The information provided meets the minimum requirements to authorize the DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG assay and the LIAISON® Control SARS-CoV-2 S1/S2 IgG under the Interim Order.

The LIAISON instrument has a Class III medical device licence, thus this application builds off a platform with experience of use in Canada. Pre-clinical studies included assessment of many of the requested potentially interfering substances outlined in the serological guidance. The remaining information will be requested as a post-authorization study, given the high demonstrated clinical sensitivity and specificity.

Clinical sensitivity (97%) was assessed in 76 patients and presented over time: The highest sensitivity for the test is observed 2 weeks after diagnosis with PCR, which is consistent with known available evidence on the development of IgG antibodies post-infection. Clinical specificity (99%) was assessed using 1090 samples collected prior to COVID-19.

The labelling includes detailed information to communicate test performance, and includes clear information to distinguish clinical sensitivity over time. The minimum requirements outlined in both the Regulations and in the serological guidance have been met.

The product is manufactured in Italy.

Based on the scientific evidence available, it is reasonable that the test will be effective for the claimed intended use. In the current context related to COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits associated with increased testing capacity that will be facilitated by the authorization for sale of this assay.

RECOMMENDATION:

Authorize the DiaSorin LIAISON® SARS-CoV-2 S1/S2 IgG assay and the LIAISON® Control SARS-CoV-2 S1/S2 IgG with the following conditions:

Within one month:

1) Submit a plan to Health Canada that will assess the performance of the test when used in the intended sites. This may be supported by identification of a minimum of two Canadian sites where the performance of the test will be monitored.

2) Provide complete biotin interference data determining the lowest concentration of biotin that may cause clinically significant interference.

3) To supplement information on endogenous cross-reactivity studies already included in your application, provide a cross reactivity study for the following endogenous

substances: protein, total IgM, total IgG and antibodies developed against protein expression system used to generate recombinant antigens.

4) Given that some samples to assess cross reactivity are unavailable, provide a plan to assess cross-reactivity for the following endogenous substances and pathogens:

Mandatory organisms

- Human coronavirus 229E
- Human coronavirus NL63
- Adenovirus (e.g. C1 Ad. 71)
- Parainfluenza virus 1- 4
- Human Metapneumovirus (hMPV)
- Enterovirus (e.g. EV68)
- Rhinovirus

Optional organisms

- MERS
- HIV
- Norovirus
- *Haemophilus influenza*
- *Legionella pneumophila*
- *Mycobacterium tuberculosis*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Chlamydia pneumonia*
- *Pneumocystis jiroveci (PJP)*
- *Candida albicans*
- *Pseudomonas aeruginosa*
- *Staphylococcus epidermis*
- *Staphylococcus salivarius*
- *T. pallidum*

When available:

5) Provide a summary of the cross-reactivity studies.

6) Provide the final reagent stability report upon completion of the study. Health Canada expects that the stability studies will be initiated immediately upon authorization.

[signed in docuBridge]		I concur / Je suis d'accord	
	2020-05-9		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date