TO **A**	Rosslynn Miller-Lee Executive Director, Medical Device Evaluation Bureau MDD
FROM **DE**	Emily Hollink Medical Device Directorate

Application Information *Information de soumission*			
Application ***Soumission*** 313727	**Name of device** ***Nom de l'homologation*** ANTI-SARS-COV-2 ELISA (IGG).	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument***
Application Type ***Type de soumission*** APPLICATION UNDER IO	**Licence Type** ***Type d'homologation*** SINGLE DEVICE	**Manufacturer** ***Fabricant*** EUROIMMUN MEDICAL DIAGNOSTICS CANADA INC.	**Company ID** ***No. d'entreprise*** 116604
Division: IN VITRO DIAGNOSTICS	Date Assigned: *Date assignée:* 2020-09-09		Date Completed: *Date d'achèvement:* 2020-09-17

Technology	Antibody
Test Setting	Lab

1 Background/*Antécédents*

The application for the Euroimmun Anti-SARS-CoV-2 ELISA (IgG) assay was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order allows 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, and the Notice on Sensitivity and Specificity Values.

The Anti-SARS-CoV-2 ELISA (IgG) assay received a US FDA Emergency Use Authorization on May 4, 2020.

2 Intended Use

ANTI-SARS-COV-2 ELISA (IGG) Package Insert [EI_2606G_A_CA_CQ3.docx, Version: 2020-08-2]

The EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) is an enzyme-linked immunosorbent assay intended for the qualitative in vitro determination of human antibodies of the immunoglobulin class IgG against SARS-CoV-2 in human serum and plasma (EDTA, heparin or citrate) in the general population

- The assay is for use in conjunction with the testing strategy outlined by the respective public health authorities in charge.
- Negative results do not exclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- False positive results for IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
- This assay is not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 infection.
- This assay is not intended for home-testing (or self-testing).
- Negative results must be combined with clinical observations, patient history and epidemiological information.
- False negative results can occur in elderly and immunocompromised patients.

3 Discussion/*Évaluation*

The information provided meets the minimum requirements for issue of Authorization under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.

The manufacturer holds a valid MDSAP Certificate. Completed preclinical studies included limit of detection, precision and endogenous interference. Studies for cross-reactivity, class specificity and interference are on-going. The outstanding results will be the subject of a condition.

Evidence of acceptable clinical performance was demonstrated through two studies. The first study tested 1,151 negative clinical samples that demonstrated specificity between 98.7% to 100% depending on the population. In the second study, 75 clinical positive samples and 1419 negative clinical samples were tested and demonstrated sensitivity at 90.7% to 94.7% and specificity at 99.1% to 99.6%, depending on how borderline results were interpreted. Clinical results demonstrate cross reactivity in patients with SARS-CoV-1 antibodies, thus the labelling includes a limitation to inform the user.

Information from 12 peer-reviewed scientific publications was also considered. These publications demonstrate that the sensitivity meets the minimum Health Canada requirements in all cases, although the specificity is variable: Only 9/12 of the studies included results that would meet Health Canada specificity requirements. As with the manufacturer's data, some of this variability may be attributed to how borderline results are interpreted. This variability has been risk managed by communicating the clinical implications of borderline results interpretation in the labelling.

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.

4 Recommendation

Authorize the Euroimmun Anti-SARS-CoV-2 ELISA (IgG) assay 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 sites where the performance of the test will be monitored.

2) Provide the results of a shipping stability study.

3) Provide the results of a class specificity study.

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

Mandatory cross-reactivity studies

- Epstein-Barr virus (infectious mononucleosis)
- Human Metapneumovirus (hMPV)
- Influenza A & B
- Parainfluenza virus 1- 4
- Rhinovirus

Optional organisms

- Mycoplasma pneumoniae
- Chlamydia pneumoniae
- Haemophilus influenzae
- Legionella pneumophila
- Mycobacterium tuberculosis
- Streptococcus pneumoniae
- Streptococcus pyogenes
- Bordetella pertussis
- HBV
- Pneumocystis jiroveci (PJP)
- Candida albicans
- Pseudomonas aeruginosa
- Staphylococcus epidermis
- Staphylococcus salivarius
- HCV
- Norovirus
- HIV

When available:

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

6) Provide the final in-use and real-time reagent stability report upon completion of the studies.

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Signed in Docubridge		Signed in Docubridge	
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date