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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: Roche Diagnostics GmbH

Device: ELECSYS Anti-SARS-CoV-2
Application: 314982

Background

The application for the ELECSYS Anti-SARS-CoV-2 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.

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

Intended Use

Elecsys Anti-SARS-CoV-2 is an immunoassay for the in vitro qualitative detection of antibodies (including IgG) to Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in human serum and plasma. The test is intended as an aid in the determination of the immune reaction to SARS-CoV-2.

This assay is not intended to be used for screening patients or as an aid for diagnosis of patients with suspected COVID-19 infection.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.

Negative results must be combined with clinical observations, patient history, and epidemiological information.

False negative results can occur in elderly and immunocompromised patients.

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

The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers”

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Discussion: The information provided meets the minimum requirements to authorize the ELECSYS Anti-SARS-CoV-2 assay under the Interim Order.

The cobas e 801, 411, 601 and 602 instruments all have Class IV medical device licences, 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 was assessed in 102 patients and presented over time: The highest sensitivity for the test is observed 2 weeks after diagnosis with PCR (99%), which is consistent with known available evidence on the development of IgG antibodies post-infection. Clinical specificity (>99%) was assessed using 10,453 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 assay is manufactured in Germany.

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 ELECSYS Anti-SARS-CoV-2 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 Canadian sites where the performance of the test will be monitored.

2) To supplement information on cross-reactivity studies already included in your application, provide a study that assesses potential interference for hematocrit, anti-nuclear antibodies, and human anti-mouse antibodies; and for the potential interference by medications commonly prescribed in the intended patient population.

3) To further supplement information on cross-reactivity studies already included in your application, provide a plan to assess cross-reactivity for the following endogenous substances and pathogens:

Mandatory organisms

- Adenovirus (e.g. C1 Ad. 71)
- Parainfluenza virus 1- 4
- Human Metapneumovirus (hMPV)
- Enterovirus (e.g. EV68)
- Rhinovirus
- Respiratory synctytial virus
- SARS

Optional organisms

- MERS
- Norovirus
- *Haemophilus influenza*
- *Legionella pneumophila*
- *Mycobacterium tuberculosis*
- *Streptococcus pneumoniae*
- *Streptococcus pyogenes*
- *Bordetella pertussis*
- *Mycoplasma pneumonia*
- *Pneumocystis jiroveci (PJP)*
- *Candida albicans*
- *Staphylococcus epidermis*
- *Staphylococcus salivarius*

4) To supplement the precision results already included in your application, provide the results of a full study evaluating the repeatability of the assay (20x2x2) or a full study evaluating reproducibility (3x5x5) per CLSI EP05-A3.

When available:

5) Provide a summary of the cross-reactivity studies and a study assessing the potential for the assay to demonstrate a hook effect.

6) Provide the final reagent stability report upon completion of the study.

[signed in docuBridge]		I concur / Je suis d'accord	
	2020-06-4		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date