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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: Abbott Laboratories, Diagnostics Division

Device: SARS-CoV-2-IgG (Aliniti i instrument)
Application: 315790

Background

The application for the SARS-CoV-2-IgG (Aliniti i instrument) 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.

Performance for the SARS-CoV-2-IgG (Aliniti i instrument) is cross-referenced with the application for the ARCHITECT SARS-CoV-2-IgG Assay (authorization 314941).

The SARS-CoV-2-IgG (Aliniti i instrument) Assay received a US FDA Emergency Use Authorization (EUA) on April 26, 2020.

Intended Use

The SARS-CoV-2 IgG assay is a chemiluminescent microparticle immunoassay (CMIA) intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum, serum separator tube and plasma (ACD, CPD, CPDA-1, dipotassium EDTA, tripotassium EDTA, lithium heparin, lithium heparin separator tube, sodium citrate, sodium heparin). The SARS-CoV-2 IgG assay 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 SARSCoV-2 IgG assay should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C 263a, to perform moderate or high complexity test.

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.

Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of SARS-CoV-2 IgG early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

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

The SARS-CoV-2 IgG assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

[Package Insert SARS-CoV-2 IgG For use with Alinity i, 06R90, H14814R01, April 2020]

Discussion: The information provided meets the minimum requirements to authorize the SARS-CoV-2-IgG (Aliniti i instrument) Assay under the Interim Order.

The Aliniti i instrument has a Class IV medical device licence, thus this application builds off a platform in the highest risk class, and with experience of use in Canada.

Studies to demonstrate performance for a medical device licence using different instruments with the same assay were discussed with the manufacturer on October 5, 2016: The studies contained in this application were consistent with the requirements outlined at this 2016 meeting. These analytical studies included precision, calibration frequency, stability, clinical agreement, and within-assay sample carryover.

Analytical studies demonstrate consistent results between the two instruments (ARCHITECT and Alinity i). Clinical agreement was demonstrated by assessment of 35 positive and 100 negative samples. Results were concordant for 134/135 samples; the one discordant sample was close to the cutoff index, and is more likely reflective of variability of results at this concentration, rather than variability of results between instrument technologies.

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.

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 SARS-CoV-2-IgG (Aliniti i instrument) Assay with the following conditions:

Given that performance for the SARS-CoV-2-IgG (Aliniti i instrument) is cross-referenced with the ARCHITECT SARS-CoV-2-IgG Assay (authorization 314941), some of the conditions that are currently in place will not be repeated in this authorization.

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.

When available:

2) Provide revised labelling to remove references to CLIA and other US-specific language from the intended use statement and other sections in the labelling.
3) When commercial reference material is available, provide the results of an analytical sensitivity study for the SARS-CoV-2 IgG assay on the Alinity i instrument.

[signed in docuBridge]		I concur / Je suis d'accord	
	2020-06-10		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date