



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: Luminex Corporation

Device: ARIES SARS-CoV-2 Assay

Application: 313812

Background

The application for the ARIES 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 Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes COVID-19, issued by the US FDA on March 12, 2020. While an updated version of this template has since been issued, the application for this assay and instrument were first reviewed in early April, thus the assay was assessed using the guidance in place at the time of application.

The ARIES SARS-CoV-2 Assay received a US FDA Emergency Use Authorization on April 3, 2020.

Intended Use

ARIES® SARS-CoV-2 Assay is a Real-Time reverse-transcriptase polymerase chain reaction (RT-PCR) based qualitative in vitro diagnostic test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories are required to report all positive results to the appropriate public health authorities.

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.

The ARIES SARS-CoV-2 Assay is intended for use by trained clinical laboratory personnel specifically instructed and trained on Luminex® ARIES Systems and in vitro diagnostic procedures. The ARIES SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

The ARIES SARS-CoV-2 Assay is indicated for use with the ARIES Systems.

89-30000-00-868 Rev 3

Discussion: The information provided meets the minimum requirements to authorize the ARIES SARS-CoV-2 Assay under the Interim Order.

There are two ARIES instruments with a Class III medical device licence, thus this application builds off a platform with experience of use in Canada. Pre-clinical studies included limit of detection, inclusivity, and cross reactivity studies.

According to a public list of all US FDA authorized PCR tests, the ARIES SARS-CoV-2 Assay is one of the least sensitive tests authorized (75,000 copies/mL). The package insert includes information about the limit of detection study, thus a knowledgeable user could assess performance.

Clinical performance was evaluated using 30 contrived positive samples, including 20 samples at two times the limit of detection, and 30 individual negative clinical samples collected from patients with signs and symptoms of upper respiratory tract infection. All samples generated expected results.

The labelling includes detailed information to communicate test performance, and includes clear information to distinguish clinical sensitivity over time. The minimum requirements outlined in the Regulations and in the FDA template 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 ARIES SARS-CoV-2 Assay with the following condition:

Within three months:

- 1) To supplement information on cross-reactivity studies already included in your application, provide a cross reactivity study for *Pneumocystis jiroveci* (PJP).

[signed in docuBridge]

I concur / Je suis d'accord

Emily Hollink

2020-06-9
Date

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Bureau/ Bureau de
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médicaux

Date