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MEMORANDUM / **NOTE DE SERVICE**

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

FROM / DE Patrice Sarrazin
IVD Device Evaluation Division
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SUBJECT / OBJET Recommendation for Authorization under Interim Order 32 COVID-19
Manufacturer: **Quidel**

Device: Lyra SARS-CoV-2 Assay (application #312783)

Background

On March 19, 2020, Health Canada received an application from Quidel seeking authorization for sale for the Lyra SARS-CoV-2 RT-PCR assay intended for the detection of SARS-CoV-2 in nasal or nasopharyngeal (NP) swabs specimens.

This application was submitted under the Interim Order 32 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 pursuant to 33 subsection 30.1(1) of the Food and Drugs Act. 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.

To support the safety and effectiveness of the assay, a copy of the application for Emergency Use Authorization submitted by Quidel to the USA FDA for the Lyra SARS-CoV-2 RT-PCR assay was submitted to Health Canada.

The information submitted was evaluated based on the *Policy for Diagnostics Tests for Coronavirus Disease 2019 during the Public Health Emergency* guidance issued by the US FDA on March 16, 2020, and on the *EUA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 That Causes COVID-19* issued by the US FDA on March 12, 2020. The requirements described in the Interim Order (IO) were also evaluated.

The Lyra SARS-CoV-2 RT-PCR assay received an FDA USA Emergency Use Authorization (EUA) on March 17, 2020.

Intended Use

The Lyra SARS-CoV-2 Assay is a real-time RT-PCR assay intended for the in vitro qualitative detection of human coronavirus SARS-CoV-2 from viral RNA extracted from nasopharyngeal (NP) or oropharyngeal (OP) swab specimens from patients suspected of COVID-19 by their healthcare provider. The Assay targets the non-structural Polyprotein (pp1ab) of the SARS-CoV-2 virus. The authorized testing consists of nucleic acid extraction on the bioMerieux NucliSENS® easyMAG® system or EMAG system, followed by RT-PCR on the FDA-cleared real-time PCR Instrument.

Results are for the identification of SARS-CoV-2. The SARS-CoV-2 is generally detectable in nasopharyngeal and oropharyngeal 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. Laboratories within the United States and its territories 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 Lyra SARS-CoV-2 Assay is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Lyra SARS-CoV-2 Assay is only for use under the Emergency Use Authorization.

[Lyra SARS-CoV-2 Assay product insert; PIM120000EN00 (03/20)]

Discussion: The information provided meets the minimum requirements for issue of Authorization under Interim Order 32.

Studies for Limit of Detection, Reactivity/Inclusivity, Cross-reactivity and Clinical evaluation using contrived specimens, were provided and determined to be acceptable. Endogenous interference was not validated. However, this is not identified as a minimum requirement since PCR is a well-established PCR method thus evaluation of endogenous interference is not critical.

Labelling meets the minimum requirements of the Regulations. The package insert includes information on the LoD study, Inclusivity, Cross-Reactivity, and Clinical Performance information that was presented in this application. Limitations section is included to indicate that the assay should be interpreted in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests.

The box and vial labels include the manufacturer's name and address, as well as the name of the device and its part number. They comply with the requirements described in Section 10 of the Interim Order.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer are sufficient for a temporary authorization given that the benefits that may be obtained from authorizing this assay for SARS-CoV-2 detection outweigh the risks related to the current COVID-19 national health emergency.

RECOMMENDATION:

Authorization of the Lyra SARS-CoV-2 Assay under Interim Order 32.

I concur / Je suis d'accord

Patrice Sarrazin In Vitro Diagnostic Section / Matériels diagnostiques in vitro Device Evaluation Division / Division de l'Évaluation des Matériels	2020-03-25 Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date