Government of Canada / **Gouvernement du Canada**

MEMORANDUM / **NOTE DE SERVICE**

TO Jeffrey Skene
A/ Director,
Medical Device Evaluation Bureau
MDD

FROM Emily Hollink
DE Medical Device Directorate

SUBJECT Recommendation for Authorization under Interim Order COVID-19
OBJET

Manufacturer: Diagnostic Hybrids, Inc. - Also trading as Quidel Corporation

Device: Lyra Direct SARS-CoV-2 Assay

Technology: Molecular ***Setting:*** Laboratory

Application No.: 315563

Background

On 2020-05-04, Health Canada received an application for authorization under the Interim Order of the Lyra Direct SARS-COV-2 ASSAY submitted by Diagnostic Hybrids, Inc. also trading as Quidel Corporation. The device is intended for the molecular-based detection of SARS-CoV-2 in nasal (NS), nasopharyngeal (NP), or oropharyngeal (OP) direct swab specimens.

The assay is a modification of the Lyra SARS-CoV-2 Assay which received an Interim Order Authorization (IO312783) on March 25, 2020 and a FDA EUA200016/A002. The Lyra Direct SARS-CoV-2 Assay employs an extraction-less method, e.g., without easyMAG® system or EMAG® system and uses the same SARS-CoV-2 primers and probes as the Lyra SARS CoV-2 Assay (M120). The 'direct' assay design follows the methodology that was used for the Class III Lyra Direct Strep (licence #98677, licence discontinued 2018) and Lyra Direct HSV 1+2/VZV (licence #93578) assays.

The Lyra Direct SARS-CoV-2 Assay is based on the chemistry and testing protocol used by four (4) FDA-cleared (Class II Health Canada licenced) assays [Lyra Influenza A+B Assay (k131728; Licence No.: 91194), Lyra RSV+hMPV Assay (k131813; Licence No.: 91007 (801086)), Lyra Parainfluenza Virus Assay (k141927; Licence No.: 95842 (809917)), Lyra Adenovirus Assay (k141931 Licence No.: 95831 (809823))] and one FDA-Emergency Use Authorization (Lyra Influenza A Subtype H7N9 Assay).

Intended Use

The Lyra Direct SARS-CoV-2 Assay is a real-time RT-PCR assay intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal (NS), nasopharyngeal (NP), or oropharyngeal (OP) direct 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.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 is generally detectable in upper respiratory 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 Direct 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.

Discussion:

The information provided meets the minimum requirements to issue an Authorization under the Interim Order.

Studies for Limit of Detection, Reactivity/Inclusivity, Cross-reactivity and Clinical evaluation using contrived specimens, were provided and determined to be acceptable. Endogenous interference validation was supported with data from the endogenous interference study performed with the Lyra Direct Strep Assay (Application 249743), which demonstrated the absence of interference with 17 potentially interfering/cross-reactive substances that may be present in throat specimens at clinically relevant levels. As the Lyra Direct SARS-CoV-2 Assay and the Lyra Direct Strep Assay use the same technology, the results of the can be applied to the Lyra Direct SARS-CoV-2 Assay.

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. A limitations section indicates 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.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer are sufficient for an 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 Direct SARS-CoV-2 Assay under the Interim Order with the following conditions:

Within one month:

1) 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: Human Coronavirus HKU, Candida albicans, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus salivarius and Mycobacterium tuberculosis.

When available:

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

3) Provide the results of the real-time stability study.

I concur / Je suis d'accord

Emily Hollink	2020-07-17 Date	**Jeffrey Skene** A/ Director/ Directeur Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date