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MEMORANDUM **NOTE DE SERVICE**

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

FROM / DE Maria Carballo, Manager
IVD Device Evaluation Division
MDD

SUBJECT / OBJET Recommendation for Authorization under Interim Order 32 COVID-19
Manufacturer: **SOLGENT Co. Ltd.**

Device: DIAPLEXQ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT
Application: 312756

Background

On March 18th, 2020, Health Canada received an application submitted by SOLGENT Co. for authorization of their DIAPLEXQ NOVEL CORONAVIRUS (2019-NCOV) DETECTION KIT intended for the detection of SARS-CoV-2 in nasopharyngeal swab, oropharyngeal swab, or sputum specimens. Further information was received on March 26, March 31, and April 1, 2020.

The application was reviewed 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.

The information submitted was evaluated based on the Medical Devices Regulations and the "*Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency"* Guidance issued by the US FDA on February 29, 2020.

The device was approved by the Korea Centers for Disease Control and Prevention (KCDC) under Emergency Use Approval February 27th 2020. CE marked as of Feb. 2020.

Intended Use

"DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the

SARS-CoV-2 in respiratory specimens such as nasopharyngeal swab or oropharyngeal swab or sputum from individuals suspected of COVID-19 that meet the CDC SARS-CoV-2 clinical criteria.

Results are for the presumptive detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2 but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
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 test is intended for use by trained clinical laboratory professionals.
a) The patients being tested meet the CDC SARS-CoV-2 clinical criteria.
b) Positive results are indicative of active infection.
c) 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.
d) The test is intended for use by trained clinical laboratory professionals.

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, Microbial interference, and Clinical evaluation using contrived specimens, were provided and determined to be acceptable except for the Limit of detection study which was not conducted with an artificial matrix or clinical matrix. The manufacturer has committed to complete the study as required by April 20, 2020. Completion of this test is the subject of one of the conditions imposed on the Authorization. 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 with minor exemptions that will be addressed by the manufacturer as per the second condition imposed on the Authorization.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer provide reasonable assurance that the DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit will perform as claimed for its intended use under the current COVID-19 national health emergency.

RECOMMENDATION:

Authorization of the DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit under Interim Order 32 with the following conditions:

Provide by April 20, 2020:

1. An analytical sensitivity study (protocol, results, conclusion) using samples diluted in an artificial or clinical matrix.

2. Revise the Instructions for Use (IFU) as follows:

a) delete sections 5.8, 5.9 and 5.10.

b) include, under the Performance characteristics section, a summary of the inclusivity study and the clinical study including the results.

c) revise the Intended use statement to read:
"DiaPlexQ™ Novel Coronavirus (2019-nCoV) Detection Kit is a real-time RT-PCR test intended for the presumptive qualitative detection of nucleic acid from the SARS-CoV-2 in respiratory specimens such as nasopharyngeal swab or oropharyngeal swab or sputum from individuals suspected of COVID-19 that meet the CDC SARS-CoV-2 clinical criteria.
Results are for the presumptive detection and identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2 but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
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 test is intended for use by trained clinical laboratory professionals.

d) Include a version number and date in the IFU

I concur / Je suis d'accord

	2020-04-03		
Maria Carballo Manager, In Vitro Diagnostic Section / chef, Matériels diagnostiques in vitro Device Evaluation Division / Division de l'Évaluation des Matériels	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date