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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
MDD

SUBJECT
OBJET Recommendation for Authorization under Interim Order 32 COVID-19
Manufacturer: **Abbott**

Device: Abbott RealTime SARS-CoV-2 assay (application #312977)

Background

On March 25, 2020, Health Canada received an application from Abbott seeking authorization for sale for the Abbott RealTime SARS-CoV-2 assay intended for the detection of SARS-CoV-2 in nasal or nasopharyngeal (NP) swabs specimens.

This application was submitted under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 pursuant to 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 Abott to the USA FDA for the Abbott RealTime SARS-CoV-2 assay was submitted to Health Canada.

The information submitted is currently 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) are also being evaluated.

The Abbott RealTime SARS-CoV-2 assay received an FDA USA Emergency Use Authorization (EUA) on March 18, 2020.

Intended Use

The Abbott RealTime SARS-CoV-2 assay is a real-time (rt) reverse transcriptase (RT) polymerase chain reaction (PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal (NP) and oropharyngeal (OP) swabs from patients suspected of COVID-19 by their health care provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal and oropharyngeal swabs 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 Abbott RealTime 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 Abbott RealTime SARS-CoV-2 assay is only for use under the Food and Drug Administration's Emergency Use Authorization. [Abbott RealTime SARS-CoV-2 assay product insert; 51-608445/R1 (03/20)]

Discussion:

The pre-market documentation provided by Abbott is deemed to include satisfactory information to allow the scientific review. The review of this application is currently ongoing. However, Abbott informed Health Canada that approximately 200 000 COVID-19 tests allocated for Canada are ready to ship from a US warehouse. If these tests are not moved quickly, these kits will be reallocated elsewhere. Abbott Canada would like to ship them today to secure the Canadian allocation.

In the absence of a final decision confirming that the test can detect SARS-CoV-2, Health Canada will issue an authorization under the Medical Devices Interim Order, with a condition that the sale or import of the product is to be for research use only until such time as Health Canada assesses the documentation submitted by Abbott. If the safety and effectiveness of the test are adequately supported, this condition will be removed by Health Canada.

RECOMMENDATION:

Authorization of the Abbott RealTime SARS-CoV-2 assay under the Interim Order with the following condition:

The sale or import of the product is to be for research use only until such time as Health Canada assesses the documentation submitted by Abbott and removes this condition.

I concur / Je suis d'accord

	2020-03-25		
Patrice Sarrazin In Vitro Diagnostic Section / 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