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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 COVID-19

Manufacturer: BGI AMERICAS CORP

Device: Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV

Application No.: 312912

Background

On 2020-04-02, Health Canada received an application for authorization under the Interim Order for the Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV submitted by BGI AMERICAS CORP. The device is intended for the molecular-based detection of SARS-CoV-2 in throat swabs and bronchoalveolar lavage fluid (BALF).

Further information was received on April 21, 2020. In this response, the manufacturer also included new information, specifically the addition of a new extraction method (to be performed both manually and automatically) and addition of three additional RT-PCR instruments. A further response to a request for information was received on April 28, 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.

Intended Use

The *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* is an *in vitro* diagnostic real-time reverse transcription-PCR assay for the qualitative detection of SARS-CoV-2 nucleic acids in throat (oropharyngeal) swabs, nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage fluid (BALF) from individuals who are suspected of COVID-19 by their healthcare provider.

Test results are for the 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 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 *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and *in vitro* diagnostic procedures.

[PI April 28 2020]

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

The manufacturer holds a valid ISO 13495 Certificate. Studies for Limit of Detection (LoD), Reactivity/Inclusivity, Cross-reactivity, and reagent stability, and Clinical evaluation using clinical samples were determined to be acceptable. The added extraction method was properly validated with both the manual and automated modes. Validation of 3 extra PCR instruments (ABI 7500 Fast real time PCR system, Roche LightCycler 480 System, and QuantStudio 5 Real-Time PCR System) to run the assay was performed in a bridging study using both recommended specimens, throat swabs and BAL. The data obtained showed that the LoD of assay on the 3 instruments is comparable to that obtained with the originally validated Applied Biosystems Real Time PCR System 7500.

Labelling meets the minimum requirements of the Regulations with minor exemptions that will be addressed through the condition imposed to the authorization. The other conditions refer to stability and wet testing of two additional microorganisms.

In the context of the COVID-19 pandemic, the validation studies provided by the manufacturer provide reasonable assurance that the *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* will perform as claimed for its intended use under the current COVID-19 national health emergency.

RECOMMENDATION:

Authorization of the *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* under Interim Order 32 with the following conditions:

1. As the last time point evaluated in the stability study for the JEV assay is 12 months, the stability claim cannot be 12 months. Revise the current stability claim for the Real-Time fluorescent RT-PCR kit to 8 months at -18°C.

2. Provide, when available, data from wet testing *Staphylococcus epidermidis and Staphylococcus salivaris*.

3. Revise the IFU to exclude the entire section "Conditions of authorization for the laboratory" as well as the first paragraph of the "Limitations" section.

I concur / Je suis d'accord

	2020-05-03		
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