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MEMORANDUM **NOTE DE SERVICE**

TO **Rosslynn Miller-Lee**
Executive Director/ Directrice Executive
Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux

FROM / DE **Emily Hollink**

SUBJECT / OBJET Recommendation for Authorization under Interim Order COVID-19

Manufacturer: Ningbo Health Gene Technologies CO., LTD
Device: SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR method)

Technology: Molecular *Setting:* Laboratory

Application No.: 312918

Background

The application for the SARS-CoV-2 Virus Detection Diagnostic Kit was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.

The information submitted was evaluated based on the Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes COVID-19, issued by the US FDA on March 12, 2020. While an updated version of this template has since been issued, the application for this assay was submitted in March, thus the assay was assessed using the guidance in place at the time of application.

Intended Use

This kit is used for in vitro qualitative detection of SARS-CoV-2 ORF1ab gene, N gene and S gene in specimens of sputum, nasopharyngeal or oropharyngeal swabs. The test is intended for use by trained clinical laboratory professionals.

The patients being tested should meet SARS-CoV-2 clinical criteria. Positive results are indicative of active infection. 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.

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

Preclinical performance was demonstrated through studies to support the limit of detection, inclusivity, precision, and analytical specificity (endogenous interference; cross reactivity with medications and other viral and bacterial pathogens).

Clinical performance was assessed using contrived and clinical specimens. The 30 positive and 30 negative contrived results were as expected. Sensitivity and specificity were both 100% for 215 patient samples, which included 127 positive samples.

Labelling meets the minimum requirements of the Regulations. A 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 assay is manufactured in China.

Based on the scientific evidence available, it is reasonable that the test will be effective for the claimed intended use. In the current context related to COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits that will be facilitated by the authorization for sale of this assay.

RECOMMENDATION:

Authorization of the SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method) under the Interim Order with the following condition:

When available:

1. Provide shelf life and in-use stability study results, as well as results from a study validating shipping at high temperatures (≥37°C).

[signed in docuBridge]		I concur / Je suis d'accord	
_____	2020-08-07	_____	_____
Emily Hollink Medical Devices Directorate/ Direction des instruments médicaux	Date	**Rosslynn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date