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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: OSANG HEALTHCARE CO., LTD.

Device: GENEFINDER COVID-19 PLUS REALAMP KIT Application: 312757

**Background**

On March 18, 2020, Health Canada received an application submitted by OSANG HEALTHCARE CO. LTD, for authorization of their GENEFINDER COVID-19 PLUS REALAMP KIT intended for the detection of SARS-CoV-2 nucleic acid in sputum, bronchoalveolar lavage fluid (BAL), nasopharyngeal swab, and oropharyngeal swab specimens. Further information was received on March 30, April 6, and April 17, 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***

GeneFinderTM COVID-19 Plus RealAmp kit is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in Sputum, bronchoalveolar lavage fluid (BAL), nasopharyngeal swab, and oropharyngeal swab from individuals suspected of COVID-19.

Results are for the 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 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
[Package Insert March-2020 (rev.2) IFMR-45]

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

The assay received FDA EUA on April 18, 2020.

Studies for Limit of Detection, Reactivity/Inclusivity, reagent stability, and Cross-reactivity. The cross reactivity studies provided, covering the majority of the recommended organisms that should be tested, either by *in silico* analysis or testing of nucleic acid, showed no cross reactivity (except to SARS-CoV-1) was detected. However, it is recommended that a condition be imposed on the authorization for the completion of *in silico* analysis or wet testing to evaluate cross reactivity with the organisms that were not tested. Clinical performance of the assay, evaluated using residual clinical specimens (nasopharyngeal swab and sputum) previously collected from patients with signs and symptoms of respiratory infection, was acceptable. 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 through the conditions imposed to the authorization. Included in the conditions is the request to complete stability studies.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer provide reasonable assurance that the GENEFINDER COVID-19 PLUS REALAMP KIT will perform as claimed for its intended use under the current COVID-19 national health emergency.

## RECOMMENDATION:

Authorization of the GENEFINDER COVID-19 PLUS REALAMP KIT under Interim Order 32 with the following conditions:

1. Provide, by May 24, 2020:
   a) the analysis of cross reactivity by *in silico* testing of the following organisms: Adenovirus, Parainfluenza virus 1-4, Influenza A & B, Respiratory syncytial virus, Rhinovirus, Mycoplasma pneumonia, Staphylococcus epidermis and

Staphylococcus salivarius.

b) evaluation of cross reactivity using wet testing for Human Metapneumovirus (hMPV), Enterovirus, Chlamydia pneumonia, Haemophilus influenza, Legionella pneumophila, Mycobacterium tuberculosis, Streptococcus pneumonia, Streptococcus pyogenes, Bordetella pertussis, Mycoplasma pneumoniae, Pneumocystis jirovecii (PJP), Pooled human nasal wash - to represent diverse microbial flora in the human respiratory tract, Candida albicans, Pseudomonas aeruginosa, Staphylococcus epidermis and Staphylococcus salivarius.

c) Provide a revised IFU with:
   i. the updated cross reactivity in silico and wet testing studies that include a list of the organisms tested,
   ii. revise the second sentence in Section 9.1: "For the diagnostic tests for SARS-CoV-2, please refer to your National Guidelines for the handling and transport of the samples."

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

I concur / Je suis d'accord

| | 2020-04-21 | | |
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| **Maria Carballo**<br>Manager, In Vitro Diagnostic Section / chef, Matériels diagnostiques in vitro<br>Device Evaluation Division / Division de l'Évaluation des Matériels | Date | **Rosslyn Miller-Lee**<br>Executive Director/ Directrice Executive<br>Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux | Date |