Application Information *Information de soumission*			
Application ***Soumission*** 312912	**Licence Name** ***Nom de l'homologation*** REAL-TIME FLUORESCENT RT-PCR KIT FOR DETECTING SARS-COV-2	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument*** 3
Application Type ***Type de soumission*** Application under IO	**Licence Type** ***Type d'homologation*** Test Kit	**Manufacturer** ***Fabricant*** BGI AMERICAS CORP	**Company ID** ***No. d'entreprise*** 151819

Note to File Purpose *Objet de Note au dossier*		
Subject/*Objectif* **Response to conditional authorization #2**		
Division: IVDD	Date Assigned: *Date assignée:* **May 22, 2020**	Date Completed: *Date d'achèvement:* **May 22, 2020**
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1 Background/*Antécédents*

On May 4, 2020, BGI Americas Corp. was granted, under Interim Order in relation to COVID-19, an Authorization for Import or Sale of Real-Time fluorescent RT-PCR kit for detecting SARS-CoV-2 with conditions. On May 05, 2020, the manufacturer provided the responses to request 1 and 3. After review, a request for additional information was sent to the manufacturer on May 08, 2020. The response to this request was submitted to Health Canada on May 19, 2020 and is reviewed below.

2 Evaluation/*Évaluation*

AI-1: Regarding the Instructions For Use (IFU);

a) You were asked to remove the first paragraph (or sentence) of the limitation section and not the entire limitation section. Please revise the IFU to include the limitation section but without the first sentence as shown below:

~~The use of this assay as an *in vitro* diagnostic under the Interim Order for use in relation to COVID19 is limited to laboratories to perform high complexity tests.~~

Use of this assay is limited to personnel who are trained in the procedure. Failure to follow these instructions may result in erroneous results.

The performance of *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* was established using throat (oropharyngeal) swabs and bronchoalveolar lavage fluid (BALF) samples. Nasopharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates are also considered acceptable specimen types for use with the *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* but performance has not been established. Testing of nasal and mid-turbinate nasal swabs (self-collected or collected by a healthcare provider) is limited to patients with symptoms of COVID-19.

Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.

Extraction and amplification of nucleic acid from clinical samples must be performed according the specified methods listed in this procedure. Other extraction approaches and processing systems have not been evaluated.

False-negative results may arise from:

- Improper sample collection
- Degradation of the viral RNA during shipping/storage
- Using unauthorized extraction or assay reagents
- The presence of RT-PCR inhibitors
- Mutation in the SARS-CoV-2 virus
- Failure to follow instructions for use

False-positive results may arise from:

- Cross contamination during specimen handling or preparation
- Cross contamination between patient samples
- Specimen mix-up
- RNA contamination during product handling

The effect of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated.

Negative results do not preclude infection with SARS-CoV-2 virus and should not be the sole basis of a patient management decision.

A positive result indicates the detection of nucleic acid from SARS-CoV-2.

Nucleic acid may persist even after the virus is no longer viable.

Laboratories are required to report all positive results to the appropriate public health authorities.

b) In addition, please update the revision date on the IFU from April 28, 2020 to the date of the latest revision.

Reviewer's Discussion
A revised IFU (version V3, May 09, 2020) was provided containing the requested modifications.

3 Conclusion

The manufacturer properly addressed the request for IFU revision. Therefore, the recommendation is for the removal of conditions 1 and 3. As condition 2 has not been addressed yet, the conditions to the authorization should be revised to keep only condition 2.

4 Recommendation

Removal of conditions 1 and 3. Conditions should be revised as follows:

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