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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 Re-issue of 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 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 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.

On May 05, 2020, the manufacturer provided the responses to remove conditions 1 and 3. A further information request was issued on May 8 to revise the IFU to which the manufacturer responded on May 19, 2020.

Discussion: The manufacturer addressed conditions 1 and 3 as requested. However, the request under condition 2 to submit data from wet testing Staphylococcus epidermidis and Staphylococcus salivaris is still pending.

RECOMMENDATION:

Remove conditions 1 and 3, response to condition 2 is still pending. Re-issue Authorization of the *Real-Time Fluorescent RT-PCR Kit for Detecting SARS-CoV-2* under Interim Order 32 with the following condition:

1. Provide by June 30, 2020, data from wet testing *Staphylococcus epidermidis and Staphylococcus salivaris*.

I concur / Je suis d'accord

	2020-05-25		
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