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**MEMORANDUM** **NOTE DE SERVICE**

**TO** Rosslynn Miller-Lee
Executive Director,
Medical Device Evaluation Bureau
MDD

**FROM** Emily Hollink
**DE** MDD

**SUBJECT** Recommendation for Authorization under the COVID-19 Interim Order
**OBJET** Manufacturer: Biomeme, Inc.

Device: Biomeme SARS-CoV-2 Go-Strips for use with the Biomeme's Franklin Real-Time PCR System
Application: 312839

Background

The application for the Biomeme SARS-CoV-2 Go-Strips for use with the Biomeme's Franklin Real-Time PCR System was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order allows 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 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 and instrument were submitted in March, thus the assay was assessed using the guidance in place at the time of application.

The Biomeme SARS-CoV-2 Go-Strips and the Biomeme's Franklin Real-Time PCR System have not received an Emergency Use Authorization (EUA) from the US FDA to sell these devices as of June 26, 2020. However, One Health Systems, LLC received an EUA from the US FDA to perform SARS-CoV-2 testing in a CLIA-certified laboratory using these devices on May 13, 2020.

***Intended Use***

Biomeme SARS-CoV-2 for use on the Biomeme's Franklin Real-Time PCR System is a real-time RT-PCR test intended for qualitative detection of RNA from SARS-CoV-2 in nasopharyngeal and oropharyngeal (throat) swab samples collected by a healthcare professional from patients who meet SARS-CoV-2 clinical and/or epidemiological criteria. Testing is for use by trained clinical laboratory personnel only. This device is not intended for use at the point-of-care (near-patient). Positive results are indicative of an active infection; 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 target 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 Biomeme SARS-CoV-2 Real-Time RT-PCR Test 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.

This device is not intended for use at the point of care (near patient).

*Note: Nasal swabs and mid-turbinate swabs are considered acceptable specimen types for use with Biomeme's SARS-CoV-2 Real Time RT-PCR test, but performance with these specimen types has not been established. Testing of nasal and mid-turbinate nasal swabs (collected by a healthcare provider) is limited to patients with symptoms of COVID-19.*

Discussion: The information provided meets the minimum requirements to authorize the Biomeme SARS-CoV-2 Go-Strips for use with the Biomeme's Franklin Real-Time PCR System under the Interim Order.

The instrument is portable and its format permits point of care use; however, the device is intended for laboratory use only at this time.

Given that the manufacturer has never participated in a quality systems audit, the Quality Systems group of the Bureau of Planning and Operations contributed significantly to this review through a series of questions and teleconferences with the manufacturer. While not all quality systems requirements to meet ISO 13485 are currently in place, the manufacturer indicated that they intend to become a recognized medical device manufacturer, and seek Quality Systems certification in the future. The sum total of quality systems information provides sufficient evidence of quality systems under the Interim Order.

The authorization is for the instrument and the assay, and includes a device-specific extraction method. Information to support authorization of the instrument included a declaration of conformity to Health Canada recognized standards, and a software review conducted by the Digital Health group of the Evaluation Bureau. Preclinical performance of the assay with the instrument included studies to support the limit of detection, assay carry-over, inclusivity and endogenous interference. "Wet" cross reactivity studies will be undertaken to supplement the in silico analyses.

Clinical data was supported through two studies: The first study evaluated 20 positive and 30 negative contrived clinical samples, and all results were as expected. The second study evaluated 65 patient samples and compared results using US or Health Canada authorized tests: The final correlation was 64/65, reflecting a sensitivity of 100% for 47 positive samples, and a specificity of 94.4% when considering 18 reference negative samples.

The labelling includes detailed information to communicate test performance. The minimum requirements outlined in both the Regulations and in the US FDA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes COVID-19.

The assay is manufactured in the United States.

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 b facilitated by the authorization for sale of this assay. A post-market condition to monitor test performance will further facilitate assessment.

**RECOMMENDATION:**

Authorize the Biomeme SARS-CoV-2 Go-Strips for use with the Biomeme's Franklin Real-Time PCR System with the following conditions:

Within one month:

1) Submit a plan to Health Canada that will assess the performance of the test when used in the intended sites. This may be supported by identification of a minimum of two Canadian sites where the performance of the test will be monitored.

2) To supplement information included in your application, provide the results of the "wet" cross-reactivity study with the organisms recommended in the EUA Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that Causes COVID-19, published by the USA FDA.

Within two months:

3) Provide the results of a precision study evaluating repeatability of the assay. The study should follow the guidelines established in CLSI EP05.

When available:

4) Provide the results of the stability studies, including the Sample Prep Cartridge, SARS-CoV-2 Go-Strips, and RPC buffer.

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| [signed in docuBridge] | | I concur / Je suis d'accord | |
| | 2020-06-29 | | |
| **Emily Hollink** | Date | **Rosslyn Miller-Lee**<br>Executive Director/<br>Directrice Executive<br>Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux | Date |