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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: BIOFIRE DEFENSE, LLC

Device: **BIOFIRE COVID - 19 TEST &**
BIOFIRE COVID - 19 External Control test kit (+)

Application No.: 314097

Background

On 2020-04-17, Health Canada received an application for authorization under the Interim Order for the Biofire *COVID-19 Test* submitted by Biofire Defense. The device is intended for the molecular-based detection of SARS-CoV-2 in nasopharyngeal swabs. The application includes the following:

BioFire COVID -19 Test Ref. 423744

BioFire COVID-19 Test External Control Kit (+) Ref. 423748

Further information was received on April 29, 2020.

The Biofire COVID-19 test can be run on both the Film Array 2.0 and the FilmArray Torch, which is a modification of the FilmArray 2.0 with a smaller footprint and higher throughput. Both systems are licensed in Canada under licence 96211 and 102421 respectively.

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

The BioFire® COVID-19 Test is a nested multiplexed real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs in transport media from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to U.S. laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity tests, and in U.S. laboratories certified under CLIA to perform high complexity tests, or in similarly qualified non-U.S. laboratories.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal swabs in transport media during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; 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 agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

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 BioFire COVID-19 Test is intended for use by laboratory personnel who have received specific training on the use of the FilmArray® 2.0 and/or the FilmArray® Torch Instrument Systems. The BioFire COVID-19 Test is only for use under the Food and Drug Administration's Emergency Use Authorization.
For In Vitro Diagnostic Use.

[PI DFA2-PRT-0080-01, March 2020]

The BioFire COVID-19 Test External Control Kit (+) is external positive assayed quality control kit to monitor the performance of the BioFire COVID-19 Test performed on FilmArray® 2.0 and FilmArray Torch® systems.
[Biofire External Control kit Quick Guide for Biofire COVID-19 test – DFA2-PRT-0084-01].

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

The BIOFIRE COVID - 19 TEST and the Biofire COVID-19 External control test (+) are approved by the US FDA under EUA. Sales have only been reported to occur on the US market.

The manufacturer holds a valid MDSAP Certificate. Studies for Limit of Detection (LoD), Reactivity/Inclusivity, Cross-reactivity, and reagent stability, and Clinical evaluation using contrived specimens and clinical samples were determined to be

acceptable. Justification was provided to leverage the previous testing data obtained from the BioFire RP2 Panel for other studies such as endogenous interference and verification of the LoD on the Film Array Torch Instrument.

Note: the Biofire RP2 panel test is approved by the FDA. In Canada the previous version of this test, the Biofire RP panel is licensed. Approval of the Biofire RP2 by the FDA is recognized and accepted by HC. Substantial equivalence of the FilmArray RP panel (licence # 96037) used with the FilmArray Torch and the FilmArray 2.0 instrument was already demonstrated.

Labelling meets the minimum requirements of the Regulations with minor exemptions that will be addressed through the condition imposed to the authorization.

In the context of the COVID-19 pandemic, the validation studies provided by the manufacturer provide reasonable assurance that the BIOFIRE COVID - 19 TEST and the BIOFIRE COVID-19 External control test (+) will perform as claimed for their intended use under the current COVID-19 national health emergency.

RECOMMENDATION:

Authorization of the BIOFIRE COVID - 19 TEST and the Biofire COVID-19 External control test (+) under Interim Order 32 with the following condition:

1. Once logistical challenges are resolved, provide an IFU with the following changes:
a) Revise the Intended use statement by removing the reference to CLIA and other FDA specific language.
b) Revise the Limitations section to include the following sentence: "It has been noted high titers of *Candida albicans* may interfere with the internal yeast RNA control".

Note: At this time, no time frame for this revision is being imposed.

I concur / Je suis d'accord

	2020-05-02		
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