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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: 1DROP INC

Device: 1copy™ COVID-19 qPCR Multi Kit – **Application No. 312777**

**Background**

On March 19, 2020, Health Canada received an application from Drop Inc. for their 1copy™ COVID-19 qPCR Multi Kit in the context of Health Canada's Interim Order regarding 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.

As of March 29, 2020, the 1copy™ COVID-19 qPCR Multi Kit is not included in the FDA USA Emergency Use Authorization (EUA) listing of diagnostic kits for COVID 19.

***Intended Use***

1copy™ COVID-19 qPCR Multi Kit is an in vitro real-time RT-PCR test for qualitative detection of the E gene and RdRp gene of SARS-CoV-2 extracted RNA from nasopharyngeal swab and oropharyngeal swab from individuals with signs and symptoms of infection who are suspected of COVID-19.

The patients being tested meet the CDC SARS-CoV-2 clinical criteria. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable

in nasopharyngeal swab and oropharyngeal swab during the acute phase of infection. Positive results are indicative of active infection. 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 1copy™ COVID-19 qPCR Multi Kit 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.
[DR-M22-2088-E-00 Rev. Date: March 2020].

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

Studies for Limit of Detection, Reactivity/Inclusivity, Cross-reactivity/Microbial interference, reagent stability, and Clinical evaluation using contrived specimens, were provided and determined to be 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. The manufacturer has provided the protocols to validate and establish the stability claims for the device. A condition is being imposed on the Authorization for the manufacturer to provide when available the results for the shelf life, in-use stability as well as shipping stability at high temperatures. The current claim for shelf life is 12 months and is based on the similarities of the test with other similar devices produced by the manufacturer.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer provide reasonable assurance that the 1copy™ COVID-19 qPCR Multi Kit will perform as claimed for its intended use under the current COVID-19 national health emergency.

## RECOMMENDATION:

Authorization of the1copy™ COVID-19 qPCR Multi Kit under Interim Order 32 with the following condition:

Provide, when available, 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

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| | 2020-03-29 | | |
| **Maria Carballo**<br>Manager, In Vitro Diagnostic Device Evaluation / chef, Matériels diagnostiques in vitro | Date | **Rosslyn Miller-Lee**<br>Executive Director/ Directrice Executive<br>Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux | Date |