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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: ThermoFisher Scientific
Device: TaqPath COVID-19 Combo Kit Assay
Application: 312749

Background

The TaqPath COVID-19 Combo Kit Assay was initially authorized as one of the first two available COVID-19 tests on March 18, 2020. The manufacturer submitted a response to two previous and iterative conditions that sought information on endogenous interference and software. The latest letter describing the condition on the authorization is specific to software only, since the condition for information on endogenous interference was imposed at the original authorization, prior to formal documentation using existing processes. However, the information reviewed and summarized herein addressed both of these conditions.

In addition to providing information to respond to the two conditions, the manufacturer also submitted an amendment request that included:

1) The addition of two new PCR instruments (QuantStudio 5 96-well and 384-well PCR platforms)
2) Updates to the interpretive software
3) Addition of new sample types (oropharyngeal, nasal, and mid-turbinate)

This information 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. Further, the information was evaluated based on the March, May and June versions of the US FDA Molecular Diagnostic Template for Manufacturers.

The TaqPath COVID-19 Combo Kit Assay received a US FDA Emergency Use Authorization (EUA) on March 13, 2020.

Intended Use

TaqPath™ COVID-19 Combo Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the presumptive qualitative

detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal oropharyngeal, nasal, and mid- turbinate swabs, and nasopharyngeal aspirate) and bronchoalveolar lavage (BAL) specimens from individuals meeting COVID-19 clinical criteria (e.g., clinical signs and symptoms associated with SARS-CoV-2 infection) in conjunction with COVID-19 epidemiological criteria (e.g., history of residence in or travel to a geographic region with active SARS-CoV-2 transmission at the time of travel, or other epidemiologic criteria for which SARS- CoV-2 testing may be indicated).

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory and bronchoalveolar lavage (BAL) specimens during the acute phase of infection. Positive results are indicative of active infection but do not rule out bacterial infection or co- infection with other viruses. The agent 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.

Testing with the TaqPath™ COVID-19 Combo 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. The TaqPath™ COVID-19 Combo Kit is only for use under the Health Canada Special Authorization.

[MAN0019211_TaqPath COVID-19 Combo Kit_IVD_IFU_RevC_22Apr2020]

Discussion: The information provided meets the minimum requirements to authorize requested amendments to the TaqPath COVID-19 Combo Kit Assay under the Interim Order, and to modify the existing conditions to the authorization.

To support changes to the authorization, the following information was submitted:

A study that examined 11 common interfering substances found no clinically relevant impact on the test results;
Bridging studies supported validation of software updates, and use of the assay on new claimed instruments; and
Additional sample types supported by the US CDC were added, with a limitation in the labelling indicating that these sample types have not been explicitly validated, and that they must be collected by a health care professional.

The bridging studies in support of use of the TaqPath COVID-19 Combo Kit Assay on the two new instruments were nearly complete. While interim information on the limit of detection was provided, a confirmatory study remains outstanding. By allowing this study to be conducted as a post-authorization condition, the manufacturer indicated that they could work with customers to implement software changes immediately, and increase access through use on additional instruments. This outstanding study will affirm analytical sensitivity on the new instruments, while allowing laboratories time to perform their respective validations of the assay on the new instruments in advance of the expected seasonal influx of infections this fall.

The labelling includes detailed information to communicate test performance. The minimum requirements outlined in the Regulations have been met.

In the current context related to COVID-19 pandemic, the risks related to the use of this assay are outweighed by the benefits associated with increased testing capacity that will be facilitated by the authorization for sale of this assay.

RECOMMENDATION:

Previously, the TaqPath COVID-19 Combo Kit Assay was authorized with the following conditions:

The results of the study evaluating interference by endogenous substances must be submitted to Health Canada upon conclusion of the study by March 20, 2020.

Provide, when available, information on the differences between the Interpretive Software v1.1 and v1.0.

Authorization of the TaqPath COVID-19 Combo Kit Assay is now recommended with the following revised condition:

Within two months:

To supplement information already included in your application, provide a limit of detection confirmatory study for the TaqPath COVID-19 Combo Kit Assay when used on the QuantStudio 5 96-well and 384-well PCR platforms.

[signed in docuBridge]		I concur / Je suis d'accord	
	2020-08-11		
Emily Hollink	Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date