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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 removal of conditions/ re-issuance of IO Authorization

Manufacturer: **Hologic Inc.**

Device: Panther Fusion® SARS-CoV-2 Assay **Application: 312758**

Technology: Molecular Setting: Laboratory

Background

On March 25, 2020, Hologic Inc. was granted, under Interim Order in relation to COVID-19, an Authorization for Import or Sale of their Panther Fusion SARS-COV-2 assay with the following condition:

1. Revise and submit, when available, the Instructions for Use (IFU) to create an IFU specific for use in Canada that contains all of the same information as the IFU submitted except for the US specific EUA statements and US specific lab authorization requirements language.

The response to this condition was received on April 24, 2020. The revised IFU provided by the manufacturer contained additional claims: the use nasal and lower tract respiratory specimens (brochoalveolar lavage fluid and bronchial wash specimens); the use of other transport media and swabs that had not been validated in the initial submission. A request for additional information was sent to the manufacturer on April 28, 2020 to substantiate the new claims. The response was received by Health Canada on May 04, 2020.

Intended Use (revised)

The Panther Fusion™ SARS-CoV-2 assay is a real-time RT-PCR in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, oropharyngeal (OP) swab specimens and lower respiratory tract (LRT) specimens obtained from individuals who meet COVID-19 clinical and/or epidemiological criteria.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in nasopharyngeal (NP), nasal, oropharyngeal (OP) swab specimens and lower respiratory tract (LRT) specimens 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. Laboratories 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 other clinical observations, patient history, and epidemiological information.

The Panther Fusion SARS-CoV-2 assay on the Panther Fusion system utilizes Open Access reagents and functionality and is intended for use by trained clinical laboratory personnel specifically instructed and trained in the operation of the Panther Fusion system and in vitro diagnostic procedures
[PI AW-21388-001 Rev 002]

Discussion:

The manufacturer complied with the condition imposed on the authorization by revising, as requested, the intended use and removing all regulatory specific FDA language.

However, the following significant changes were made to the Package insert that triggered a request for validation studies to support these changes:

- use of nasal and lower tract respiratory specimens (brochoalveolar lavage fluid and bronchial wash specimens);
- use of other transport media, specifically, Saline, Liquid Amies and Specimen Transport Medium (STM) as compatible specimen collection media for NP, nasal and OP swabs
- use of the Aptima Swab Specimen Collection kit (The Aptima® Multitest Swab Specimen Collection Kit is intended to be used for clinician collection of throat and nasal swab specimens for testing with Hologic assays to detect the presence of RNA for SARS-CoV-2).

Studies for Limit of Detection with lower respiratory tract specimens support the claim of 0.01 TCID50/mL for lower respiratory specimens (LRT), which is the same as that obtained and approved previously with upper respiratory tract specimens. Results from a clinical performance evaluation of the Panther Fusion SARS-CoV-2 assay performed with LRT specimens showed a 100% positive and negative percent agreement with the expected results, supporting an acceptable performance of the Panther Fusion SARS-CoV-2 assay performed with bronchoalveolar lavage fluid.

A LoD study was performed to confirm that the previously determined detection capabilities of the Panther Fusion SARS-CoV-2 assay reamined the same when using saline, Liquid Amies and Hologic Specimen Transport Medium (STM) as specimen collection media. Data obtained confirmed that the LoD of the Panther Fusion SARS-

CoV-2 assay is 0.01 $TCID_{50}$/mL in saline, Liquid Amies and Hologic Specimen Transport Medium, validating their compatibility with the assay.

The Aptima® Multitest Swab, a polyester swab currently manufactured by Puritan Medical, is appropriate for use with the assay. According to CDC guidelines, flocked or spun polyester swab are recommended for collection of nasal specimens. As per FDA FAQ, Puritan swabs (polyester) are recommended for nasopharyngeal and oropharyngeal specimen collection.

Changes to the package insert meet the requirements of the Medical Devices Regulations and accurately capture the new claims and supporting evidence.

In the context of the COVID-19 pandemic, the claims made regarding the specimens intended to be used with the assay, the collection transport medium, swabs, and labelling have been supported and provide reasonable assurance that the Panther Fusion SARS-CoV-2 Assay will perform as claimed for its intended use under the current COVID-19 national health emergency.

RECOMMENDATION:

Remove the condition imposed on the current Authorization and re-issue an Authorization of the Panther SARS-CoV-2 assay under Interim Order 32 with for a revised intended use and package insert.

I concur / Je suis d'accord

Maria Carballo Manager, In Vitro Diagnostic Section / chef, Matériels diagnostiques in vitro Device Evaluation Division / Division de l'Évaluation des Matériels	2020-05-16 Date	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date