



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: Hologic, Inc.

Device: Aptima SARS-CoV-2 Assay

Application: 316954

Technology: Nucleic acid technology **Setting:** Laboratory

Background

The application for the Aptima™ SARS-CoV-2 assay 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 Medical Devices Regulations and the “*Emergency Use Authorization Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 that causes Coronavirus disease 2019 (COVID-19)*” issued by the US FDA (Version May 11, 2020).

The Aptima™ SARS-CoV-2 assay received a US FDA Emergency Use Authorization (EUA) in May 2020.

Intended Use

Aptima SARS-CoV-2 assay kit

The Aptima™ SARS-CoV-2 assay is a nucleic acid amplification in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 isolated and purified from nasopharyngeal (NP), nasal, mid-turbinate and oropharyngeal (OP) swab specimens, nasopharyngeal wash/aspirate or nasal aspirates obtained from individuals meeting 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 upper respiratory 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.

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 Aptima SARS-CoV-2 assay on the Panther™ and Panther Fusion™ system is intended for use by clinical laboratory personnel specifically instructed and trained in the operation of the Panther and Panther Fusion systems and in vitro diagnostic procedures.

[Package Insert_AW-21677-001 Rev. 001]

Aptima Multitest swab specimen collection kit for SARS-CoV-2 specimen collection

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.

[Package Insert_AW-18109-001 Rev. 003]

Discussion: The information provided meets the minimum requirements to authorize the Aptima™ SARS-CoV-2 assay under Interim Order.

The assay is performed using the Panther or Panther Fusion System, which are Class IV authorized instruments.

Studies for limit of detection, in silico inclusivity, and cross-reactivity were performed. Endogenous interference was not assessed, given that the extraction technology is identical to other licenced devices, and is well established.

The clinical evaluation performed with 55 negative and 50 positive nasopharyngeal samples provides reasonable evidence that assay is able to detect SARS-CoV-2 targets, with 100% sensitivity and 98.2% specificity observed.

An additional two studies were performed to verify different workflows. The first study examined 50 negative clinical samples, and 65 contrived positive samples near the limit of detection: Results were in 100% agreement with the expected result. The second study examined 15 positive clinical samples that were serially diluted: For the workflows assessed, either 40 or 41 of the 45 diluted samples were correctly identified as positive. Since the intent of the study was to compare results across workflows, and not to verify the limit of detection of clinical samples, the demonstrated agreement of a minimum of 95% between workflows demonstrates comparable performance. This information has been communicated appropriately in the labelling.

The labelling meets the minimum requirements of both the Regulations and the additional COVID-19 related labeling information outlined in the EUA FDA template.

The assay is manufactured in the US and in the UK.

Based on the scientific evidence available, it is reasonable that the product 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 associated with increased testing capacity that will be facilitated by the authorization for sale of this assay.

RECOMMENDATION:

Authorization of the Aptima SARS-CoV-2 Assay under the Interim Order with the following condition:

1. Provide, when available, the results of the real-time shelf life stability study.

[signed in docuBridge]

I concur / Je suis d'accord

_____	2020-08-13	_____	_____
Emily Hollink	Date	Rosslyn Miller-Lee Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date