COVID-19 Diagnostic Testing

NAT Technical Screening

Name of the device	**APTIMA SARS-COV-2 ASSAY**
Manufacturer	**HOLOGIC, INC.**
Application #	**316954**
Technology	**PCR**
Test Setting	**Lab**
DED Screener	**Ian Aldous**

Notes to reviewer	**FDA approved, prioritized**

	Guidance	Acceptable	Comment
Device Description	**Type of Technology** **Instrumentation required** **Sample type/collection methods** **Testing setting:** Laboratory / Point of Care **Extraction methods** **Targeted sequence** **Sequences of Probes and primers** **Controls** (value assignment, supplied with kit) **Detection method**: potential for Biotin interference **Intended use assessed during review**	Y	
Limit of Detection	Spiking RNA / inactivated virus into clinical (preferred) or artificial matrix. The matrix should represent the most challenging clinical matrix. **Initial study** Dilution series including 3 replicates for each concentration. **Confirmatory study** 20 replicates of the final concentration. Acceptance criteria: 19/20 positive	Y	
Inclusivity	• Provide results of in silico analysis including the % identity to published COVID19 sequences. • 100% of the published sequences should be detectable.	Y	
Cross-Reactivity (Exclusivity)	• Provide results of in silico analysis of primers and probes against: common respiratory flora, other viral infections • Wet testing is recommended • Cross-reactivity is defined as greater than 80% homology • Matrix-specific cross-reactivity should be assessed, • Exogenous/Endogenous interferents: these depend on sample type (blood, sputum, stool). The interfering substances studies are not required for the classic/well established PCR (RT-PCR) using respiratory specimens, however for newer molecular type of assays, such as various isothermal methods, testing of potential interferents will be required even for respiratory specimens. Can reference CLSI EP07.	Y	
Precision	Conduct internal precision testing (i.e., at the manufacturer's site) in accordance with CLSI, EP5-A2. In the context of SAP, the 3x5x5 (3 instruments x 5 days x 5 replicates) design is acceptable to provide preliminary estimates of the repeatability (within run) and reproducibility of the assay. Full assessment of repeatability using the 20x2x2 (20 days × 2 run per day × 2 replicates) is expected at time of licensing.	Y	
Stability	**Description of stability test plan** • reagent stability studies do not need to be completed at the time of IO issuance, however the study design should be agreed upon during review and the stability studies started immediately following authorization	Y	
Clinical Evaluation	Known positive samples or contrived clinical samples Minimum of 30 reactive and 30 non-reactive specimens • 20 samples at 1x-2x LoD (95% agreement) • Other concentrations and non-reactive (100% agreement)	Y	
Point of Care	**Near patient studies** performed in clinical setting by intended users. Minimum of 9 operators and questionnaire to assess IFU clarity.	n/a	
Labeling	**Instructions for use** **Reagent labels** Intended Use Statement will be assessed during review	Y	

Quality	• QMS certificate provided? • Evidence of lot release programme	Y	

Accept for review.

Review of Responses / New Questions (Rounds #2 etc., as deemed appropriate):

<< Date >>
<< Screener >>
<< Insert Responses/HC Comment to Screening Deficiency Questions >>

Copy/Paste this section as needed, depending on the number of rounds of questions.
Resave/reupload to dB new file as "IO Technical Screening application #xxxxxx #2, #3, etc.

File Disposition:

1. **Background/*Antécédents***
   The applicant has requested authorisation for the above named device under the ***Interim order respecting the importation and sale of medical devices for use in relation to COVID-19.***

   In their original application, the applicant did not provided adequate evidence to allow for a full assessment the safety, effectiveness and quality of the subject device. As a result, additional information was sought, as documented above.

2. **Evaluation/*Évaluation***
   <*Provide a short description of the type of information that was requested, and what is still either missing or inadequate.*

3. **Conclusion**
   The applicant has not provided the required level of scientific evidence to allow for an assessment of device safety, effectiveness and quality, as required under the IO, and as outlined in the ***Guidance on Requirements for serological antibody tests submitted under the COVID-19 Interim Order***. No further review is possible at this time.

4. **Recommendation**

   Recommend for Review…… ☐
   Recommend for Rejection…… ☐

   The applicant should be notified that their application cannot be evaluated further based on the evidence provided to date.

Chose one of the 4 choices below as applicable; delete others:

< The application is recommended for rejection because the evidence submitted does not meet the requirements set out in Section 5(a) of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19, to enable us to issue the authorization. >

< The application is recommended for rejection because Health Canada did not receive a response to the questions sent on [xxx]. The lack of a response therefore did not satisfy Section 5(b) of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19. >

< The application is recommended for rejection because the evidence submitted was not sufficient to allow Health Canada to conclude the benefits of this product outweigh the risks to the general public. This is a requirement of Section 5(c) of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19, to enable us to issue the authorization. >

< The application is recommended for rejection because the evidence submitted was not sufficient to allow Health Canada to conclude that the health or safety of patients, users or other persons will not be

unduly affected. This is a requirement of Section 5(d) of the Interim Order respecting the importation and sale of medical devices for use in relation to COVID-19, to enable us to issue the authorization. >

The following deficiencies remain:
<List deficiencies here, as they are to appear in the letter to the applicant. For example: Missing or deficient cross-reactivity testing, etc>

OR

<insert technical assessment, if necessary for explaining our conclusion>