Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **APTIMA SARS-COV-2 ASSAY**	Application Number/Numéro de soumission **316954**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **HOLOGIC, INC.**	Company ID/Identificateur d'entreprise: **104123**
Risk Class: **3**	Rationale: **IVDD Rule 2(b)(i)**
*Licence Type/Type d'homologation: **Test Kit**	Rationale:

☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)

*Intended Use and/or Indications for Use/ Utilisation Prévue et/ou Indications

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.

OEM Licence Information	
OEM Licence Name :	OEM Manufacturer :
OEM Intended Use and/or Indications for Use	

Reason for Change		Comment(s)
Change to classification of a device	☐	
Manufacturer name change	☐	
License name change	☐	
Device name change	☐	
Change to the purpose/indication of license	☐	
Addition of device(s)	☐	
Deletion of device(s)	☐	

Reason for Change		Comment(s)
Change in name and/or address of the Private Label Manufacturer	☐	
Private Label License name change	☐	
Private Label Device name change	☐	
Addition of device(s)	☐	
Deletion of device(s)	☐	

Certificate Screening Checklist:

Cert # (new):	Cert Revisions / Comments (If Applicable):
Cert. # (old):	
Replacing Existing Cert on File (Y/N):	

Criteria	conforms	Comments/info for MDS
Issued to full name of manufacturer as it appears on application/licence and label.	☐	
Issued to complete civic address matching application/licence and label.	☐	
Criteria are ISO 13485:2016 and Medical Devices Regulations – Part 1 – SOR 98/282	☐	
Scope activities limited to design, development, manufacture, production, servicing, installation, or distribution.	☐	
Activities include “manufacture” or “production” Activities include “design” or “development and development” for class III/IV devices.	☐	
Scope is unambiguous and covers app./lic. devices. Does not contain product names/models/licence numbers.	☐	
Auditing Organisation is Authorized or Recognized	☐	
Statement of Authorization or Recognition.	☐	
Field labelled “Effective Date”	☐	
Field labelled “Expiry Date”	☐	
Validity period ≤ 3 years	☐	
Unique identification code labelled “certificate number” or “certification document number”	☐	☐ new ☐ revised
Name, title, and signature of certification authority	☐	
Pagination (page x or y) included on all pages . All pages present.	☐	
Method to verify validity	☐	

Screening Decision

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Accept	
Gregory Jackson Device Licensing Services Division Medical Devices Bureau	**Date**: 2020-06-11

Regulatory Assessment Checklist for Class I/II/III/IV IO Medical Devices Submissions

For all Class IO Medical Devices:

Section 4(1) of the Interim Order

Section of Interim Order	Requirement	A	D	N/A	Guidance	Comments
4(1)(a)	The name of the device	☒	☐	☐	Requires including the name of the device. This is the name that appears on the labelling proper and for which the authorization shall be issued under the Order. It includes any information necessary for the user to identify the device and to distinguish it from similar devices.	
4(1)(b)	The class of the device	☒	☐	☐	Specify the class of the device. This is the classification that is attributed to the device according to the rules set out in Schedule 1 of the Medical Devices Regulations. According to the classification scheme, Class I represents the lowest risk and Class IV represents the highest risk. For this purposes of submitting an application under the Interim Order, a COVID-19 medical device can be classified into more than one class, the class representing the higher risk applies.	
4(1)(c)	The identifier of device	☒	☐	☐	Requires the identifier of the device, including the identifier of any medical device that is part of a system, test kit, medical device group, medical device family or medical device group family be provided. For greater certainty, the definitions of each of these instances have been included above (see "Definitions").	
4(1)(d)	Name and address of the manufacturer as it appears on the device label	☒	☐	☐	4(1)(d) and 4(1)(e) requires the submission of the name and address of the manufacturer as it appears on the device label, including the address where the device is manufactured (if different). For greater certainty, this should be listed as the legal manufacturer of the device	
4(1)(e)	the address where the device is manufactured, if different from the one referred to in paragraph (d)	☐	☐	☒		
4(1)(f)	the diagnosis, treatment, mitigation or prevention for which the device is required	☒	☐	☐	Requires the submission include information related to the diagnosis, treatment, mitigation, or prevention for which the COVID-19 medical device be provided. This information is crucial in establishing an understanding of the device and the device classification. The following information should be included in this section: -intended purpose, mechanism of action, indications for use, conditions for which the device is used (the intended use statement should be verbatim as it appears on the device labelling); -patient population for which the device is intended including age range, if applicable, and specific diagnoses; - anatomical and physiological particulars related to the patient using the device, if applicable; -whether or not the device uses an energy source and whether energy is transferred to the patient; - the document version number and the date where the formal intended use appears.	
Section of Interim Order	**Requirement**	**A**	**D**	**N/A**	**Guidance**	**Comments**
4(1)(g)	the known information in relation to the quality, safety and effectiveness of the device	☒	☐	☐	See Note 1 below.	

4(1)(h)	the directions for use, unless directions are not required, for the device to be used safely and effectively;	☒	☐	☐	Requests that the applicant provide the directions for use, unless directions are not required for the device to be used safely and effectively. This is the information supplied to the lay person and/or the health care professional enabling them to use the device without causing unnecessary harm to themselves or another person and to achieve the desired result. The Directions for Use should be written at a level commensurate with the training of the expected users. For some complex, active or powered devices, the Directions for Use may require a special Surgeon's Instruction Manual, Operator's Manual, and a User's Manual. All documents should have a control or version number clearly indicated in the document	
4(1)(i)	an attestation by the applicant that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls	☒	☐	☐	Requires the applicant to provide an that documented procedures are in place in respect of distribution records, complaint handling, incident reporting and recalls. Appendix A provides an example of what Health Canada would look for in an attestation from an applicant.	
4(1)(j)	a copy of the label of the device	☒	☐	☐	Requires that the applicant provides a copy of the label of the COVID-19 medical device. This label should be expressed in a legible, permanent and prominent manner, in terms that are easily understood by the intended user. Additionally, where a package that contains a COVID-19 medical device is too small to display all the information required according to section 10 of the Interim Order, the directions for use shall accompany the device but need not be on the outside of the package or be visible under normal conditions for sale.	

Note 1

4(1)(g) of the Interim Order requests that the applicant provide the known information in relation to the quality, safety and effectiveness of the device. To clarify the type of information that should be submitted, the following non-exhaustive list is provided as a guide to inform a submission. The Minister, under section 9 of the Interim Order, may request any additional information, if the information provided is deemed insufficient to render a decision whether to grant an authorization under this Interim Order.

a) A clear description of the device, including how it works, any accessories to be used with it, and diagrams/photos of the device;
b) A copy of the manufacturer's Quality Manufacturing System Certificate, evidence of Good Manufacturing Practices, or other;
c) A discussion of whether any components are manufactured using additive manufacturing (3D printing, laser sintering, bioprinting, etc.);
d) If this device is manufactured from or incorporates animal or human tissue or their derivative, evidence of biological safety of the device;
e) A summary of any mechanical/bench testing data performed for the device;
f) A summary of any animal testing and clinical investigations carried out with the device;
g) A summary of any biocompatibility testing performed with the device (if applicable);
h) A summary of the evidence of shelf-life and packaging validation testing (if applicable);
i) A summary of electrical safety and electromagnetic compatibility (EMC) testing (if applicable);
j) If the device is intended to be used at point of care or sold directly to a consumer, marketing materials for the device;
k) If the device is intended to be sold in a sterile condition, a description of the sterilization method and a summary of sterilization validation testing performed;
l) A list of applicable standards used in the design/manufacture of the device;
m) Incidents with a discussion of each event and response from the manufacturer;
n) A comparison table outlining technological differences between this device and predecessors that are or were licensed in Canada (if applicable);
o) A comparison table outlining technological differences between the proposed COVID-19 medical device and any available (authorized) comparators, to the applicants knowledge
p) If the COVID-19 medical device is, or includes software, a discussion of the software validation testing performed;
q) If the COVID-19 medical device is, or includes an in-vitro diagnostic device, analytical validation studies including but not limited to, specimen validation testing, sample preparation validation, the limit of detection, when applicable, inclusivity, cross reactivity (in silico analysis and cross reactivity testing), preliminary precision results (if applicable),stability of samples, preliminary reagent stability and clinical validity studies.

ONLY FOR CLASS III and IV IO Medical Devices:
Section 4(2) of the Interim Order

Section of Interim Order	Requirement	A	D	N/A	Guidance	Comments
4(2)(a)	a description of the materials used in the manufacture and packaging of the device	☒	☐	☐	Requires that, for Class III and IV COVID-19 medical devices, the applicant provides a description of the materials used in the manufacture and packaging of the device. Additionally, if there are any materials that are patient contacting for any period of time, biocompatibility testing of those materials may be required in order to render a decision on whether the Minister may issue an authorization.	
4(2)(b)	a list of the countries, other than Canada, where the device has been sold, the total number of units sold in those countries and a summary of any reported problems with the device and any recalls of the device in those countries	☒	☐	☐	Requires that, for Class III and IV COVID-19 medical devices, the applicant provides a list of countries other than Canada where the device has been sold, the total number of units sold in those countries, and a summary of any reported problems with the device and any recalls of the device in those countries. This information can be provided in any format, however, summary tables are preferred.	

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Check GMDN

GMDN Name	GMDN Code	GMDN Description	Issue	Action for Screener	Regulatory Action	Reference Material