Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **ATELLICA IM SARS-COV-2 TOTAL (COV2T)**	Application Number/Numéro de soumission **316693**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **SIEMENS HEALTHCARE DIAGNOSTICS INC.**	Company ID/Identificateur d'entreprise: **107081**
Risk Class: **4**	Rationale: **Rule 2(a)**
*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

Atellica IM SARS-CoV-2 Total (COV2T) assay

The Atellica IM SARS-CoV-2 Total (COV2T) assay is for *in vitro* diagnostic use in the qualitative and quantitative detection of total antibodies (IgG and IgM), including neutralizing antibodies, to SARS-CoV-2 in human serum and plasma (potassium EDTA and lithium heparin) obtained by venipuncture or capillary puncture using the Atellica IM Analyzer.
This assay is intended as an aid in identifying patients with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.
Test results should be interpreted in conjunction with clinical observations, patient history, epidemiological information, and other laboratory findings.
A negative result does not exclude the possibility of exposure to or infection with SARS-CoV-2 and should not be used as the sole basis for patient management decisions. SARS-CoV-2 antibodies may be detectable after infection and a positive result may be indicative of acute or recent infection.

Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM)

The Atellica IM SARS-CoV-2 Total Master Curve Material (COV2T MCM) is for *in vitro* diagnostic use in the verification of calibration and measuring interval of the Atellica IM SARS-CoV-2 Total (COV2T) assay

Atellica Im Sars-Cov2- Total Quality Control (Cov2t Qc)

The Atellica IM SARS-CoV-2 Total Quality Control (COV2T QC) is for in vitro diagnostic use in monitoring the precision and accuracy of the Atellica IM COV2T assay using the Atellica IM systems.

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):	

Note to RC: Change in licence name (addition of 3rd device makes original pattern of naming surpass the 150 character limit in MDS)
Note to reviewer: Amendment to add device to IOA and changes to IFU (see cover letter).

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	
Accept	
Mohammad Jamal	**Date**:2020-10-26

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Device Licensing Services Division Medical Devices Directorate	

Review Division – DLSD Communication	
Review Division Screener Action: Review Division Screener Response:	
Review Division Screener Medical Devices Directorate	Date:

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Check GMDN

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