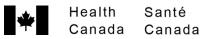


Application Information / Information de soumission					
*Licence Name/Nom de l'homologation: ATELLICA IM SARS-COV-2 TOTAL (COV2T)		Application Number/Numéro de soumission 316693			
Licence # / # de l'homologation:		Application Type/Type de soumission:			
0		Interim Order			
Manufacturer/Fabricant:		Company ID/Identificateur d'entreprise:			
SIEMENS HEALTHCARE DIAGNOSTICS INC. Risk Class:		107081 Rationale:			
4		Rule 2(a)			
*Licence Type/Type d'homologation:		Rationale:			
Test Kit ▼					
☐ Contains Controlled Substance(s) ☐ Contains Drug(s) ☐ Contains Biological Material(s)					
*Intended Use and/or Indications for Use/ Utilisation Prévue	et/ou Indication	ons			
Atellica IM SARS-CoV-2 Total (COV2T) assay The Atellica IM SARS-CoV-2 Total (COV2T) assay is for <i>in vitro</i> 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 <i>in vitro</i> diagnostic use in the verification of calibration and measuring interval of the Atellica IM SARS-CoV-2 Total Quality Control (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 SARS-CoV-2 Total Quality Control (COV2T QC) is for in vitro diagnostic use in monitoring the precision and accuracy of 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 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.					
	Licence Info				
OEM Licence Name :	OI	EM 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 Lahel Device name change					



Health Sante Canada Canada		Note to file Note au dossier
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):		
rese to tree change in meeting traine (addition of 5		
Note to RC: Change in licence name (addition of 3rd 150 character limit in MDS) Note to reviewer: Amendment to add device to IOA		
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria	conforms	to IFU (see cover letter). Comments/info for MDS
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA		
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria Issued to full name of manufacturer as it appears	conforms	
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria Issued to full name of manufacturer as it appears on application/licence and label. Issued to complete civic address matching	conforms	
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria 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	conforms	
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria 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,	conforms	
150 character limit in MDS) Note to reviewer: Amendment to add device to IOA Criteria 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	conforms	

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"	│	\square 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		



Review Division Screener Medical Devices Directorate

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

Santé Canada Check GMDN

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