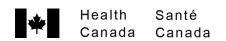


*Licence Name/Nom de l'homologation:		Application Number/Numéro de soumission AL) 320577					
·	O COVID-19 AG RAPID TEST DEVICE (NASOPHARYNGEAL)						
Licence # / # de l'homologation:  0		Application Type/Type de soumission:  Interim Order					
Manufacturer/Fabricant:	Company ID/Identificateur d'entreprise:						
ABBOTT RAPID DIAGNOSTICS JENA GMBH Risk Class:	161646  Rationale:						
AISK Class:		Rule 2(a)					
*Licence Type/Type d'homologation:		Rationale:					
Test Kit ▼							
☐ Contains Controlled Substance(s) ☐ C	ontains Drug	g(s) Contains Biological Material(s)					
*Intended Use and/or Indications for Use/ Utilisation Prévue	et/ou Indicatior	ns					
test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal swab specimens from individuals who meet COVID-19 clinical and / or epidemiological criteria. Panbio™ COVID-19 Ag Rapid Test Device is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.  The test provides preliminary test results. Negative results don't preclude SARS-CoV-2 infection and they cannot be used as the sole basis for treatment or other management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. The test is not intended to be used as a donor screening test for SARS-CoV-2							
combined with clinical observation information. The test is not intende	s, patien	t history, and epidemiological					
combined with clinical observation information. The test is not intende for SARS-CoV-2	s, patien d to be u	t history, and epidemiological sed as a donor screening test					
combined with clinical observation information. The test is not intende for SARS-CoV-2	s, patien d to be u	t history, and epidemiological sed as a donor screening test					
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combined with clinical observation information. The test is not intende for SARS-CoV-2  OEM Licence Name:  OEM Intended Use and/or Indications for Use  Reason for Change 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)	Licence Info	t history, and epidemiological sed as a donor screening test					
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Application Information / Information de soumission



Addition of device(s)							
Deletion of device(s)							
Certificate Screening Checklist:		·					
ert # (new):		Cert Revisions / Comments (If Applicable):					
Cert. # (old):							
Replacing Existing Cert on File (Y/N):							
See product dossier for all technical information	on						
Criteria		conforms		Comments	/info for MD	S	
Issued to full name of manufacturer as it app on application/licence and label.	ears						
Issued to complete civic address matching application/licence and label.							
Criteria are ISO 13485:2016 and Medical Dev Regulations – Part 1 – SOR 98/282							
Scope activities limited to design, developme manufacture, production, servicing, installatior distribution.							
Activities include "manufacture" or "producti Activities include "design" or "development a 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"				$\square$ new	$\square$ 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:2020-09-02							
Device Licensing Services Division Medical Devices Directorate							



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

Santé Canada Check GMDN

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