Health Canada / Santé Canada

Note to file
Note au dossier

Application Information / Information de soumission	
*Licence Name/Nom de l'homologation: **LYRA SARS-COV-2 ASSAY**	Application Number/Numéro de soumission **312783**
Licence # / # de l'homologation: **0**	Application Type/Type de soumission: **Interim Order**
Manufacturer/Fabricant: **DIAGNOSTIC HYBRIDS, INC. - ALSO TRADING AS QUIDEL CORPORATION**	Company ID/Identificateur d'entreprise: **116717**
Risk Class: **3**	Rationale:
*Licence Type/Type d'homologation: **Test Kit**	Rationale: **Class 3 by IVDD Rule 2(b)(i)**

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

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

The Lyra SARS-CoV-2 Assay is a real-time RT-PCR assay intended for the in vitro qualitative detection of human coronavirus SARS-CoV-2 from viral RNA extracted from nasal swab and nasopharyngeal swab specimens from patients with signs and symptoms of COVID-19. The Assay targets the non-structural Polyprotein (pp1ab) of the SARS-CoV-2 virus.
The authorized testing consists of nucleic acid extraction on the bioMerieux NucliSENS® easyMAG® system or EMAG system, followed by RT-PCR on the FDA-cleared Applied Biosystems® 7500 Fast Dx Real-Time PCR Instrument.
The Lyra SARS-CoV-2 Assay with the authorized labeling in intended for use only by CLIA High Complexity Laboratories or by similarly qualified non-U.S. laboratories.
Results are for the identification of SARS-CoV-2. The SARS-CoV-2 is generally detectable in nasal swab and nasopharyngeal swab specimens during the acute phase of infection. Positive results are indicative of active infection. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
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 Lyra SARS-CoV-2 Assay is intended for use by CLIA High Complexity Laboratories or by similarly qualified non-U.S. laboratories. The Lyra SARS-CoV-2 Assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

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)	☐	

<u>Certificate Screening Checklist:</u>

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	
Accept	
Liem Whelan Device Licensing Services Division Medical Devices Bureau	**Date**: March 24th, 2020

COVID-19 Medical Device & Manufacturer Details	
Class of Device	Class III
Intended Use of Device (Section 4(1)(f))	As per screening form.

Device Name	Identifier	GMDN Code	PNC Code
Lyra SARS-CoV-2 Assay	M120	64747	88UJH

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Check GMDN

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