Recommendation for Authorization under Interim Order COVID-19
Recommandation concernant autorisation en vertu de l'Arrêté d'urgence COVID-19

TO **A**	Rosslynn Miller-Lee Executive Director, Medical Device Evaluation Bureau, MDD
FROM **DE**	Jeffrey Skene Medical Device Directorate

Application Information *Information de soumission*			
Application ***Soumission*** 315786	**Name of device** ***Nom de l'homologation*** PLATELIA SARS-COV-2 TOTAL AB	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument***
Application Type ***Type de soumission*** Application under IO	**Licence Type** ***Type d'homologation*** Single Device	**Manufacturer** ***Fabricant*** BIO-RAD	**Company ID** ***No. d'entreprise*** 109132
Division: in vitro Diagnostics	Date Assigned: *Date assignée:* 2020-09-24		Date Completed: *Date d'achèvement:* 2020-09-24

Technology	Antibody
Test Setting	Lab

1 Background/*Antécédents*

On 2020-05-05, Health Canada received an application for authorization under the Interim Order for the PLATELIA SARS-COV-2 TOTAL AB submitted and manufactured by BIORAD FRANCE.

The device is intended for the qualitative detection of SARS-CoV-2 IgG, IgA and IgM in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.

Table 1. Summary of the application

Date	Comment
May 5 2020	The applicant submitted a request for IO authorization.
May 15 2020	The application passed regulatory screening. No technical screening was conducted.
May 21 2020	The initial review was complete and an AI request was sent to the applicant.
May 29 2020	NML data were submitted.
June 10 2020	The applicant responded with additional information to the AI request.
July 3 2020	The AI response was reviewed. A second AI request was submitted to the applicant.
July 28 2020	The response to the second AI request was submitted.
August 26 2020	The AI response was reviewed. A third AI request was submitted to the applicant. An extension was granted to the applicant until September 25th, 2020.

Table 1. Summary of the application	
Date	**Comment**
September 22 2020	The response to the third AI request was submitted.
September 24 2020	The AI response was reviewed and accepted with conditions.

The PLATELIA SARS-COV-2 TOTAL AB is a one-step antigen capture format assay for detection of total anti-SARS-CoV-2 nucleocapsid antibodies (IgA/IgM/IgG) in human serum or plasma specimens. The assay can be used manually or with semi-automatic or automatic microplate washer and a microplate reader equipped with 450nm and 620nm dichroic optical filters.

The application was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 pursuant to 33 subsection 30.1(1) of the Food and Drugs Act. This Interim Order will allow the Department to issue expedited authorization for sale or import of medical devices to deal with the current significant risk of COVID-19 to the health and safety of Canadians.

2 Intended Use

Platelia SARS-CoV-2 Total Ab Package Insert [16008267CA-EN – 2020/09]

Platelia SARS-CoV-2 Total Ab assay is a qualitative one-step antigen capture ELISA test for the *in vitro* detection of IgM/IgA/IgG antibodies to SARS-CoV-2 in human serum and plasma (EDTA, heparin, ACD or citrate) specimens.

The assay can be used as a screening tool for the detection of anti-SARS-CoV-2 total antibodies in order to determine seroprevalence in the general population and/or the immune status of individuals regarding exposure to SARS-CoV-2.

Platelia SARS-CoV-2 Total Ab is intended for use by trained laboratory personnel. It can be used manually or on automated systems.

This test should not be used for screening of donated blood. Results from Platelia SARS-CoV-2 Total Ab assay should not be used for diagnosis. Canadian testing facilities are required to report all positive results to the appropriate public health authorities.

For Laboratory Use Only.

3 Discussion/*Évaluation*

The information provided meets the minimum requirements for issue of Authorization under Interim Order.

The manufacturer holds a valid MDSAP Certificate.

This device has been authorised by the FDA (EUA dated 07/21/2020).

Studies for cut-off, hook effect, sample matrix, cross-reactivity, specimen and reagent stability were provided and determined to be acceptable. Partial data for interference and repeatability

testing were provided.

Real time stability studies were submitted for a comparable device to support the stability claim and not the PLATELIA SARS-COV-2 TOTAL AB assay. Real-time stability testing specific for the PLATELIA SARS-COV-2 TOTAL AB assay is ongoing and the applicant agreed to submit the study report when available.

Complete results from repeatability and endogenous interference testing are still pending and will be the subject of conditions. Precision testing was submitted; however, it was not in compliance with CLSI EP05-A3; therefore, updated precision testing will be the subject of a condition as well.

Evidence of acceptable clinical performance was demonstrated using a total of 133 PCR-positive samples collected from 50 patients and 600 pre-pandemic negative samples. Positive serum and positive plasma samples collected 16 days after symptom onset both demonstrated 100% sensitivity. Negative samples demonstrated 99.3% [98.3% – 99.8%] sensitivity. The clinical performance meets Health Canada requirements for serological assays.

Labelling meets the minimum requirements of the Regulations. The package insert includes information on precision, cross-reactivity, hook effect, interference, and specimen matrix equivalency as was presented in this application. A limitations section indicates that the assay should be interpreted in conjunction with the testing strategy outlined by public health authorities in the user's area.

In the context of the COVID-19 pandemic, the preliminary validation studies provided by the manufacturer are sufficient for an authorization given that the benefits that may be obtained from authorizing this assay for SARS-CoV-2 detection outweigh the risks related to the current COVID-19 national health emergency.

4 Recommendation

Authorization of the PLATELIA SARS-COV-2 TOTAL AB assay under the Interim Order with the following conditions:

1. Submit the results of a repeatability (I.e. 20x2x2) and reproducibility (I.e. 3x5x5) study performed per CLSI EP05-A3 by January 22, 2021.
2. Provide the results of an interference study performed with triglycerides by January 22, 2021.
3. When available, provide the complete results for the real-time stability testing to support the shelf life claim for the device.

Signed in Docubridge

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Signed in Docubridge

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Jeffrey Skene	Date 2020-10-07	**Rosslyn Miller-Lee** Executive Director/ Directrice Executive Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux	Date 2020-10-07