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**	Emily Hollink Medical Device Directorate

Application Information
Information de soumission

Application ***Soumission*** 316782	**Name of device** ***Nom de l'homologation*** DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T)	**Licence Number** ***No. de l'homologation*** N/A	**Risk Class** ***Classe de l'instrument*** 4
Application Type ***Type de soumission*** Application under IO	**Licence Type** ***Type d'homologation*** Test Kit	**Manufacturer** ***Fabricant*** SIEMENS HEALTHCARE DIAGNOSTICS INC.	**Company ID** ***No. d'entreprise*** 113434

Division:	**Date Assigned:** **Date assignée:**	**Date Completed:** **Date d'achèvement:**
IN VITRO DIAGNOSTICS	2020-07-10	2020-08-27

Technology	Antibody
Test Setting	Lab

1 Background/*Antécédents*

On 2020-06-03, Health Canada received an application for authorization under the Interim Order for the DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T) submitted and manufactured by SIEMENS HEALTHCARE DIAGNOSTICS INC.

The device is a sandwich chemiluminescent immunoassay intended for the qualitative detection of human antibodies (IgA, IgM and IgG) to SARS-CoV-2 in serum and K2-EDTA or Li-heparin plasma based on LOCI® (**L**uminescent **O**xygen **C**hanneling **I**mmunoassay) technology. The device is designed for use with COVT Calibrators and Controls and the following automated analyzer systems: Dimension Vista (MDL No. 76662) and Dimension EXL (MDL No. 79670).

After an initial review, a request for additional information was sent on 2020-07-20. The response was received by Health Canada on 2020-07-24.

The application was reviewed under the Interim Order 32 Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 pursuant to 33 sub-section 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

Dimension Vista SARS-CoV-2 Total antibody assay (ref. K7414) Instruction for Use Rev. 01, 2020-06]

"The Dimension Vista® SARS-CoV-2 Total antibody assay (COV2T) is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 virus in human serum and plasma (EDTA, lithium heparin) using the Dimension Vista® system. 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."

SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL, ref. Kc813) Instruction for Use [Rev. 01, 2020-05]

The SARS-CoV-2 Total antibody calibrator (COV2T CAL/CV2T CAL) is an in vitro diagnostic product for calibration of the SARS-CoV-2 Total antibody assay (COV2T/CV2T) on the Dimension Vista® system and the Dimension® EXL™ integrated chemistry system with LOCI® module.

SARS-CoV-2 Total antibody Quality Control (COV2T/CV2T Pos/Neg, ref. KC815) Instruction for Use [Rev. 01, 2020-05]

The SARS-CoV-2 Total antibody Quality Control (COV2T/CV2T Pos/Neg) material is an in vitro diagnostic product to monitor the accuracy of the SARS-CoV-2 Total antibody assay (COV2T/CV2T) on the Dimension Vista® system and the Dimension® EXL™ integrated chemistry system with LOCI® module.

3 Discussion/*Évaluation*

The information provided meets the minimum requirements for issue of Authorization under Interim Order 32.

The manufacturer does hold a valid MDSAP Certificate. The manufacturer is also quality system compliant under ISO 13485:2003. A lot release validation plan was also submitted. The plan described the resources, personnel, lot release protocols, and acceptance criteria for in-process and final lot release testing for the calibrator, controls, bulk reagents, and final COV2T kit.

This device has been authorised outside of Canada by Europe (CE-marked on May 27, 2020) and the USA (FDA EUA issued on June 08, 2020).

Studies for sample matrix equivalency, hook effect, cut-off determination, precision, sample carry-over, seroconversion, precision, interference of endogenous substances and specimen/reagent stability using clinical specimens, were provided and determined to be acceptable. Note that a limit of detection study was not provided. The DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T) assay is a qualitative assay. It is recognised that the LoD study cannot be

conducted if there is no reference material or a standard panel available for the qualitative assay. Therefore, the LoD study was not requested for this assay.

Real time stability studies were provided and reviewed for closed onboard, open onboard and specimen stability. The submitted stability testing was considered acceptable.

Results from shelf-life stability and interference/cross-reactivity testing is still pending and will be the subject of a condition.

Evidence of acceptable clinical performance was demonstrated by testing on 72 RT-PCR confirmed patient samples and 1529 confirmed negative patient samples. Percent positive and negative agreements for samples collected ≥ 14 days after symptom onset were 100% and 99.8% respectively. The results met the requirements outlined by the Health Canada Notice "COVID-19 serological testing devices: Notice on sensitivity and specificity values" (June 24, 2020).

Labelling meets the minimum requirements of the Regulations. The package insert includes summaries of the sample matrix equivalency, hook effect, cut-off determination, precision, sample carry-over, seroconversion, precision, interference of endogenous substances and clinical performance information that was presented in this application. A limitations section indicates that the assay should be interpreted in conjunction with the patient's medical history, clinical signs and symptoms, and the results of other diagnostic tests.

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 DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T) assay under the Interim Order with the following conditions:

Within one month:

1. **You indicated that the clinical study was not conducted at independent external sites. Within one month following IO authorization, submit a plan to Health Canada that will assess the performance of the device when used in the intended use sites.**

When available:

2. **Provide a detailed cross reactivity/analytical specificity study report. Every effort should be made to assess cross-reactivity using a minimum of 5 pre-pandemic samples positive for IgM and for IgG antibodies directed against the pathogens listed below.**

Human coronavirus 229E	**Influenza A & B**
Human coronavirus OC43	**Human Metapneumovirus (hMPV)**
Human coronavirus HKU1	**Enterovirus (e.g. EV68)**
Human coronavirus NL63	**Respiratory syncytial virus**
Adenovirus (e.g. C1 Ad. 71)	**Rhinovirus**
Parainfluenza virus 1- 4	**Epstein-Barr virus (infectious**

	mononucleosis)
SARS	**Mycoplasma pneumoniae**
MERS	**Chlamydia pneumoniae**
Haemophilus influenzae	**Pneumocystis jiroveci (PJP)**
Legionella pneumophila	**Candida albicans**
Mycobacterium tuberculosis	**Pseudomonas aeruginosa**
Streptococcus pneumoniae	**Staphylococcus epidermis**
Streptococcus pyogenes	**Staphylococcus salivarius**
Bordetella pertussis	**HCV**
HIV	**Norovirus**
HBV	

3. **Provide a real-time stability study report for the DIMENSION VISTA SARS-COV-2 TOTAL ANTIBODY (COV2T). Health Canada expects that stability studies will be initiated upon authorization.**

I concur / Je suis d'accord

Signed in Docubridge

Emily Hollink

Date

Signed in Docubridge

Rosslyn Miller-Lee

Executive Director/ Directrice Executive

Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux

Date