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| TO<br>A | Rosslynn Miller-Lee<br>Executive Director, Medical Device Evaluation Bureau<br>MDD |
| FROM<br>DE | Emily Hollink<br>Medical Device Directorate |

| Application Information<br>Information de soumission | | | |
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| Application<br>*Soumission*<br>316783 | Name of device<br>*Nom de l'homologation*<br>DIMENSION EXL SARS-COV-2 TOTAL ANTIBODY (CV2T) | Licence Number<br>*No. de l'homologation*<br>N/A | Risk Class<br>*Classe de l'instrument*<br>4 |
| Application Type<br>*Type de soumission*<br>Application under IO | Licence Type<br>*Type d'homologation*<br>Test Kit | Manufacturer<br>*Fabricant*<br>SIEMENS HEALTHCARE DIAGNOSTICS INC. | Company ID<br>*No. d'entreprise*<br>113434 |

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| Technology | *Antibody* |
| Test Setting | Lab |

## 1 Background/Antécédents

This application was reviewed under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. This Interim Order allows 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.

The information submitted was evaluated based on the Health Canada Requirements for serological antibody tests submitted under the COVID-19 Interim Order, and the Notice on sensitivity and specificity values.

The Dimension *EXL* SARS-CoV-2 Total antibody assay (COV2T) received a US FDA Emergency Use Authorization (EUA) on June 8, 2020.

## 2 Intended Use

Dimension® EXL™ integrated chemistry system- SARS-CoV-2 Total Antibody (CV2T) Assay. [11417686_EN Rev. 02, Draft 2020-07-06]

The Dimension® EXL™ SARS-CoV-2 Total antibody assay (CV2T) 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® EXL™ integrated chemistry system with LOCI Module. 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.

Dimension Vista/Dimension EXL SARS-CoV-2 Total Antibody Calibrator (COV2T CAL/CV2T CAL) [11417434_EN 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.

Dimension Vista/DiSARS-CoV-2 Total Antibody Quality Control (COV2T/CV2T Pos/Neg) [11417436_EN 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 to issue an Authorization under the Interim Order.

The test is designed for use with COV2T Calibrators and Controls and the Dimension EXL *instrument* (Class III MDL No. 79670).

The manufacturer holds a valid MDSAP Certificate.

Studies for sample matrix equivalency, hook effect, cut-off determination, precision, sample carry-over, precision, interference of endogenous substances, seroconversion, and reagent and specimen stability were provided and determined to be acceptable.

Evidence of acceptable clinical performance was demonstrated by testing on 206 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”.

Labelling meets the minimum requirements of the Regulations. 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.

The assay is manufactured in the US.

In the context of the COVID-19 pandemic, 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 EXL SARS-COV-2 TOTAL ANTIBODY (CV2T) under the Interim Order with the following conditions:

Within one month:

1. Submit a plan to Health Canada that will assess the performance of the device when used in the intended sites.
2. To supplement stability data provided in your application, provide freeze-thaw stability testing to support the specimen stability claim in the labelling.
3. To supplement information on cross-reactivity studies included in your application, provide a plan to assess cross-cross reactivity. 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.

**Mandatory Viruses**

- Human coronavirus 229E
- Human coronavirus OC43
- Human coronavirus HKU1
- Human coronavirus NL63
- Parainfluenza virus 1- 4
- Adenovirus (e.g. C1 Ad. 71)
- Enterovirus (e.g. EV68)
- Human Metapneumovirus (hMPV)
- Rhinovirus
- Epstein-Barr virus

**Optional Organisms**

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

When available:

4. Provide a summary of the cross-reactivity study.
5. Provide revised labelling that removes US-specific language (e.g. "For use under Emergency Use Authorization only").
6. Provide a real-time stability study report for the DIMENSION EXL SARS-COV-2 TOTAL ANTIBODY (COV2T). Health Canada expects that stability studies will be initiated upon authorization.

I concur / Je suis d'accord

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| Signed in Docubridge | | Signed in Docubridge | |
| Emily Hollink | Date | Rosslyn Miller-Lee<br>Executive Director/ Directrice Executive<br>Medical Devices Evaluation Bureau/ Bureau de l'évaluation des instruments médicaux | Date |