LumiraDx™ SARS-CoV-2 Antibody (Ab) Test Specifications

For *in vitro* diagnostic use.

Intended use*

The LumiraDx SARS-CoV-2 Ab Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform for the qualitative detection of total antibodies to SARS-CoV-2 in human whole blood (capillary fingerstick or venous), plasma or serum. The LumiraDx SARS-CoV-2 Ab Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

Results are for the detection of SARS-CoV-2 total antibody. Antibodies (IgM, IgG, IgA) to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.

Test description

The LumiraDx SARS-CoV-2 Ab Test uses specific SARS-CoV-2 antigens in a sandwich immunofluorescence assay to detect the presence of SARS-CoV-2 antibodies present in the test sample.

Built-in Quality Controls

The LumiraDx Platform Instrument and Test Strip are integrated with several control checks to ensure the Instrument and Test are functioning correctly for every test run. These checks include:

- Electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance
- Test Strip positioning, and Test Strip expiry
- Monitoring of Test Strip performance and controls during test runtime
- The SARS-CoV-2 Ab Test contains an Onboard Quality Control (OBC) assay
- Sufficient sample volume and hematocrit determination on the Test Strip to confirm within 22-55 % range

SARS-CoV-2 Ab Quality Controls

Positive and negative liquid controls for SARS-CoV-2 Ab are available from LumiraDx to complete Quality Control assessment of the Instrument and SARS-CoV-2 Ab Test Strips.

*See SARS-CoV-2 Ab Test Product Insert for full Intended Use statement.

Clinical performance

Fingerstick sample performance

In clinical studies, fingerstick samples showed 100 % positive and 100 % negative agreement when samples were collected from individuals who were 8 days or more post RT-PCR test.

	Positive agreement	Negative agreement
Direct fingerstick	100 % (62/62)	100 % (54/54)
Fingerstick via Transfer Tube	100 % (62/62)	100 % (56/56)

Plasma sample performance

In clinical studies, plasma samples demonstrated an overall 97.2 % (n=72) positive agreement and 100 % (n=290) negative agreement when compared to RT-PCR.

Days from RT-PCR to blood collection	Number of positive samples	LumiraDx SARS-CoV-2 Ab Test result as compared to RT-PCR
≤ 6 days	13	84.6 %
7-13 days	7	100 %
14-20 days	6	100 %
≥ 21 days	46	100 %
Total	72	97.2% (90.4 – 99.2%)

Matrix equivalency

Matrix equivalency demonstrated 100 % agreement across venous, plasma and serum matrices therefore clearly demonstrating that the performance between the matrices can be considered equivalent. The study looked at 3 different antibody concentrations (negative, low positive and moderate positive) in duplicate from 5 different donors and was run as a blind randomized study.

Cross reactivity

SARS-CoV-2 Ab Test was found not to cross-react with a panel of positive samples including Influenza A, Influenza B, Hepatitis C Virus, Hepatitis B Virus (Genotype D) Hemophilus influenzae, human coronaviruses (HKU1, NL63, OC43 and 229E), Anti-Nuclear Antibody, Respiratory Syncytial Virus (RSV) and Human Immunodeficiency Virus (HIV). See LumiraDx SARS-CoV-2 Ab Test Product Insert for full details.

Specifications

Sample types	Fingerstick capillary blood, venous whole blood (EDTA), plasma (EDTA) or serum
Sample size	20 µL
Time to result	11 minutes
Result display	Qualitative – positive or negative
Storage temperature	2-30 °C (36-86 °F)
Operating temperature	15-30 °C (59-86 °F)
Interferences	See LumiraDx SARS-CoV-2 Ab Test Product Insert for details
Onboard Control	Onboard Quality Control (OBC) assay and sample processing control
Quality Control material	Positive or negative liquid controls

For more information visit lumiradx.com or contact the LumiraDx Customer Services by email: CustomerServices@lumiradx.com or Tel: +44 (0) 1172 842535

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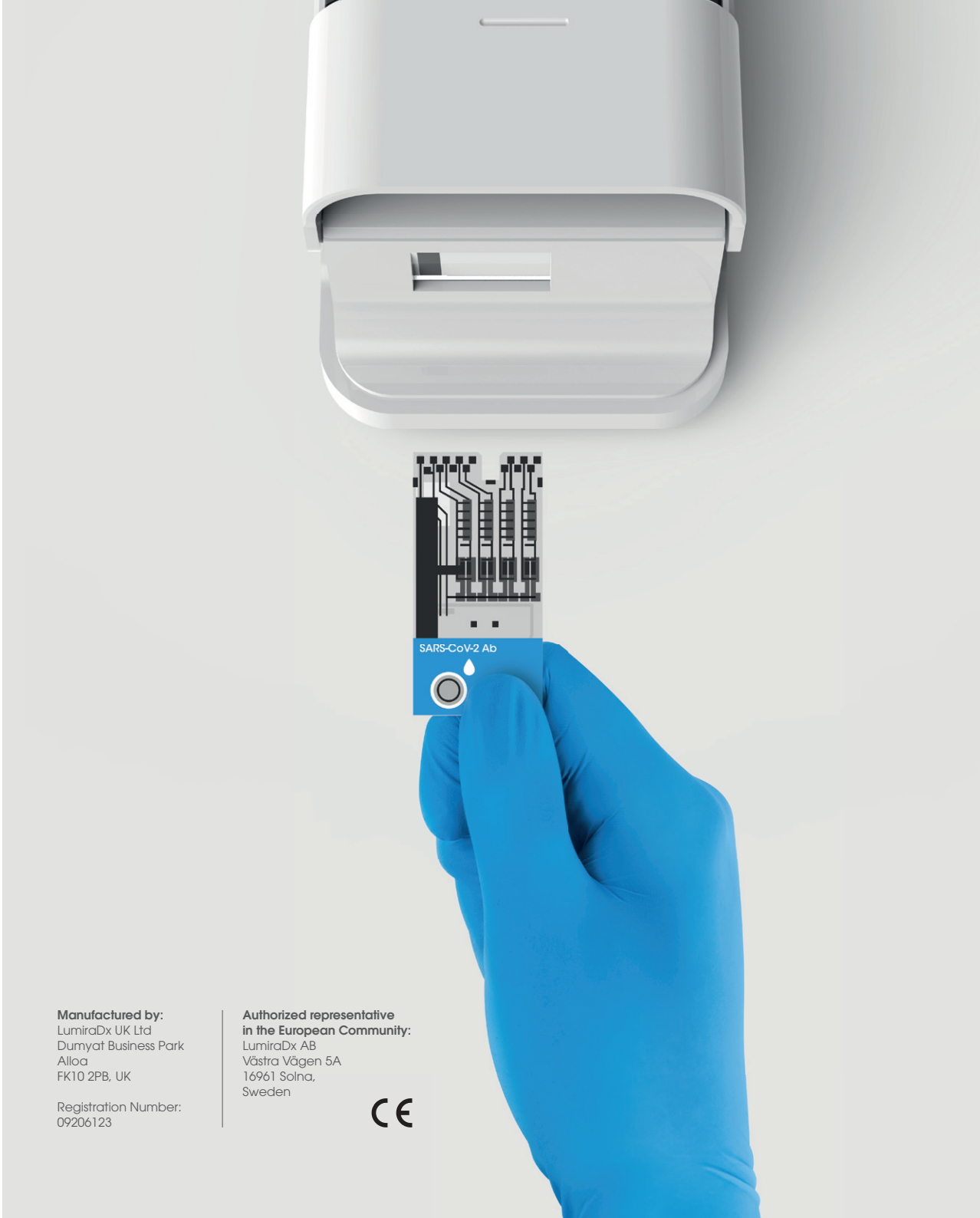

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