LumiraDx™ SARS-CoV-2 Antigen (Ag) Test Specifications

For *in vitro* Diagnostic Use.

Intended Use

The LumiraDx SARS-CoV-2 Ag Test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the qualitative detection of the nucleocapsid protein antigen to SARS-CoV-2 in nasal swab and nasopharyngeal swab samples. Samples are collected from individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals. The Test aids in the diagnosis of current SARS-CoV-2 infection by detection of SARS-CoV-2 antigen.*

Test Description

The LumiraDx SARS-CoV-2 Ag Test uses SARS-CoV/SARS-CoV-2 specific antibodies in a particle-particle sandwich immunoassay to determine the presence of SARS-CoV-2 Nucleocapsid Protein (NP) antigen 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, optics, and Test Strip expiry
- Monitoring of Test Strip performance and controls during test runtime
- The SARS-CoV-2 Ag Test contains an Onboard Quality Control (OBC) assay

SARS-CoV-2 Ag External Quality Controls

Positive and Negative Quality Controls are available from LumiraDx to complete Quality Control assessment of the Instrument and SARS-CoV-2 Ag Test Strips.

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

Clinical performance

Direct nasal swabs (257) and nasopharyngeal swabs (255) were prospectively collected from symptomatic patients suspected of COVID-19 from six sites across the United States and United Kingdom. The performance of the LumiraDx SARS-CoV-2 Ag Test was compared to an EUA authorized PCR method.

Clinical performance up to 12 days post symptoms onset

	Reference PCR results					
	Nasal swab			Nasopharyngeal swab		
LumiraDx SARS-CoV-2 Ag results	**POS**	**NEG**	**Total**	**POS**	**NEG**	**Total**
POS	81	6	87	39	5	44
NEG	2	168	170	1	210	211
Total	83	174	257	40	215	255
	PPA	**NPA**	**OPA**	**PPA**	**NPA**	**OPA**
	97.6% (CI 91.6% -99.3%)	96.6% (CI92.7% -98.4%)	96.9% (CI 94.0% -98.4%)	97.5% (CI 87.1% -99.6%)	97.7% (CI 94.7% -99.0%)	97.6% (CI 95.0% -98.9%)

PPA- Positive Percent Agreement; NPA – Negative Percent Agreement; OPA – Overall Percent Agreement, CI – Confidence Interval

Analytical performance

Limit of Detection

Starting material concentration	Estimated LoD	No. Positive/Total	% Positive
2.8×10^5 $TCID_{50}$/mL	32 $TCID_{50}$/mL	20/20	100

Cross reactivity

SARS-CoV-2 Ag Test was found not to cross-react with a panel of organisms and viruses including several human coronaviruses. See LumiraDx SARS-CoV-2 Ag Test Product Insert for full details.

Specifications

Sample type	Nasal and nasopharyngeal swabs
Time to result	12 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 Ag Test Product Insert for details
Onboard control	Onboard Quality Control (OBC) assay and sample processing control
Quality control material	Positive and Negative external liquid controls
Validated swabs	See swabs technical bulletin at lumiradx.com

For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 Ag Test please visit lumiradx.com.

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

Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.

lumiradx.com

CE

Manufactured by:
LumiraDx UK Ltd
Dumyat Business Park
Alloa
FK10 2PB, UK

Registration Number:
09206123

Authorized representative in the European Union:
LumiraDx AB,
Västra Vägen 5A,
16961 Solna, Sweden

S-COM-ART-00459 R4