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 directly from nasal swab specimens collected from individuals suspected of, or at increased risk of, COVID-19 by their healthcare provider within the first twelve days of symptom onset.

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) 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.

	Reference PCR results		
LumiraDx SARS-CoV-2 Ag results	**POS**	**NEG**	**Total**
POS	81	6	87
NEG	2	168	170
Total	83	174	257
PPA: 97.6% (CI 91.6%- 99.3%)			
NPA: 96.6% (CI 92.7%- 98.4%)			
OPA: 96.9% (CI 94.0%- 98.4%)			

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 x 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 swab
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

Swabs

When collecting nasal swab samples, the following swabs have been validated for use with the LumiraDx SARS-CoV-2 Ag Test: Copan Nasal FLOQswab™ Regular, Puritan HydraFlock™ Sterile Standard Flock Swab, Aspen Surgical™ Polyester Swab, SteriPack™ Sterile Polyester Spun Swab, mwe medical wire Dryswab™ Rayon Swab, Kang Jian™ Virus Collection Swab. Swabs from other suppliers have not been validated and the performance with other swabs may not perform as expected. This is a complete list of swabs currently validated for use with the LumiraDx SARS-CoV-2 Ag Test. Commercial availability of swabs may vary by country.

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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