



# SARS-CoV-2 Ag Test Specifications

For Emergency Use Authorization Only (EUA). For *in vitro* Diagnostic Use. Rx Only.

## 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 antigens from SARS-CoV-2 in direct anterior nasal swab and nasopharyngeal swab specimens collected by a healthcare provider from individuals who are suspected of COVID-19 within the first twelve (12) days of symptom onset when tested at least twice over three days with at least 48 hours between tests and from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

## 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 LumiraDx 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 LumiraDx SARS-CoV-2 Ag Test Strips.

\*See LumiraDx SARS-CoV-2 Ag test Product Insert for full Intended Use statement.

## Clinical performance up to 12 days post symptom onset

Direct anterior 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.

| LumiraDx SARS-CoV-2 Ag results | Reference PCR results     |                           |       |                           |                           |       |
|--------------------------------|---------------------------|---------------------------|-------|---------------------------|---------------------------|-------|
|                                | Anterior nasal swabs      |                           |       | Nasopharyngeal swab       |                           |       |
|                                | 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                       |       | PPA                       | NPA                       |       |
|                                | 97.6%<br>(CI 91.6%-99.3%) | 96.6%<br>(CI 92.7%-98.4%) |       | 97.5%<br>(CI 87.1%-99.6%) | 97.7%<br>(CI 94.7%-99.0%) |       |

PPA- Positive Percent Agreement; NPA – Negative Percent Agreement

## Analytical performance

Limit of Detection (LoD)

| Starting material concentration              | Estimated LoD             | No. positive/total | % positive |
|----------------------------------------------|---------------------------|--------------------|------------|
| 2.8 x 10 <sup>5</sup> TCID <sub>50</sub> /mL | 32 TCID <sub>50</sub> /mL | 20/20              | 100        |

## Cross reactivity

The LumiraDx 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                                               |
| Nasal collection swabs   | Validated Nasal Collection Swabs (Available with product codes L016000609024, L016000609048) |

## Swabs

Individually packaged sterile nasal collection swabs are included in certain kits and should be used where provided.

For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 Ag test please visit [lumiradx.com](https://lumiradx.com) and consult the technical bulletin.

Commercial availability of swabs may vary by country.

Please be aware that the CDC does not recommend use of calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and inhibit PCR testing<sup>1</sup>.

**For more information visit [lumiradx.com](https://lumiradx.com) or contact the LumiraDx Customer Services by email: [CustomerServices.US@lumiradx.com](mailto:CustomerServices.US@lumiradx.com) or Tel: 1-888-586-4721**

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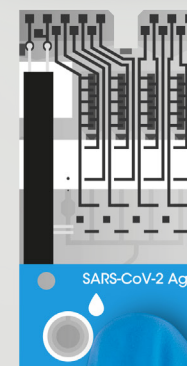
**Product is not available in all countries and regions. Please check with your local LumiraDx sales representative or distributor for availability in specific markets.**

In the USA, this product has not been FDA cleared or approved but has been authorized by FDA under an EUA for use by authorized laboratories; use by laboratories certified under the CLIA, 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. In the USA, - the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or the authorization is revoked sooner.

1. see <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

[lumiradx.com](https://lumiradx.com)

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