LumiraDx™

# SARS-CoV-2 Ag Ultra Test Specifications

For *in vitro* Diagnostic Use.

## Intended use*

The LumiraDx SARS-CoV-2 Ag Ultra test is an automated rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform, for near-patient testing, intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 directly from anterior nasal swab samples collected from individuals suspected of COVID-19 by their healthcare provider within the first twelve days of symptom onset or from individuals without symptoms or other epidemiological reasons to suspect COVID-19.

## Test description

The LumiraDx SARS-CoV-2 Ag Ultra 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 Instrument and LumiraDx SARS-CoV-2 Ag Ultra test have several quality control functions integrated to ensure validity of each 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 Ultra 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 Ultra Test Strips.

## Clinical performance*

### SARS-CoV-2 Ag Ultra test – symptomatic and asymptomatic data

In clinical studies, the LumiraDx SARS-CoV-2 Ag Ultra test demonstrated 97.4%** positive agreement versus RT-PCR in samples to Ct <34 from individuals with symptoms up to and including 12 DSSO.

| | Symptomatic | Asymptomatic |
|---|---|---|
| PPA | 97.4%** | 95.7% |
| NPA | 100% | 100% |

*See SARS-CoV-2 Ag Ultra product insert for full Intended use statement and clinical data

**Ct <34

PPA- POSITIVE PERCENT AGREEMENT; NPA – NEGATIVE PERCENT AGREEMENT; DSSO – DAYS SINCE SYMPTOM ONSET

## Analytical performance

| Starting Material Concentration | Estimated LoD | No. Positive/Total | % Positive |
|---|---|---|---|
| 1.26 x $10^6$ $TCID_{50}$/mL | 800 $TCID_{50}$/mL | 20/20 | 100 |

## Cross reactivity

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

## Specifications

| | |
|---|---|
| **Sample Type** | Nasal swabs |
| **Time to Result** | 5 minutes |
| **Kit Size** | 24 or 48 Tests |
| **Result Display** | Qualitative – Positive or Negative |
| **Storage temperature** | 2-30 $^{0}$C (36-86 $^{0}$F) |
| **Operating temperature** | 15-30 $^{0}$C (59-86 $^{0}$F) |
| **Interferences** | See LumiraDx SARS-CoV-2 Ag Ultra 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** | Sterile nasal collection swabs available with certain product codes |

## Swabs

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

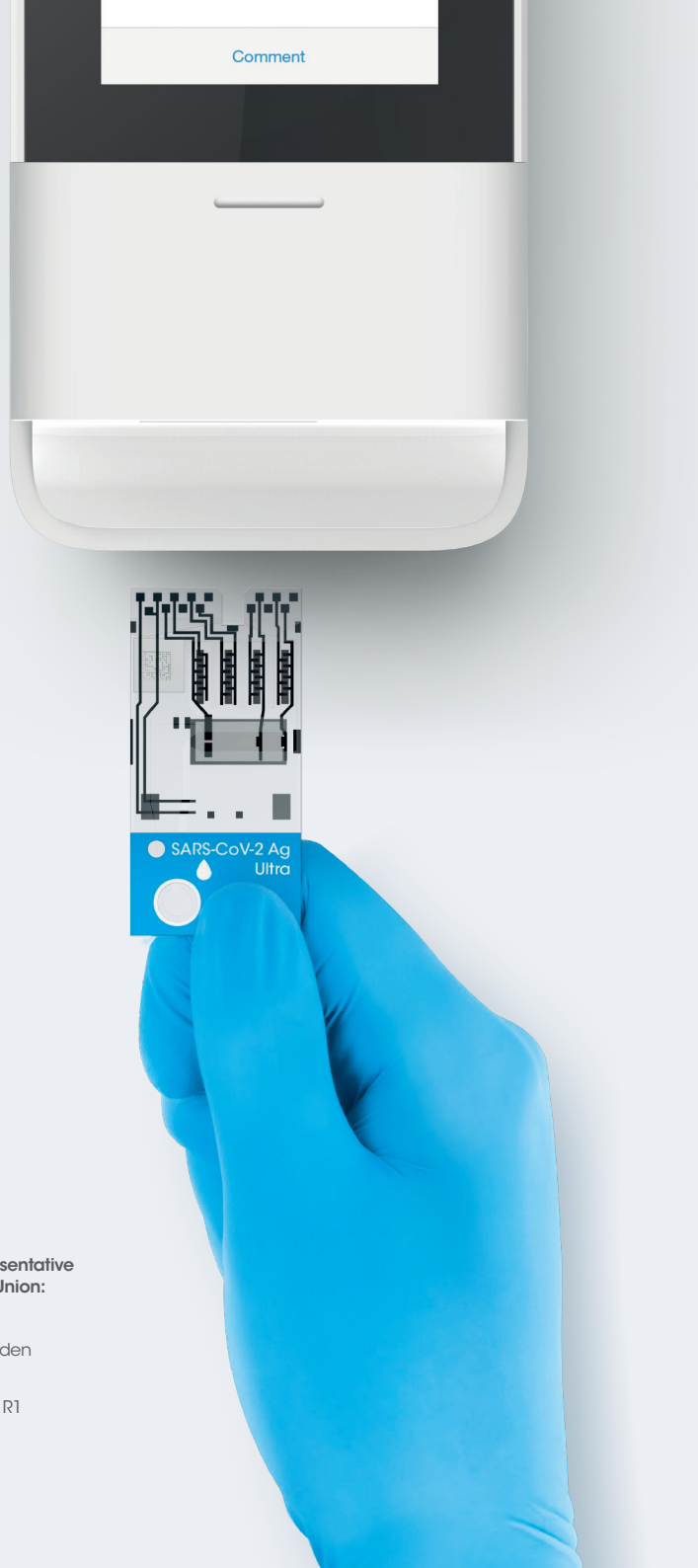
For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 Ag Ultra test please visit lumiradx.com and consult the technical bulletin.

**For more information visit lumiradx.com or contact the LumiraDx Customer Services by email: customerservices@lumiradx.com or Phone: 0080058647239**



**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**

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