SARS-CoV-2 Ag Ultra Pool Test Specifications

For *in vitro* diagnostic use.

Intended use*

The LumiraDx SARS-CoV-2 Ag Ultra Pool test is an automated 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 1 to 5 individual samples from professionally supervised & self-collected nasal swab samples or professionally collected nasal samples which are then pooled for testing. Samples should be collected from 1 to 5 individuals suspected of COVID-19 infection within the first twelve days of symptom onset or from asymptomatic individuals.

Test description

The LumiraDx SARS-CoV-2 Ag Ultra Pool 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 test samples.

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 Pool 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 Pool 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%

**Ct <34

SARS-CoV-2 Ag Ultra Pool test with 5 nasal samples

In clinical studies, the LumiraDx SARS-CoV-2 Ag Ultra Pool test demonstrated 93.1% positive agreement versus RT-PCR in pooled samples to Ct <34.

Grouping	N	PPA	95% CI
Ct (all)	30	90%	74.4-96.5%
Ct < 34 (all)	29	93.1%	78.0-98.1%
Ct < 33 (all)	28	92.9%	77.4- 98.0%
Ct < 33 (all)	26	96.2%	81.1-99.3%
Ct < 33 (all)	22	100%	85.1-100.0%

PPA- POSITIVE PERCENT AGREEMENT; NPA – NEGATIVE PERCENT AGREEMENT; CI – CONFIDENCE INTERVAL

Analytical performance (Limit of Detection)

Starting Material Concentration	Estimated LoD	No. Positive/Total	% Positive
1.26 x 10^6 $TCID_{50}$/mL	400 $TCID_{50}$/mL	19/20	>95

Cross reactivity

SARS-CoV-2 Ag Ultra Pool 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 Pool Product Insert for full details.

*SEE SARS-CoV-2 AG ULTRA POOL PRODUCT INSERT FOR FULL INTENDED USE STATEMENT AND CLINICAL DATA

SARS-CoV-2 Ag Ultra Pool test specifications

Sample type	Nasal swabs
Time to result	5 minutes
Kit size	48 Tests
Pooling test capabilities	1-5 patient samples
Result display	Qualitative – Positive or Negative
Storage temperature	2-30 °C (36-86 0F)
Operating temperature	15-30 °C (59-86 0F)
Interferences	See LumiraDx SARS-CoV-2 Ag Ultra Pool 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

For information on swabs that have been validated for use with the LumiraDx SARS-CoV-2 Ag Ultra Pool 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

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