LumiraDx™

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 antigen to SARS-CoV-2 directly from anterior nasal swab and nasopharyngeal swab specimens 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 when tested twice over three days with at least 24 hours (and no more than 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 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 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.

	Reference PCR results					
	Anterior nasal swabs			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**		**PPA**	**NPA**	
	97.6% (CI 91.6%-99.3%)	96.6% (CI 92.7%-98.4%)		97.5% (CI 87.1%-99.6%)	97.7% (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 10^5 $TCID_{50}$/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
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 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.[1]

For more information visit lumiradx.com or contact the LumiraDx Customer Services by email: CustomerServices.US@lumiradx.com or Tel: 1-888-586-4721

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

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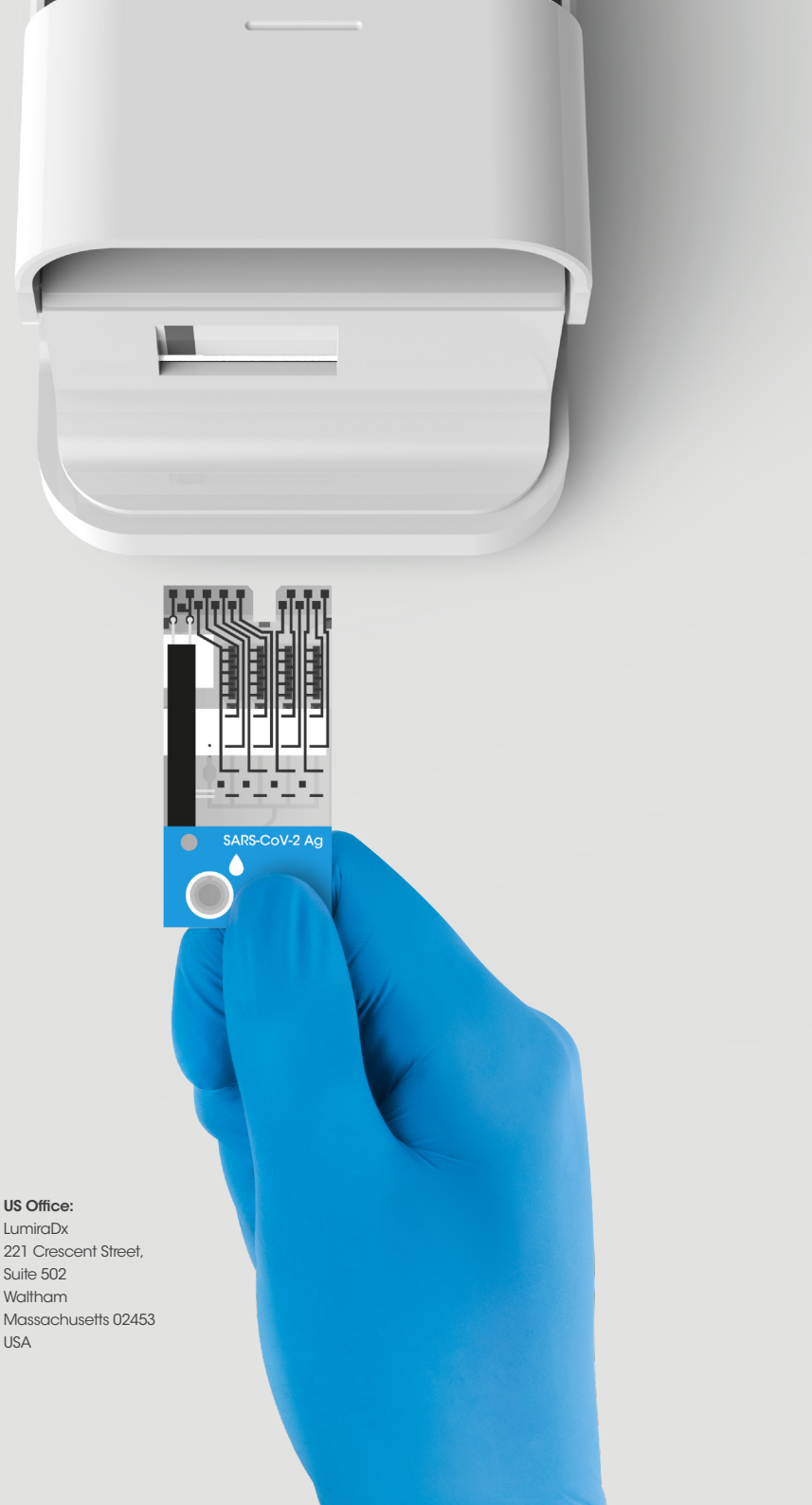

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