SARS-CoV-2 & RSV Test Specifications

For *In Vitro* Diagnostic Use.

Intended use*

The LumiraDx SARS-CoV-2 & RSV test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the simultaneous detection and differentiation of SARS-CoV-2 & RSV viral antigens direct from nasal swab specimens from individuals suspected of viral infection consistent with COVID-19 by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and respiratory syncytial virus (RSV) may be similar.

Test description

The LumiraDx SARS-CoV-2 & RSV test is a Point of Care rapid microfluidic immunofluorescence assay. The assay uses SARS-CoV/SARS-CoV-2 specific antibodies and RSV specific antibodies in individual channel particle-particle sandwich immunoassays to determine the presence of SARS-CoV-2 nucleocapsid protein antigen and RSV viral antigens present in the test sample.

Clinical performance*

The performance of the LumiraDx SARS-CoV-2 & RSV test was established with direct nasal swabs prospectively collected from individual subjects. Due to the lack of circulating RSV since the start of the COVID-19 pandemic, prospectively collected frozen samples were used in this performance evaluation. Samples were collected from sequentially enrolled subjects who presented with symptoms of RSV or COVID-19.

LUMIRADX	REFERENCE PCR RESULTS TO CT < 33		
SARS-CoV-2 Ag Results**	POS	NEG	Total
POS	118	5	123
NEG	2	339	341
Total	120	344	464
	PPA	NPA	
	98.3% (94.1% - 99.5)	98.5% (96.6% - 99.4%)	

LUMIRADX	REFERENCE PCR RESULTS TO CT < 30		
RSV Results	POS	NEG	Total
POS	43	0	43
NEG	3	432	435
Total	46	432	478
	PPA	NPA	
	93.5% (82.5% - 97.5%)	100% (99.1%-100%)	

**up to 12 days since symptom onset

* See LumiraDx SARS-CoV-2 & RSV Test Product Insert for additional details

Expanded clinical dataset - SARS-CoV-2

DSSO	PCR +ve	LDx +ve	PPA	CI	PCR -ve	LDx -ve	NPA	CI
0-5	120	106	88.3%	81.4% - 92.9%	297	293	98.7%	96.6% - 99.5%
0-6	128	112	87.5%	80.7% - 92.2%	312	308	98.7%	96.8% - 99.5%
0-7	140	121	86.4%	79.8% - 91.1%	332	328	98.8%	96.9% - 99.5%
0-10	142	123	86.6%	80.0% - 91.3%	337	333	98.8%	97.0% - 99.5%
0-12	145	125	86.2%	79.7% - 90.9%	338	334	98.8%	97.0% - 99.5%

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

Built-in quality controls

LumiraDx Platform is integrated with several control checks when starting the Instrument and for every test run to ensure that the Instrument and Test are functioning correctly, including:

- Automatically checking the Test Strip expiration date and that adequate specimen volume is added prior to running a test
- Electrical component operation, heater operation, battery charge state, mechanical actuators and sensors and optical system performance
- Monitoring of the Test Strip performance and controls during test runtime
- Ability to perform Quality Control Tests using LumiraDx Quality Control solutions to meet regulatory compliance requirements.

SARS-CoV-2 & RSV quality controls

Positive and Negative Quality Controls are available from LumiraDx to complete Quality Control assessment of the Instrument and Test Strips.

Analytical performance; Limit of Detection (LoD)

The final LoD of the LumiraDx SARS-CoV-2 & RSV test was determined to be the lowest concentration resulting in positive detection of at least 95% of replicates. Based on this testing the LoD for nasal swab specimens was confirmed as:

VIRUS MATERIAL	STARTING CONCENTRATION	ESTIMATED LOD	NO. POSITIVE/TOTAL	% POSITIVE
SARS-CoV-2 (Zeptometrix 0810622UV)	1.26×10^6 $TCID_{50}$ /mL	800 $TCID_{50}$ /mL	20/20	100
RSV A 2006 isolate	3.55×10^5 $TCID_{50}$ /mL	252 $TCID_{50}$ /mL	20/20	100
RSV A 2014 isolate 341	1.70×10^5 $TCID_{50}$/mL	680 $TCID_{50}$ /mL	19/20	95
RSV B CH93(18)-18	1.05×10^6 $TCID_{50}$ /mL	900 $TCID_{50}$ /mL	20/20	100
RSV B 3/2015 isolate 1	1.41×10^5 $TCID_{50}$ /mL	200 $TCID_{50}$ /mL	20/20	100

Cross reactivity

SARS-CoV-2 & RSV was found not to cross-react with a panel of organisms and viruses including several human coronaviruses. See LumiraDx SARS-CoV-2 & RSV Product Insert for full details. The LumiraDx SARS-CoV-2 & RSV test does not differentiate between SARS-CoV and SARS-CoV-2.

Specifications

Sample Type	Nasal 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)
Relative Humidity	10% - 75%
Interferences	See LumiraDx SARS-CoV-2 & RSV Product Insert for details
Onboard Control	Onboard Quality Control (OBC) assay and sample processing control
Quality Control Material	Positive and Negative liquid controls

Swabs

Sterile Nasal swabs may be provided with the LumiraDx SARS-CoV-2 & RSV kit. Alternatively, please refer to the LumiraDx SARS-CoV-2 & RSV Technical Bulletin – Swabs, available on our website, for the most up to date list of all swabs currently validated for use with the LumiraDx SARS-CoV-2 & RSV 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: 0080058647239

See LumiraDx SARS-CoV-2 & RSV Test Product Insert for additional details

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