SARS-CoV-2 & Flu A/B Specifications

For *In Vitro* Diagnostic Use.

Intended use*

The LumiraDx SARS-CoV-2 & Flu A/B test is a rapid microfluidic immunofluorescence assay for use with the LumiraDx Platform intended for the simultaneous detection and differentiation of SARS-CoV-2, Influenza A, and/or Influenza B 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 Influenza may be similar.

Test description

The LumiraDx SARS-CoV-2 & Flu A/B test is a Point of Care rapid microfluidic immunofluorescence assay. The assay uses SARS-CoV/SARS-CoV-2 specific antibodies, Influenza A specific antibodies and Influenza B specific antibodies in individual channel particle-particle sandwich immunoassays to determine the presence of SARS-CoV-2, Influenza A and/or Influenza B Nucleocapsid Protein (NP) antigen present in the test sample.

Clinical performance up to 12 days since symptom onset*

The performance of the LumiraDx SARS-CoV-2 & Flu A/B test was established with anterior nares swabs prospectively collected from individual subjects. Due to the lack of circulating influenza 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 Influenza A/B or COVID-19.

LUMIRADX	REFERENCE PCR RESULTS		
SARS-CoV-2 Ag Results	POS	NEG	Total
POS	42	9	51
NEG	2	230	232
Total	44	239	283
	PPA	NPA	
	95.5% (84.9%-98.7%)	96.2% (93.0%-98.0%)	

LUMIRADX	REFERENCE PCR RESULTS		
Flu A Results	POS	NEG	Total
POS	25	6	31
NEG	5	247	252
Total	30	253	283
	PPA	NPA	
	83.3% (66.4%-97.2%)	97.6% (94.9%-98.9%)	

LUMIRADX	REFERENCE PCR RESULTS		
Flu B Results	POS	NEG	Total
POS	24	13	37
NEG	6	240	246
Total	30	253	283
	PPA	NPA	
	80.0% (62.7%-90.5%)	94.9% (91.4%-97.0%)	

*See LumiraDx SARS-CoV-2 & Flu A/B 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
5	103	95	92.2%	85.4% - 96.0%	192	190	99.0%	96.3%-99.7%
6	116	107	92.2%	85.9% - 95.9%	195	193	99.0%	96.3%-99.7%
7	126	115	91.3%	85.0% - 95.1%	213	210	98.6%	95.9%-99.5%
10	134	120	89.6%	83.2% - 93.7%	222	219	98.6%	96.1% - 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 & Flu A/B external 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 & Flu A/B 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 USA-WA1/2020	2.8 x 10^5 $TCID_{50}$ /mL	80 $TCID_{50}$ /mL	20/20	100
Flu A H1N1 California/07/2009	4.17 x10^5 $TCID_{50}$ /mL	200 $TCID_{50}$ /mL	20/20	100
Flu A H3N2 Hong Kong/6/68	5 x 10^4 $TCID_{50}$/mL	100 $TCID_{50}$ /mL	20/20	100
Flu B Brisbane 60/08	5 x 10^3 $TCID_{50}$ /mL	100 $TCID_{50}$ /mL	20/20	100
Flu B Wisconsin/1/10	3.89 x 10^4 $TCID_{50}$ /mL	40 $TCID_{50}$ /mL	20/20	100

Cross Reactivity

SARS-CoV-2 & Flu A/B was found not to cross-react with a panel of organisms and viruses including several human coronaviruses. See LumiraDx SARS-CoV-2 & Flu A/B Product Insert for full details. The LumiraDx SARS-CoV-2 & Flu A/B 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 & Flu A/B Product Insert for details
Onboard Control	Onboard Quality Control (OBC) assay and sample processing control
Quality Control Material	Positive and Negative external liquid controls

Swabs

Sterile Nasal swabs may be provided with the LumiraDx SARS-CoV-2 & Flu A/B kit. Alternatively, please refer to the LumiraDx SARS-CoV-2 & Flu A/B 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 & Flu A/B 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: +44 (0) 1172 842535

Manufactured by:
LumiraDx UK Ltd
Dumyat Business Park
Alloa, FK10 2PB, UK
Registration Number:
09206123

Authorized representative in the European Union:
LumiraDx AB
Västra Vägen 5A
16961 Solna, Sweden

lumiradx.com

S-COM-ART-01722 R4