LOMINA
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IVD CE

Lomina SARS-CoV-2+ Influenza A/B Antigen LTX Test

Instructions for Use (IFU)

[PACKING SPECIFICATION]

Variant	1 piece in a package - box/pouch	5 pieces in a package - box	25 pieces in a package - box	50 pieces in a package - box
Catalogue Nr.	L-CAB-Pro /1B - 1P	L-CAB-Pro/5B	L-CAB-Pro /25B	L-CAB-Pro /50B
IVD test strip in a plastic cassette [pcs]	1	5	25	50
Nasal swab [pcs]	1	5	25	50
Bottle with stabilisation fluid [pcs]	1	5	25	50
Dripping lid [pcs]	1	5	25	50
IFU [pcs]	1	1	1	1

[INTRODUCTION]

The novel coronaviruses belong to the ß genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. Influenza is a highly contagious, acute, viral infection of the respiratory tract. It is an infectious disease easily spreading through coughing and sneezing droplets containing live viruses. Type A viruses are typically more prevalent than type B viruses and are associated with most serious influenza epidemics, while type B infections are usually milder. Rapid diagnosis of influenza A/B has become more important due to the availability of effective antiviral therapy. Rapid diagnosis of influenza can reduce hospital stays, antimicrobial use and cost of hospital care

[INTENDED USE]

LOMINA SARS-CoV-2 + Influenza A/B Antigen Test is an antigen test kit designed for simultaneous qualitative detection of the SARS-CoV-2 and/or Influenza A/B infection in human nasal swab samples in vitro. It is used as a supplementary detection indicator for suspected cases of SARS-CoV-2 causing disease COVID-19 and/or respiratory Flu infection A/B.

[TEST PRINCIPLE]

The Lomina SARS-CoV-2 + Influenza A/B Antigen LTX test is a qualitative immunoassay for the detection of SARS-CoV-2 and/or Flu A/ B antigen in nasal swab specimens. Anti-SARS-CoV-2 antibody is coated in the test region of SARS-CoV-2. Anti-Influenza A antibody and anti-Influenza B antibody are coated in the test A region (A) and test B region (B) respectively. During testing, antigen in the specimen reacts with anti-SARS-CoV-2 antibody-coated particles and with anti-Influenza A antibody-coated particles as well as with anti-Influenza B antibody-coated particles in the reaction pad to produce the immune complex. The complex migrates along the membrane by capillary action to the test region. The complex then respectively reacts with the anti-SARS-CoV-2 antibody in the test region of SARS-CoV-2 and with anti-Influenza A antibody in the A region as well as with anti-Influenza B antibody in the B region. If the specimen contains SARS-CoV-2 antigen, a colored line will appear in the test region of SARS-CoV-2. If the specimen contains Influenza A/B, a colored line will appear in the test A/B region. If the specimen does not contain antigen of SARS-CoV-2, Influenza A/ B, no colored line will appear in the test region, indicating a negative result. To serve as a control, a colored line will always appear in the control region (C), indicating that the result is effective.

[CONTENT OF PRESENTATION]

1. IVD test strip in a plastic cassette
2. Humidity absorbing pad.
3. Stabilization fluid (Buffer)
4. Nasal Swab for sample collection CE 0197
5. Dripping lid
6. Bottles containing 300 µl (+/-5%) of buffer that are being used as extraction tubes.
7. Biohazard PVC Bag
8. Instruction for Use

[NOT INCLUDED IN THE PACKAGE]

Stopwatch/clock for measuring the duration of the test.

[PRECAUTIONS !]

- The LOMINA SARS-CoV-2+Influenza A/B Antigen Test is intended for professional in vitro diagnostic use and should only be used for the qualitative detection of the presence of SARS-CoV-2 antigen and/or Influenza A and/or Influenza B in a sample.
- Read the Package Insert (IFU) prior to use. Instructions should be read and followed carefully.
- Do not use kit or components beyond the expiration date.
- The device contains material of animal origin and should be handled as a potential biohazard. Do not use if pouch is damaged or open.
- Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices that have holes in the foil or where the pouch has not been completely sealed. Erroneous result may occur if test reagents or components are improperly stored.
- Do not use the Sample Diluent Buffer if it is discolored or turbid. Discoloration or turbidity may be a sign of microbial contamination.
- All patient specimens should be handled and discarded as if they are biologically hazardous. Prior to testing, all samples must be thoroughly mixed with the reagent to ensure the correct solution for testing.
- Do not mix different lots (LOT) of tests and reagents!

[STORAGE CONDITIONS]

1. The test package shall be stored at 4°C to 30°C.
2. Kit contents are stable until the expiration dates marked on its outer packaging and containers, its validity period is set to 18 months (based on stability study).
3. Prolonged exposure to heat and humidity will make the reagent useless.

[TRANSPORT CONDITIONS]

The test package may be temporarily transported at -10°C.

[SPECIMEN COLLECTION AND STORAGE]

Specimen Collection:

- Acceptable specimens for testing with the LOMINA SARS-CoV-2+Influenza A/B Antigen Test include samples from nasal swabs.
- Do not use specimens that are obviously contaminated with blood, as it may interfere with the flow of sample with the interpretation of test results.
- Use freshly collected samples for best test results.
- To ensure optimal performance, use ONLY THOSE SWABS supplied in the kit!
- THIS TEST IS DESIGNED TO DETECT AN ACTIVE VIRUS ! Inactivated virus may not be detected / the test sensitivity will be affected!
- Do not test nasal swab specimens intended for RT-PCR, PCR or anyhow chemically treathed.
- After sampling, the appropriate buffer provided in the kit shall be used as soon as possible. No other type of solution should be used to store the sample!
- Do not test preserved or otherwise prepared samples intended for PCR, ELISA and other methods!

[ANTERIOR NASAL SWAB PROCEDURE]

Use a nasal swab to take a sample.

Nasal swab procedure: As shown on the picture, carefully and slowly insert the sterile Nasal swab into the nostril with the most secretion under visual observation - around 2-3cm (see picture). Gently push the swab until it meets resistance at the wall of the turbinate. Rotate the swab gently against the nose wall a few times. If coughing, please wait a while and try again. After collection place the swab in the reagent bottle containing buffer.

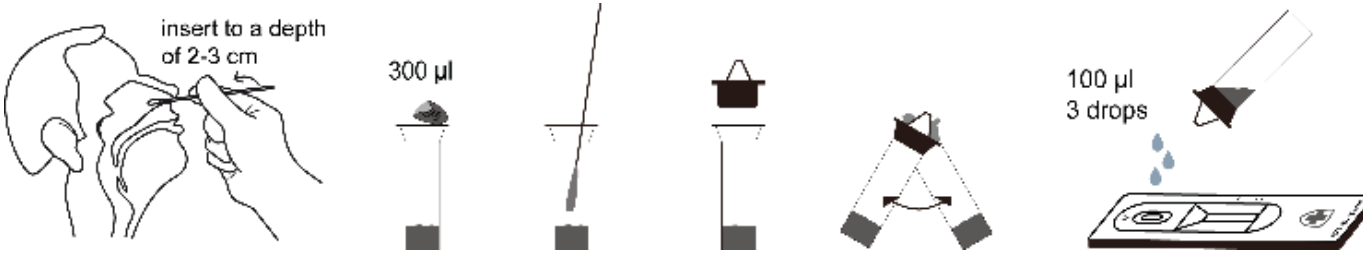
If the swab body extends beyond the top of the tube, squeeze it so that the top of the swab stem is just below the top of the tube, allowing the end of the swab tip to remain in solution and allow the sample to mix sufficiently with the Buffer. When pushing/pulling the swab, keep it gentle and do not use force to avoid injury to the patient!

[SAMPLE QUALITY REQUIREMENT]

1. The sample should be processed by preservation solution (buffer) immediately after sample collection. It is recommended to detect immediately after sample collection.
2. Reagent vials should not be opened until sample is applied.
3. Long-term storage of the samples is not recommended.

[OPERATING STEPS]

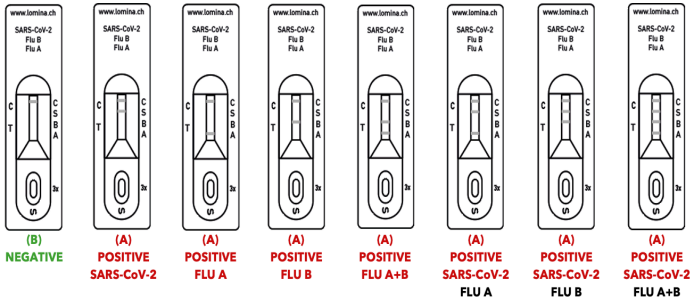
1. Before testing, read the operating instructions carefully, and restore the testing kit.
2. Take out the test card in the environment of temperature between 15°C and 28°C and humidity 30% to 50% (avoid strong convection or ventilation environment).
3. Collect the sample using SWAB as described above.
4. Place the SWAB with the swab into the tube with buffer and wash the analyte well by rotating the SWAB at least 5 times, then remove the SWAB.
5. Close the tube by a dripping lid.
6. Tear open the foil bag, take out the test card, place on a horizontaly leveled table and drip 3 drops (about 100 uL) of the treated sample solution into the sample hole of the test card.
7. Use the test card as soon as possible but no later than after 15 min. after opening the pouch. Humidity may damage the test sensitivity.
8. Apply the sample and wait for 15-20 minutes without moving the card.
9. The test is to be invalid after more than 25 minutes after dripping the analyte (sample) in to detection card.



[INTERPRETATION OF TEST RESULTS]

The test should be judged in a combination with clinical symptoms and another detecting indicators. Result is interpreted by presence of a visible strip at the „COV-2, Flu A or B" area at the test card body (see next picture), the visual inspection results are following:

SARS-COV-2 (COVID-19) AND/OR INFLUENZA A/B POSITIVE: One band/line appears in the control region „C", and another band/line or lines appears

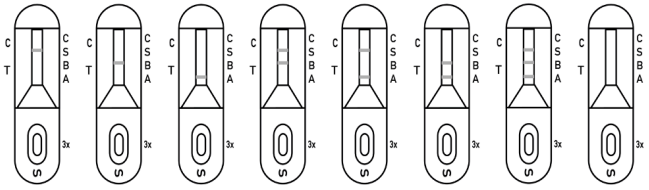


in the „COV-2, Flu A or B" region (picture A).

NEGATIVE TEST: Only one band/line appears in the control region „C" with no other bar sign elsewhere. (picture B)

INVALID TEST: No band/line appears in the control region (C), whether a test bands „COV-2, Flu A or B" are present or not. Repeat invalid tests with a new sample, new test device and reagent. Insufficient sample volume, inaccurate operating procedure or expired tests may yield an invalid result. Contact your local distributor if the problem continues. see bellow:

[LIMITATIONS OF INSPECTION METHODS]



1. Sample collection and processing methods have greater impact on virus detection. Allways ensure there is a visible sample on the SWAB surface.
2. Negative result may be caused by improper specimen collection and transfer, or by low concentration of antigen from the specimen.
3. Negative test results do not exclude the possibility of virus infection. If the test result is negative and the patient has clinical symptoms, it is recommended to use virus isolation and culture for confirmation, and a comprehensive diagnosis by the attending physician.
4. The collected samples may be contagious, and the processing and testing operations of the samples should be performed in compliance with local relevant biosafety regulations.

[CROSS-REACTIVITY]

12 types of viruses (1.0×105Pfu/mL), 8 types of bacteria (1.0×106Pfu/mL), Mycoplasma pneumoniae (1.0×106Pfu/mL) and Chlamydia pneumoniae (1.0×106Pfu/mL) listed below are confirmed to have no cross-reactivity with LOMINA SARS-CoV-2+Influenza A/B Antigen Test at all 3 bands: Human coronavirus 229E, Mycoplasma pneumoniae, Human coronavirus OC43, Legionella pneumoniae, Human coronavirus NL63, Bordetella pertusis, Human coronavirus HKU1, Staphylococcus aureus, Klebsiella pneumoniae, Streptococcus pneumoniae, Adenovirus, Staphylococcus epidermidis, Respiratory syncytial virus, Streptococcus pyogenes, Rhinovirus, Human Metapneumovirus (hMPV), Enterovirus, Haemophilus influenzae, Parainfluenza virus I-4, Pooled human nasal wash, Candida albicans, Chlamydia pneumoniae, Coxsackievirus A24, B5, Mumps virus, Human Coronavirus (MERS), Epstein-Barr virus (human herpesvirus), Human Coronavirus (SARS), Varicella-zoster virus (human herpesvirus 3), Norovirus Type GII, Human cytomegalovirus (human herpesvirus 5), Measles virus.

[INTERFERENCE FACTORS]

No interference with the following substances has been detected:
Benzocaine 150 mg/dL, Flixonase 50 MCG, Blood 5%, Tamiflu (Oseltamivir phosphate) 500mg/dL, Mucin 5 mg/mL, Pulmicort 0,5MG/m, NasoGel spray (Neil Med), Nutricius Biotin 300 mg, Neosynephrin-pos 100mg/nl, Methanol 150mg/dL, Afrin 0,5 mg/ml, Acylpyrin 500, Naso GEL spray (Neil Med) 5%
, Stopangin spray 1x30 ml, Bramitob 300 mg/4ml, Robitussin expectorans 100 mg/5 ml, Mupirocin 0.15mg/dL, Vasopirin 100mg tbl., Berodual N 10 ml, Psilo-Balsam 10mg/G gel, Alkalol Nasal Wash 10%, Dextromethorphan nutra essential 10mg/5ml, Anginal, NasaMist (NeilMed), Fortecortin 4mg tbl, Anopyrin 100mg tbl, Ventolin Inhaler N 100 mg, Symbicort Turbuhaler 160mg/4,5mg.

[REPEATABILITY]

The repeatability and reproducibility study of three lots products from different laboratories and different dates. 10 Negative controls, 3 LOD controls and 1 CV control were used to study. The coincidence rate of intra-assay and inter-assay repeatability was 100%. The coincidence rate of intra-day and inter-day repeatability was 100%.

[LIMIT OF DETECTION - LOD]

The LOD for the Novel Coronavirus LOMINA SARS-CoV-2+Influenza A/B Antigen Test has been established using limiting dilutions of a viral sample. The analyte was supplied at a concentrationf of SARS-CoV-2: 3.0 x 10^5 $TCID_{50}$/mL; Influenza A: 1.0 x 10^6 $TCID_{50}$/mL; and Influenza B: 1.0 x 10^6 $TCID_{50}$/mL. In the study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2 using Superyears PCR-2215. An initial range finding study was performed testing devices in triplicate using gradient dilution series. At each dilution, 50 µL samples were added to swabs and procedure appropriate for patient nasal swab(polyester) specimens executed. A concentration was chosen between the last dilution to give 3 positive results and the first to give 3 negative results. Using the concentration which last dilution to give 3 positive results, the LOD was further refined with a 2-fold dilution series 10x. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

Concentration of delta variant of **SARS-CoV-2** Nasal secret	Estimated LOD	No.Positive total	Positive %
3.0 × 105 TCID50/mL	40 $TCID_{50}$/mL	19/20	95%

Dilution Gradient	CT value	SARS-CoV-2 COVID-19	Dilution Gradient	CT value	SARS-CoV-2 COVID-19
$10x2^0$	22,8	positive	$10x2^5$	30,41	positive
$10x2^1$	24,45	positive	$10x2^6$	31,13	positive
$10x2^2$	26,47	positive	$10x2^7$	31,91	positive
$10x2^3$	27,22	positive	$10x2^8$	32,35	positive
$10x2^4$	28,31	positive	$10x2^9$	33,6	positive
			$10x2^{10}$	34,97	negative

Concentration of delta variant of **Influenza A** Nasal secret in concentration of 1.0 × 106 TCID50/mL	Estimated LOD	No.Positive total	Positive %
Flu A/Texas/50/2012(H3N2)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/NYMC X-223A(H3N2)	$1.5×10^3$ TCID50/mL	19/20	95%
Flu A/Kiev/301/1994(H3N2)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/New Caledonia/20/1999(H1N1)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/Solomon Islands/03/06(H1N1)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/shangdong/9/93(H3N2)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/blue-winged teal/Wisconsin/11OS2873/2011(H3N2)	$1.5×10^3$ TCID50/mL	19/20	95%
Flu A/Brisbane/10/2007(H3N2)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/GUANGDONG/2019 (H1N1)	$1.5×10^3$ TCID50/mL	20/20	100%
Flu A/CNIC-1909 (H1N1)	$1.5×10^3$ TCID50/mL	20/20	100%

Concentration of delta variant of **Influenza B** Nasal secret in concentration of 1.0 × 106 TCID50/mL	Estimated LOD	No.Positive total	Positive %
Flu B/Washington/02/2019 (Victoria)	1.5×103 TCID50/mL	20/20	100%
Flu B/Phuket/3073/2013 (Yamagata)	1.5×103 TCID50/mL	19/20	95%
Flu B/Malaysia/2506/04 (Victoria)	1.5×103 TCID50/mL	20/20	100%
Flu B/Florida/04/06(Yamagata)	1.5×103 TCID50/mL	20/20	100%
Flu B/Tokyo/53/1999	1.5×103 TCID50/mL	20/20	100%
Flu B/Florida/07/04	1.5×103 TCID50/mL	20/20	100%
Flu B/Victoria/504/2000	1.5×103 TCID50/mL	19/20	95%

[SENSITIVITY/SPECIFICITY]

The LOMINA SARS-CoV-2+Influenza A/B Antigen Test is useful for the detection of SARS-CoV-2 coronavirus nucleocapsid (N) antigen from orolaryngeal or nasopharyngeal swabs.

Overall sensitivity and specificity were determined from the results of all the above tests. The resulting values were determined by summing the individual positive and negative samples for the same reference method:

- Reference method: PCR (2103 samples - positive samples (439 COVID-19 positive, 71 Influenza A positive, 82 Influenza B positive - 1511 negative samples).
- Reference material:
  - Comparative PCR: samples taken with a nasal swab
  - Nasal swab - CE0197 (1322 samples for LOMINA SARS-CoV-2+Influenza A/B Antigen Test)
- Number of samples for sensitivity determination (number of PCR-positive samples): 592
- Number of samples for specificity determination (number of PCR-negative samples): 1511

Test results to SARS-CoV-2 virus

		PCR	
		POSITIVE	NEGATIVE
LOMINA SARS-CoV-2+Influenza A/B Antigen Test	POSITIVE	426	2
	NEGATIVE	13	1018

Sensitivity: 97,04% (95% CI: 94,99%-98,41%)
Specificity: 99,80% (95% CI: 99,29%-99,98%)
Accuracy: 98,97 (95% CI: 98,31%-99,42%)
The results to SARS-CoV-2 virus of LOMINA SARS-CoV-2+Influenza A/B Antigen Test with correlation to Ct value of the positive samples were as follows:

CT Value	Diagnostic sensitivity LOMINA SARS-CoV-2 +Influenza A/B Antigen Test	95% CI
PCR positive	97,04%	94,99-98,41%
PCR – Strongly positive (CT < 20)	100%	90,3-100%
PCR – Positive (CT 20-30)	97,9%	95,9-99,1%
PCR - Weakly pozitive (CT > 30)	81,5%	61,9-93,7%

Test results to Influenza A virus

		PCR	
		POSITIVE	NEGATIVE
LOMINA SARS-CoV-2+Influenza A/B Antigen Test	POSITIVE	68	0
	NEGATIVE	3	238

Sensitivity: 95,77% (95% CI: 88,14%-99,12%)
Specificity: >99,9% (95% CI: 98,46%-100%)
Accuracy: 99,03% (95% CI: 97,19%-99,80%)
The results to Influenza A virus of LOMINA SARS-CoV-2+Influenza A/B Antigen Test with correlation to Ct value of the positive samples were as follows.

CT Value	Diagnostic sensitivity LOMINA SARS-CoV-2 +Influenza A/B Antigen Test	95% CI
PCR positive	95,77%	88,1-99,1%
PCR – Strongly positive (CT < 20)	100%	47,8-100%
PCR – Positive (CT 20-30)	96,7%	88,4-99,6%
PCR - Weakly pozitive (CT > 30)	83,33%	35,9-99,6%

Test results to Influenza B virus

		PCR	
		POSITIVE	NEGATIVE
LOMINA SARS-CoV-2+Influenza A/B Antigen Test	POSITIVE	78	0
	NEGATIVE	4	253

Sensitivity: 95,12% (95% CI: 87,98%-98,66%)
Specificity: >99,9% (95% CI: 98,55%-100%)
Accuracy: 98,87% (95% CI: 96,97%-99,67%)
The results to Influenza B virus of LOMINA SARS-CoV-2+Influenza A/B Antigen Test with correlation to Ct value of the positive samples were as follows.

CT Value	Diagnostic sensitivity LOMINA SARS-CoV-2 +Influenza A/B Antigen Test	95% CI
PCR positive	95,12%	87,9%-98,7%
PCR – Strongly positive (CT < 20)	100%	73,5-100%
PCR – Positive (CT 20-30)	95,24%	86,7-99,0%
PCR - Weakly pozitive (CT > 30)	85,71%	42,1-99,6%

[*INTEGRATED NC MEMBRANE CROSS-REACTIVITY]

Integrated NC membrane of 3 target pathogens - SARS-CoV-2 has no cross-reactivity with Flu A and Flu B at LOMINA SARS-CoV-2+Influenza A/B Antigen Test. Flu A and Flu B at a concentration of 1.0 × 106 TCID50/mL have no cross-reactivity with SARS-CoV-2 at LOMINA SARS-CoV-2+Influenza A/B Antigen Test.

TYPE	Concentration	SARS--CoV-2 Test	Flu A Test	Flu B Test
SARS-CoV-2 Delta variant	3.0 × 105 TCID50/mL	positive	negative	negative
SARS-CoV-2 Omicron variant	3.0 × 105 TCID50/mL	positive	negative	negative
Flu A/Texas/50/2012(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/NYMC X-223A(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/Kiev/301/1994(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/New Caledonia/20/1999(H1N1)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/Solomon Islands/03/06(H1N1)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/Shangdong/9/93(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/blue-winged teal/Wisconsin/11OS2873/2011(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/Brisbane/10/2007(H3N2)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/GUANGDONG/2019 (H1N1)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu A/CNIC-1909 (H1N1)	1.0 × 106 TCID50/mL	negative	positive	negative
Flu B/Washington/02/2019(Victoria)	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Phuket/3073/2013 (Yamagata)	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Malaysia/2506/04 (Victoria)	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Florida/04/06(Yamagata)	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Tokyo/53/1999	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Florida/07/04	1.0 × 106 TCID50/mL	negative	negative	positive
Flu B/Victoria/504/2000	1.0 × 106 TCID50/mL	negative	negative	positive

[ANNOUNCEMENTS]

1. The test must be performed in accordance with local requirements for safe laboratory procedures and it is critical to avoid cross-contamination of the material. All samples, rinses and wastes must be considered and treated as infectious material.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. False negative results may occur if a specimen is improperly collected, transported, or handled.
4. False results may occur if specimens are tested later than 1 hour after collection. (Specimens should be test as quickly as possible after specimen collection).
5. Insert the test sample into the test card very slowly and observe the exact amount of 3 drops of sample!
6. The reaction time of the test is 15-20 minutes to the nearest 1 minute. After the reaction is complete, do not read the result later than 25 minutes. In other words, the result is invalid 25 minutes after loading the test solution.
7. The color intensity or thickness of the positive strip cannot be considered „quantitative or semi-quantitative".
8. Keep in mind that a positive patient is likely to be infectious, so follow the rules issued by your country's responsible authorities.

	Consult instructions for use		Caution		Use by date
IVD	In vitro diagnostic medical device		Do not use if package is damaged		Do not re-use/Intended for one use
	Manufacturer	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight	Σ	Contains sufficient for <n> tests		Temperature limit 4-30 °C
	Keep dry	STERILE EO	Sterilised by ethylene oxide		

MANUFACTURER:
LOMINA SUPERBIO a.s.
Na Radosti 184/59, Praha 5,
155 21, CZECH REPUBLIC
www.lomina.ch sales@lomina.ch

REF
L-CAB-Pro

Date of least revision: 2022/05/05
Version: L-CAB-Pro / EN-IFU-1.0