LOMINA
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Lomina SARS-CoV-2 Antigen LTX Selftest

Instructions for Use (IFU)

[PRODUCT NAME]
Lomina SARS-CoV-2 Antigen LTX Selftest

[PACKING SPECIFICATION]

Variant	1 piece in a package - pouch	1 piece in a package - box	2 pieces in a package - box	50 pieces in a package - box
Catalogue Nr.	L-LTX-ST/1P	L-LTX-ST/1B	L-LTX-ST/2B	L-LTX-ST/50B
IVD test strip in a plastic cassette [pcs]	1	1	2	50
Nasal swab [pcs]	1	1	2	50
Bottle with stabilisation fluid [pcs]	1	1	2	50
Dripping lid [pcs]	1	1	2	50
Biohazard PVC bag [pcs]	1	1	2	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.

[INTENDED USE]
Lomina SARS-CoV-2 Antigen LTX Selftest is a test kit designed for home use by lay persons for qualitative detection of the new coronavirus nucleocapsid (N) antigen in self-collected human nasal swab samples in vitro. It is used as a supplementary detection indicator for suspected cases of new coronavirus designed for virus detection from approximately 5th day after infection including asymptomatic cases. It should not be used as the only basis for the diagnosis and exclusion of pneumonitis caused by the new coronavirus. Lomina SARS-CoV-2 Antigen LTX Selftest is intended for self-testing of all age groups for adults or under adults supervision. Patients with limited abilities shall ask an assistance of a professional or for this purpose trained person.

[TEST PRINCIPLE]
This test uses the double antibody sandwich method to detect the Nucleocapsid Protein of the novel coronavirus SARS-CoV-2. The test strips are coated with rabbit anti-Nucleocapsid Protein antibody B and Goat anti-mouse IgG polyclonal antibodies in the nitrocellulose membrane test area (T) and quality control area (C) respectively, and the binding pad is coated with latex-labeled anti- Nucleocapsid Protein antibody A and mouse IgG, when added to the sample, is chromatographed toward the absorbent paper by capillary action. If the sample contains the novel coronavirus, it will specifically bind to the anti- Nucleocapsid Protein antibody A on the binding pad. When the sample flows through the nitrocellulose membrane (NC membrane), it will be captured by the anti- Nucleocapsid Protein antibody B pre-coated on the nitrocellulose membrane (NC membrane) and form a color band (strip) in the detection area (T), indicating a positive result; if the sample does not contain the novel coronavirus, the detection area cannot produce a color band, indicating a negative result. Regardless of whether the sample contains virus or not, a ribbon will always appear in the quality control area (C) as an internal quality control, indicating that the test is correct and chromatographic reaction run effective.

[CONTENT OF PRESENTATION]
1. DETECTION CARD composed of:
   - A rabbit anti-SARS-CoV-2 N protein antibody and goat anti-mouse secondary antibody (immobilized on a nitrocellulose membrane).
   - Another mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled and mouse IgG labeled with latex spheres (mixed and sprayed on the marker pad).
   - Sampling pad.
   - Liquid absorbent pad.
   - Plastic case/card (also often called a cassette).
2. Humidity absorbing pad.
3. Buffer - PBS based preservation solution buffer (vial).
   - sodium chloride (NaCl)
   - potassium chloride (KCl)
   - potassium dihydrogen phosphate (KH2PO4)
   - disodium hydrogen phosphate (Na2HPO4)
   - dH2O water

   (PH Value ~ 7,0-7,6)
4. Sterile 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

[MATERIALS NOT PROVIDED]
Stopwatch / a clock for measuring the time duration of the test.

[PRECAUTIONS !]
- For In Vitro Diagnostic Use by laymen for selftesting.
- Read the Package Insert (IFU) prior to use. Directions 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.
- In individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of COVID-19 infections and without known exposure to COVID-19, more false positive results may occur. Testing of individuals without symptoms should be limited to contacts of confirmed or probable cases or to other epidemiological reasons to suspect a COVID-19 infection and should be followed by additional confirmatory testing with a molecular test.

[STORAGE CONDITIONS]
1. The test package shall be stored at 4°C to 30°C.
2. The components of different batches must not be mixed.
3. Each component is stable under the specified conditions, and can reach the specified validity period of the kit.
4. 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).
5. 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 Antigen LTX Selftest 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 and bottles with Buffer supplied in the kit!
- Do not test nasal swab specimens intended for RT-PCR, PCR or anyhow chemically treated.
- 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!

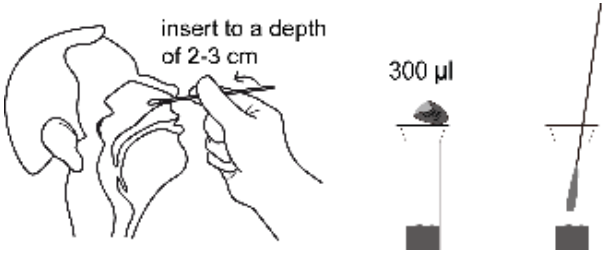
[ANTERIOR NASAL SWAB PROCEDURE]
Use in the kit provided nasal swab to take a sample.

Nasal swab procedure:
As shown in the enclosed figure, 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 (see picture). 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. 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 reagent.

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.

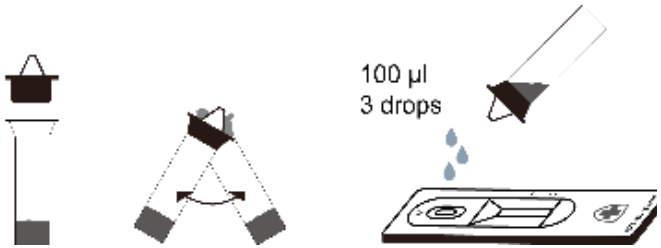


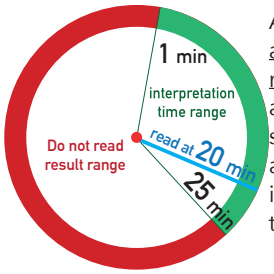
[OPERATING STEPS]

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 ventilation environment).
3. Collect the sample using SWAB as described above.
4. Carefully check there is some visible sample gathered on the swab before inserting the swab into a bottle with buffer. If you dont see any visible secret (slime) on the SWAB, collect the nasal swab again or use second nostril.
5. Place the SWAB with the swab into the tube with buffer and wash the analyte well by rotating the SWAB at least 10 times, then remove the SWAB. Squeeze both sides of the bottle to allow better release and mixing of the sample with the buffer.
6. Close the tube by a dripping lid.
7. Tear open the foil bag, take out the test card, place on a horizontally levelled table and drip 3 drops (about 100 uL) of the treated sample solution into the sample hole of the test card marked by letter „S" (yellow spot on the enclosed picture).
8. 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.
9. Apply the sample and wait for **15-20 minutes without moving the card.**
10. The test is to be invalid after more than 25 minutes after dripping the analyte into the detection card.
11. Refer also to the quick reference guide at last page.

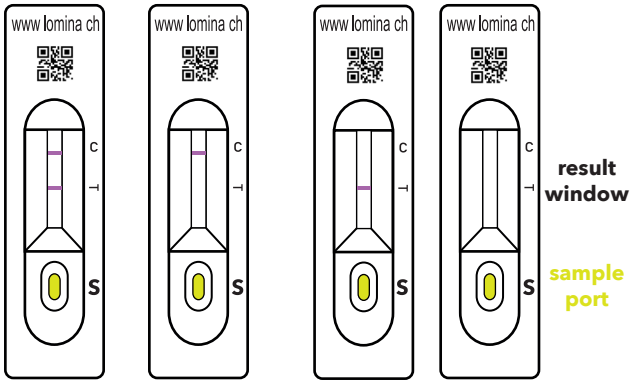
[INTERPRETATION OF TEST RESULTS]

1. The test should be judged in a combination with clinical symptoms and another detecting indicators. **If uncertain always consult your medical doctor.**
2. **Result is interpreted by presence of a visible strip at the „T" area at the test card body (see picture bellow),** the visual inspection results are following:





After applying the sample, start a stopwatch and wait for 15-20 minutes with out moving the card and then read the result at the „T" section at the testing card. Strip may appear withing few seconds at high infections, weaker infection will draw the strip little later.



SARS-CoV-2 (COVID-19) Positive:
One band/line appears in the control region „C", and another band/line appears in the „T" 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 band „T" is 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. (picture C).

[LIMITATIONS OF INSPECTION METHODS]

1. Sample collection and processing methods have greater impact on virus detection. 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.
2. 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]

No significant cross-over with other coronavirus:

Human coronavirus 229E	Mycoplasma pneumoniae
Human coronavirus OC43	Legionella pneumoniae
Human coronavirus NL63	Bordetella pertussis
Human coronavirus HKU1	Staphylococcus aureus
Influenza A&B	Streptococcus pneumoniae
Adenovirus	Staphylococcus epidermidis
Respiratory syncytial virus	Streptococcus pyogenes
Rhinovirus	Candida albicans
Enterovirus	Haemophilus influenzae
Parainfluenza virus I-4	Pooled human nasal wash
Human Metapneumovirus (hMPV)	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	Klebsiella pneumoniae

[INTERFERENCE FACTORS]

1. No interference with mucin samples.
2. No interference reaction when the blood concentration in the sample is not higher than 2%
3. No interference reaction with the following drugs has been detected:

Substances:

Benzocaine 150 mg/dL	Fluticasone 0.000126mg/dL
Blood 5%	Tamiflu (Oseltamivir phosphate) 500mg/dL
Mucin 5 mg/mL	Budenoside 0.00063 mg/dL
Naso GEL (NeilMed) 5%	Biotin 0.35mg/dL
Phenylephrine 15%	Methanol 150mg/dL
Afrin Oxymetazoline 15%	Acetylsalicylic Acid 3mg/dL
CVS Nasal Spray (Cromolyn) 15%	Diphenhydramine 0.074mg/dL
Alkalol Nasal Wash 10%	Dextromethorphan 0.00156mg/dL
Sore Throat Phenol Spray 15%	Dexamethasone 1.2 mg/dL
Tobramycin 3.3mg/dL	Mucinex 5%
Mupirocin 0.15mg/dL	

[LIMIT OF DETECTION - LOD]

The LOD for the Novel Coronavirus Lomina SARS-CoV-2 Antigen LTX Selftest has been established using limiting dilutions of a viral sample. The material was supplied at a concentration of 3.0 x 10 TCID50/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 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.

Dilution Gradient	CT value	SARS--CoV-2 CO-VID-19	Dilution Gradient	CT value	SARS--CoV-2 CO-VID-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

[REPEATABILITY]

The repeatability and reproducibility study of three batches of products in a laboratory and on different dates. 10 negative controls, 3 LOD controls and 1 CV control were used in the study. The coincidence rate of intra-assay and inter-assay repetition rate was 100%. The coincidence rate of day and room repeatability was 100%.

[SENSITIVITY/SPECIFICITY]

The Lomina SARS-CoV-2 Antigen LTX Selftest is useful for the detection of SARS-CoV-2 coronavirus nucleocapsid (N) antigen from nasal 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 (1459 samples - 439 positive samples, 1020 negative samples)
- Reference material:
  - Comparative PCR: samples taken with a nasal swab
  - Nasal swab - CE0197 (1459 samples for Lomina SARS-CoV-2 Antigen LTX Selftest)
- Number of samples for sensitivity determination (number of PCR-positive samples): 439
- Number of samples for specificity determination (number of PCR-negative samples): 1020

		PCR	
		POSITIVE	NEGATIVE
Lomina SARS-CoV-2 Antigen LTX Selftest	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 with correlation to Ct value of the positive samples were as follows.

CT Value	Diagnostic sensitivity	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 positive (CT > 30)	81,5%	61,9-93,7%

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to 3.0x105 $TCID_{50}$/mL of gamma-inactivated SARS-CoV-2 for Lomina SARS-CoV-2 Antigen LTX Selftest.

[ANNOUNCEMENTS]

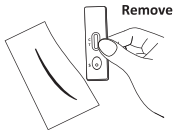
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
- False negative results may occur if a specimen is improperly collected, transported, or handled - in other words if the present Instruction For Use is not followed.
- False results may occur if specimens are tested later than 1 hour after collection. (Specimens should be test as quickly as possible after specimen collection)
- Do not mix different lots (LOT) of tests and reagents!
- Before testing, read the Instructions for Use (IFU) carefully and strictly follow the procedures in the manual.
- Insert the test sample into the test card very slowly and observe the exact amount of 3 drops of sample!
- 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.
- The Lomina SARS-CoV-2 Antigen LTX Selftest is intended for laymen selftesting in vitro diagnostic use and should only be used for the qualitative detection of the presence of SARS-CoV-2 antigen in a sample.
- The color intensity or thickness of the positive strip cannot be considered „quantitative or semi-quantitative".
- Keep in mind that a positive patient is likely to be infectious, so follow the rules issued by your country's responsible authorities.
- Positive patient should only adapt the treatment if he has received the appropriate training to do so.
- If uncertain always refer to your medical practitioner.
- The user should not take any decision of medical relevance without first consulting his or her medical practitioner.

[* SWAB MANUFACTURER'S DETAILS]

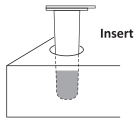
Jiangsu Rongye Technology Co.,Ltd. STERILE EO
TouQiao Town, Yangzhou City, Jiangsu, China
MDD Annex V, Notified by:
TUV Rheinland LGA Products GmbH CE 0197
Certificate Nr: SX-60148419-001 and future revisions.

QUICK USER REFFERENCE GUIDE:

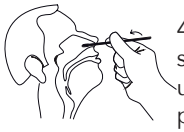
1) Wash your hands before starting the testing procedure.



2) Remove the test cassette from an alluminium pouch, place it on flat surface and use the test immediately.

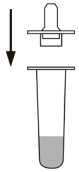


3) Insert the bottle with a buffer to a hole or to any other holder and peal off the lid.



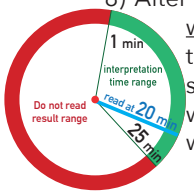
4) carefully and slowly insert the sterile Nasal swab into the nostril with the most secretion under visual observation - around 2-3cm (see picture). Gently push the swab until it meets resistance at the wall of the nose and twist at least 5 times. Carefully check there is some visible sample gathered on the swab before inserting the swab into a bottle with buffer. If you don't see any visible secret (slime) on the SWAB, collect the nasal swab again or use second nostril.

5) Place the SWAB with the swab into the tube with buffer and wash the analyte well by rotating the SWAB at least 10 times, then remove the SWAB. Squeeze both sides of the bottle to allow better release and mixing of the sample with the buffer



6) Close the lid and shake few times.

7) Drip 3 drops (about 100 µL) of the treated sample solution into the sample hole of the test card marked by letter „S"



8) After applying the sample start a stopwatch and wait for 15-20 minutes without moving the card and then read the result at the „T" section at the testing card. Strip will appear withing few seconds at high infections, weaker infection will draw the strip little later.

[EXPLANATION OF TERMS USED]

Sensitivity
Diagnostic sensitivity means the ability of a device to identify the presence of a target marker associated with SARS-CoV-2.

Specificity
Diagnostic specificity means the ability of a device to recognise the absence of a target marker associated with SARS-CoV-2.

Repeatability
Repeatability or test–retest reliability is the closeness of the agreement between the results of successive measurements of the same measure, when carried out under the same conditions of measurement.

Cross-reactivity
Cross-reactivity means the ability of non-target analytes or markers to cause false-positive results in an assay because of similarity.

Limit of detection (LOD)
The limit of detection means the smallest amount of the target marker that can be precisely detected, the LOD is part of analytical sensitivity of the device.

Interference factor
Interference means the ability of unrelated substances to affect the results in an assay.

[SYMBOL INDEX]

	Read Instruction for use	Σ	Content sufficient for <n> tests		Do not use if package is damaged
IVD	In vitro diagnostic medical device		Use by date		Do not re-use
4°C 30°C	Store between 4-30 °C	LOT	Batch code	REF	Catalogue number
	Keep away from sunlight		Keep away from rain		Manufacturer
STERILE EO	Sterilized using ethylene oxide		Caution		Production date

Lomina SARS-CoV-2 Antigen LTX Selftest

L-LTX-ST/1P	L-LTX-ST/1B	L-LTX-ST/2B	L-LTX-ST/50B

8 595706 800020 | 8 595706 800013 | 8 595706 800037 | 8 595706 800044

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

CE 2934
REF L-LTX-ST

IVD 4°C 30°C

Date of least revision: 2022/05/09 Version: L-LTX-ST / EN-IFU-3.5