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IVD CE

Lomina SARS-CoV-2 Antigen LTX Test

Instructions for Use (IFU)

[PRODUCT NAME]
Lomina SARS-CoV-2 Antigen LTX Test (swab)
[PACKING SPECIFICATION]
Variant A:
1 pouch (pack) contains 1pcs of IVD test strip in a plastic cassette, 1pcs nasopharyngeal swab or 1pcs oropharyngeal swab, 1 pcs bottle with stabilization fluid and dripping lid, an IFU.
Variant B:
1 box contains 50pcs of IVD test strip in a plastic cassette, 50 pcs nasopharyngeal swab or 50 pcs oropharyngeal swab, 50 pcs bottle with stabilization fluid and dripping lid, an IFU.

[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 I to I 4 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]
The kit is used for the qualitative detection of new coronavirus nucleocapsid (N) antigen in human oropharyngeal and/or nasopharyngeal swab samples in vitro. It is used as a supplementary detection indicator for suspected cases of new coronavirus. It cannot be used as the only basis for the diagnosis and exclusion of pneumonitis infected by new coronavirus.

[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 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 mouse anti-SARS-Co V-2 N protein antibody and goat anti-rabbit secondary antibody (immobilized on a nitrocellulose membrane.
   - Another mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled and rabbit 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. Puffer - PBS based preservation solution buffer (vial).
   - sodium chloride (NaCl)
   - potassium chloride (KCl)
   - potassium dihydrogen phosphate (KH2PO4)
   - hydrogen disodium phosphate (Na2HPO4)
   - dH2O water

   (PH Value ~ 7,1-7,6)
4. Nasopharyngeal Swabs for sample collection or
5. Oropharyngeal Swabs for sample collection
6. Dripping lid
7. Bottles containing 300 ul (+/-5%) of buffer that are being used as extraction tubes.
8. Instruction for Use

[PRECAUTIONS !]
- For In Vitro Diagnostic Use Only by professionals.
- 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.

[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. DO NOT FREEZE.
5. Kit contents are stable until the expiration dates marked on its outer packaging and containers, its validity period is tentatively set to 18 months.
6. Prolonged exposure to heat and humidity will make the reagent useless.

[SPECIMEN COLLECTION AND STORAGE]
Specimen Collection:
- Acceptable specimens for testing with the Lomina SARS-CoV-2 Antigen LTX Test (swab) include samples from oroharyngeal and/or nasopharyngeal swabs.
- Avoid collecting saliva when collecting oropharyngeal swab samples.
- 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!

- Test the oropharyngeal swab samples collected on site. THIS TEST IS DESIGNED TO DETECT AN ACTIVE VIRUS ! Inactivated virus will not be detected / the test sensitivity will be affected!
- Saliva should not be collected when sampling with orolaryngeal swabs!
- Do not test oropharyngeal or nasolaryngeal 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, frozen or otherwise prepared samples intended for PCR, ELISA and other methods!

[ORO/NASOPHARYNGEAL SWAB PROCEDURE]

Use a throat,nasal or bronchoalveolar swab to take a sample.

Nasopharyngeal swab procedure:

As shown in the figure below, carefully and slowly insert the sterile Nasal swab into the nostril with the most secretion under visual observation. Gently push the swab until it meets resistance at the wall of the turbinate (see picture - NASAL spot). Rotate the swab gently against the nose wall a few times. If coughing, please wait a while and try again.

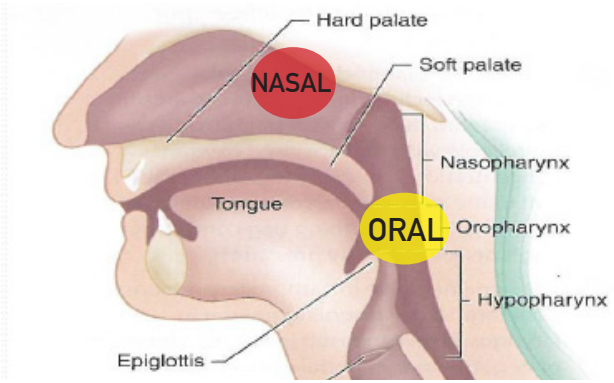
Oropharyngeal swab procedure:

When taking the patient, first rinse the mouth with saline. Alternatively, ask the patient to rinse with a small amount of water (ensure it doesnt contain chlorine or other desinficant that may affect the sample!), which will then spit out or be swallowed; ask the patient to open his mouth and make an "aaa..." sound to reveal the oropharyngeal part (see picture - ORL spot). If necessary, use a spatula to squeeze the root of the tongue. Insert the swab over the root of the tongue into the back of the pharynx or uvula. Apply with a palatal arch, over the pharynx and tonsils on both sides of the patient, applying constant pressure, and rotate the swab well to increase the contact area.

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]

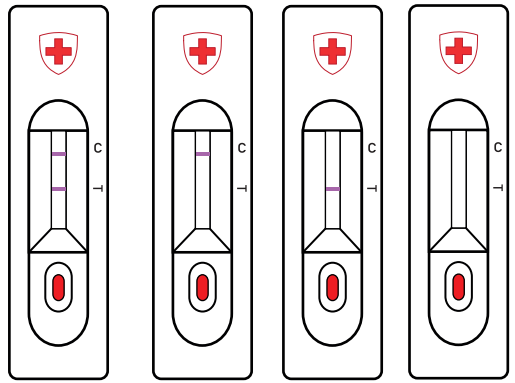
1. **The sample should be processed by preservation solution (buffer) of sample immediately after sample collection.** It is recommended to detect immediately after sample collection.
2. Reagent vials should not be opened until sample is applied.
3. of samples is not recommended.

[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. 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.
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 within 15 min. after opening the pouch. Humidity may damage the test sensitivity.
8. Wait for **15-20 minutes without moving the card**.
9. The test is to be invalid after later than 20 minutes after dripping the analyte.

[INTERPRETATION OF TEST RESULTS]

1. The test results of the kit are to be only used for clinical auxiliary diagnosis, not as the only basis for clinical diagnosis. The test should be comprehensively judged in a combination with clinical symptoms and another detecting indicators.
2. **Result is interpreted by presence of a visible strip at the „T" area at the test card body (see picture bellow),** the visual inspectlon results are following:



(A) (B) (C) (C)

POSITIVE **NEGATIVE** **INVALID**

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

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

[REPETEABILITY]

The repeatability and reproducibility study of three batches of products in different laboratories 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%.

[LIMIT OF DETECTION - LOD]

The LOD for the Novel Coronavirus Lomina SARS-CoV-2 Antigen LTX Test (swab) was established using limiting dilutions of a viral sample. The material was supplied at a concentration of 3.0 x 105 TCID50/mL. In this 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. 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 use the procedure appropriate for patient nasal swab specimens. 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. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

[SENSITIVITY/SPECIFICITY]

The Lomina SARS-CoV-2 Antigen LTX test (swab) 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:

		Nucleid Acid Testing Method	
		POSITIVE	NEGATIVE
SARS-CoV-2 Antigen test	POSITIVE	97	0
	NEGATIVE	6	250

Sensitivity: 94,17% (95% CI: 87,75%-97,83%)

Specificity: 100% (95% CI: 98,54%-100%)

The results with correlation to Ct value of the positive samples were as follows.

CT Value	Diagnostic sensitivity	95% CI
≤ 30	97,26	96,4-98,12%
≤ 33	94,95	93,7-96,2%
≤ 35	95,1	93,86-96,3%

HIGH DOSE HOOK EFFECT

No high dose hook effect was observed up to3.0x105 TCID50/mL of gamma-inactivated SARS-CoV-2 for Lomina SARS-CoV-2 Antigen LTX Test.

[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. Do not mix different lots (LOT) of tests and reagents! Any combination of batches is only possible after thorough verification testing according to a special procedure issued by the manufacturer upon request.
6. Before testing, read the Instructions for Use (IFU) carefully and strictly follow the procedures in the manual.
7. Insert the test sample into the test card very slowly and observe the exact amount of 100 µL of sample!
8. 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.
9. The Lomina SARS-CoV-2 Antigen LTX Test (swab) 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 in a sample. The color intensity or thickness of the positive strip cannot be considered „quantitative or semi-quantitative".
10. Keep in mind that a positive patient is likely to be infectious, so follow the rules issued by your country's responsible authorities.

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IVD 4°C 30°C

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