LOMINA
WWW.LOMINA.CH

GMDN #64912

IVD CE

PHARMDATA: APA4518032

REF LA-CoV-Ag

RZPRO/EUDAMED #00909708

SARS-CoV-2 N-Protein Antigen Rapid Test

(Pharyngeal Swab Fluorescence Assay)

Instructions for Use (IFU)

[PRODUCT NAME]

SARS-CoV-2 N-Protein Antigen Rapid Test
(Fluorescence Immunochromatography)

[PACKING SPECIFICATION]

2 boxes where the first (BOX B) contains 50 pcs of reagent bottles, the second (BOX A) contains 50 pcs of swabs and droppers, 50 pcs of available packaged testing cassettes and 1 UV emitter (without AA batteries), LSLC-20 MC card.

[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 SARS-CoV-2 nucleocapsid (N) antigen in human oropharyngeal swab samples in vitro. It is used as a supplementary detection indicator for suspected cases of new coronavirus negative nucleic acid detection or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonitis infected by new coronavirus.

[TEST PRINCIPLE]

A mouse anti-SARS-CoV-2 N protein antibody is coated on a nitrocellulose membrane as a test line, and a goat anti-rabbit secondary antibody is coated on a nitrocellulose membrane to make a quality control line.

Another mouse anti-SARS-CoV-2 N-protein monoclonal antibody labelled with latex fluorescent microspheres and a rabbit IgG labelled with latex fluorescent microspheres are mixed and sprayed on a glass cellulose membrane to prepare a label sample pad. One end of the nitrocellulose membrane near the quality control line is covered with a water absorption pad, and the other end near the test line is covered with a marker pad. The sample intended for testing is added to the marker pad, and the antigen will react with the marker and carry out chromatographic reaction along the nitrocellulose membrane, resulting to react with the test line and quality control line, respectively. When the test result is valid, the quality control line shows a certain light intensity. At this time, the ratio of the optical signal intensity on the test line to the optical signal intensity on the quality control line (T / C) is positively related to the sample concentration.

[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 labelled and rabbit IgG labelled with latex fluorescent microspheres (mixed and sprayed on the marker pad)
   - Liquid absorbent pad,
   - Plastic case
2. Humidity absorbing pad
3. Hank's solution based preservation solution puffer (vial).
   - Potassium Chloride
   - Magnesium sulphate heptahydrate
   - calcium chloride
   - monobasic potassium phosphate
   - glucose
   - sodium chloride
   - sodium bicarbonate
   - disodium hydrogen phosphate heptahydrate
   - phenol red sodium salt

   (PH Value 7,1-7,6)
4. Swab - Swabs for sample collection. OEM CE 0123
5. Plastic dropper (1drop/mark - 20-25ul)
6. UV lamp/emitter
7. Package insert (IFU) and LSLC-20 MC callibration card

[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 cards shall be stored at 4°C to 30°C.
2. The reagent vial (buffer) shall be stored at 2 °C to 10 °C but it may be exposed to a temperature of 4°C~30 °C for a maximum of 15 days. Dump heat test proved, such temperature shift may occur 3 times!
3. The components of different batches must not be mixed.
4. Each component is stable under the specified conditions, and can reach the specified validity period of the kit.
5. DO NOT FREEZE.
6. Kit contents are stable until the expiration dates marked on its outer packaging and containers, its validity period is tentatively set to 12 months.

[SPECIMEN COLLECTION AND STORAGE]

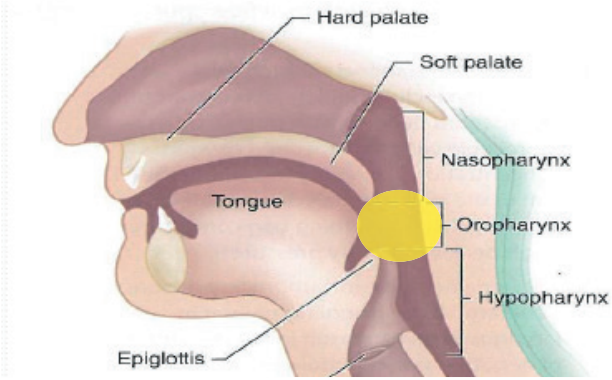
Specimen Collection:

- Acceptable specimens for testing with the SARS-CoV-2 N-Protein Antigen Rapid Test include exclusively samples from oropharyngeal swabs. (NOT NASAL !)
- Avoid collecting saliva when collecting oropharyngeal swab samples!
- Do not use specimens that are obviously contaminate 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, and **do not** test the nasopharyngeal samples. THIS TEST IS DESIGNED TO DETECT AN ACTIVE VIRUS ! Inactivated virus will not be detected / the test sensitivity will be affected!
- Saliva must not be collected when sampling with oropharyngeal swabs! Watch out not to contaminate the sample by saliva!
- Do not use samples that are obviously contaminated with blood, as this could interfere with sample flow in the membrane and lead to mis-interpretation of test results.
- Do not test oropharyngeal or nasopharyngeal swab specimens intended for RT-PCR, PCR.
- After sampling, the appropriate reagent 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!

[OROPHARYNGEAL SWAB]

Use a throat swab to take a sample. When taking the patient, first rinse the mouth with saline. Alternatively, ask the patient to rinse with a small amount of water, 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). 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. Be careful not to touch the tongue or contaminate the smear with saliva. Then 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.

[SAMPLE QUALITY REQUIREMENT]

1. **The sample should be processed by preservation solution of sample immediately after sample collection.** It is recommended to detect before 150 min after sample collection.
2. Reagent vials should not be opened until sample is applied.
3. If the test cannot be performed immediately, samples that have been placed in reagent vials immediately after collection should be stored in sealed vials at a temperature between 2 ° C and 8 ° C for a maximum of 150 minutes.
4. Long-term storage of samples is not recommended.

[INSPECTION METHODS]

1. Take out the test card in the environment of temperature between 18°C and 28°C and humidity 30% to 50% (avoid strong convection ventilation environment)
2. Cut off the packaging bag and place it on levelled table.
3. Drop 60 μL of sample solution to be tested into the sample hole of the test cassette and leave it at room temperature for **15 minutes without moving it.**
4. Use the UV torch and check the result under ultraviolet irradiation.

USE 60 ul per test exactly ! The test may fail if the sample volume is too large or too small.

[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. **When under UV light (395nm light wave length),** the visual inspection results are following:

COVID-19 Positive:

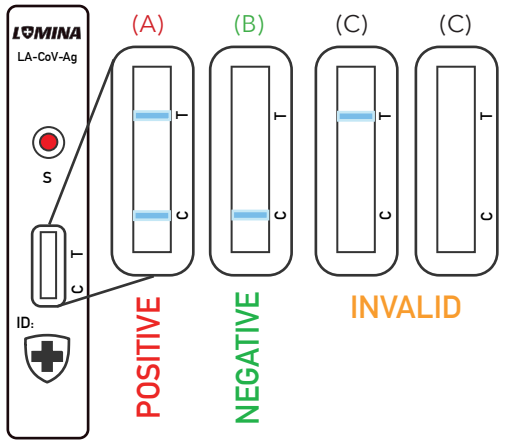
One band/line appears in the control region „C", and another band/line appears in the „T" region (picture A).

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).



3. Alternatively, use **LSLC-20** detector to read the results.

[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.

[PRODUCT PERFORMANCE INDEX]

1. Appearance: The test card should be neat and unbroken, no burrs, no damage, no pollution; the material should be firmly attached.
2. Film strip width of the film strip should be 3 mm.
3. Migration speed of the liquid migration should not be less than 10 mm/min.
4. The minimum detection limit is 100 ng/ml.
5. Use repeatable reference products for testing, and the results should all be positive.
6. The negative reference rate (-/-) should be 10/10.
7. The positive reference rate(+/+) should be 3/3.

[CROSS-REACTIVITY]

No significant cross-over with other coronavirus:

- HCo V-229E, - HCo V-OC43,
- HCo V-NL63, - HCo V-HKU 1).

[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:
   - guaiacol glyceryl ether, - ribavirin,
   - phenylephedrine, - chlortrimeton,
   - levofloxacin, - tobramycin,
   - lopinavir, - oseltamivir,
   - ritonavir, - peramivir,
   - cefradine, - zanamivir,
   - flunisolide, - fluticasone,
   - dexamethasone, - mometasone,
   - beclometasone, - triamcinolone,
   - fluocinolone acetonide 21-acetate.

[SENSITIVITY/SPECIFICITY]

Early detection - Clinical Study Result:

TEST SUMMARY SARS-CoV-2 N.protein Antigen		PCR		
		POSITIVE	NEGATIVE	TOTAL
Nc.P. CoV-2	POSITIVE	169	15	184
	NEGATIVE	18	502	520
TOTAL		187	517	704
Relative Sensitivity		90,37 % (CI 95%: 85,21%–94,19%)		
Relative Specificity		97,10 % (CI 95%: 95,26%–98,37%)/		

TOTAL:

90,37% (CI 95%: 85,21%-94,19%)/

97,10% (CI 95%: 95,26%-98,37%)

[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. Sample Processing: First, 0.5 ml of sample preparation reagent is added to a sterile tube. The swab sample is then immersed in the reagent solution after sampling and mixed. Squeeze the swab several times on the inside of the tube to completely saturate the swab with the solution and release the sample. The resulting clear solution is a sample to be tested on a test cassette. The included swab may also be wrapped after sampling and placed directly into the reagent vial. The small hole in the cap of the canister serves as a holder for the broken / cut off part of the tampon shaft. Tighten the cap of the vial by rotation.
3. Samples for testing purposes must not be inactivated (eg preservation for 30 minutes at 56 ° C, or 75% ethanol or otherwise inactivated samples cannot be used!) The test is performed in the mode of work with biohazardous material. In the case of turbid samples, it is recommended to place the samples in a centrifuge for 10 minutes and then use the supernatant.
4. Be careful not to touch the saliva. If you touch saliva, it is recommended that you take a sample again; if there is a strong viscous liquid (snot, sputum) in the collected sample, take the sample again.
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. Use only the enclosed laryngeal swabs for sampling. Do not use any other type of laryngeal swab, otherwise the test may be invalid!
7. Before testing, read the Instructions for Use (IFU) carefully and strictly follow the procedures in the manual.
8. Insert the test sample into the test card very slowly and observe the exact amount of 60 µL of sample! First, place the test cassette in a horizontal position, slowly insert the sample and wait for the chromatographic reaction. Use a precision pipette.
9. The reaction time of the test is 15 minutes to the nearest 1 minute. After the reaction is complete, do not read the result later than 10 minutes. In other words, the result is invalid 25 minutes after loading the test solution.
10. The SARS-CoV-2 N Protein Rapid 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 in a sample. The colour intensity or thickness of the positive strip cannot be considered „quantitative or semi-quantitative".
11. Keep in mind that a positive patient is likely to be infectious, so follow the rules issued by your country's responsible authorities.

[UV EMITTER (LAMP)]

- Keep a distance of 10-20 cm between the UV emitter and the body of the testing cassette.
- It works perfectly in a darker environment, the darker it is, the better you can observe the illumination of the test strips.
- When inserting the battery into the lamp, make sure that the positive and negative poles of the battery are installed correctly.

[UV FLASHLIGHT SPECIFICATIONS]

Material:	Aluminium alloy
Colour:	black / white / silver
Weight:	~ 71g *
Diameter:	~ 15 mm *
Length:	~ 100 mm *
Wavelength:	275 - 395 nm *
Bulb type:	UV LED
Battery type:	1x AA battery *

* Subject to change without notice

[UV WARNING]:

- DO NOT shine the UV emitter directly into the eyes of any person (or animal).
- Keep the radiator out of the reach of children.
- The battery is not included in the package due to air traffic regulations. Get an AA battery.
- An accurate pipette enabling accurate dosing is not included in the package, if necessary, contact the manufacturer for a range of pipettes.

[FLUORESCENCE DETECTOR]

1. The IVD test is adapted for use with both UV emitter and LOMINA fluorescence detector **LSLC-20**
2. Read the instructions for use carefully before using the detector.
3. Use the calibration card provided with the test kit to set up the instrument.
4. The sensitivity of detection using LSLC-20 is about 15% higher than when using the UV lamp and visual inspection.

Although LSLC-20 displays the intensity of detection of the activated immunocomplex in the form of a graph, it is still a qualitative immunonalaseysis and the use of a detector cannot be considered as a quantitative measurement.

REF LA-CoV-Ag

IVD CE

RZPRO/EUDAMED: 00909708
PHARMDATA: APA4518032
GMDN #64912

Package (BOX B) contains 50 bottles in 2 plastic holders with reagent puffer and an IFU.

Package (BOX A) contains 50 pcs of swabs, 50 pcs of individually packed test plastic cards and 1 pc of UV emitter (without AA battery),50 droppers ~20ul/drop, MC card for LSLC-20 calibration and an IFU

PRODUCTION:
LOMINA SUPERBIO a.s.
Bucharova 2657/12, Praha 13,
158 00, CZECH REPUBLIC
www.lomina.ch ivd@lomina.ch

Last revision date:2021/01/10
Verze: LA-CoV-Ag-EN-IFU-1.7