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IVD CE 2854

REF LSB-CoV-ST

GMDN #64756

Instruction for use - Fast COVID-19 IgM/IgG Antibody Detecton Kit (Colloidal Gold)
(Not for internal use)

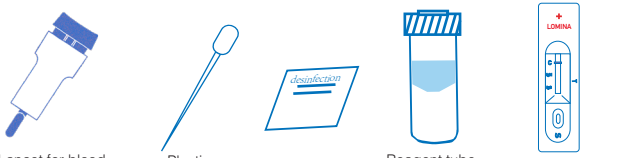
[PRODUCT NAME]
Fast COVID-19 IgM / IgG Antibody Detection Kit (Colloidal gold)

[Package variants]
Variant A - 5 pieces tests package
Variant B - 2 pieces tests package
Variant C - 1 piece test package
(Each variant contains testing cassette with colloidal gold + vial with a reagent (Buffer) accessories and labels showing the batch code, date of manufacture, and expiry date).

[Inteded use]
IVD test designed for self-testing for the detection of IgG and IgM antibodies against S1 (RBD) protein in the blood after COVID-19 disease. The test is also designed to detect the approximate level of IgG antibodies after vaccination. The product does not serve as the primary tool for early detection of COVID19!

[Test Principle]
This kit works on the principle of immunochromatography using colloidal gold. The test kit contains 1) An antigen labeled with colloidal gold and a complex of control antibodies. 2) nitrocellulose membranes with two test strips (M and G-line) and one quality control strip (C-line) marked. After dripping the required amount of sample into the hole on the test strip, the sample will run down the nitrocellulose membrane inside the test strip due to the capillary effect. If the test sample contains SARS-CoV-2 IgM / IgG antibodies, the antibody will bind to the colloidal gold-labeled SARS-CoV-2 antigen and the antibody complex will render monoclonal IgM antibodies, or monoclonal IgG antibodies on the nitrocellulose membrane as a violet-red-gray M or G lines, thereby plotting whether the sample is positive for IgM or IgG antibodies and thus demonstrating the presence of COVID-19 antibodies, thus providing evidence of past infection and / or active presence of antibodies in the body after vaccination.

[Content of presentation]
1. Testing strip in a plastic cassette
2. Plastic droppers (1 drop = 15 ul) Please use only the droppers provided in the package in order to maintain prescribed volume of liquids.
3. Vial with reagent (Buffer) (predominant component PBS - Phosphate-Buffered Saline)
4. Lancet for blood sampling (HTL-Strefa S.A. - CE 0344; Type Actilance STERILE R or wellion MED TRUST CE 0197; Type 23G double protection sterile STERILE R)
5. Disinfecting pad (alcohol-based disinfection)
6. Instructions for use



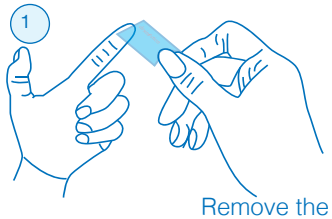
Lancet for blood collection disposable sample (contains micro-needle) | Plastic dropper | Disinfectant pad (disinfection) | Reagent tube | Test strip in a plastic cassette

[Storage conditions]
1. Store at temperatures between 4-30 °C. Protect from light. The expiration dates, along with the batch serial number, are listed on the inner protective package of the test.
2. Use the test immediately after opening the protective package. When opened, the test begins to degrade due to moisture. Use 60 minutes after opening is invalid and such a test is no longer applicable.
3. Do not use if the primary packaging is damaged.

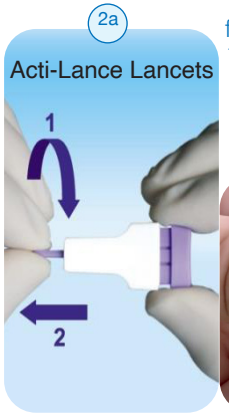
[Usable biological material]
The test is developed and tested for the general public for the use of blood samples taken from a finger.

[Instruction for use]
Open the box, remove the inner packaging and allow it to stabilize at temperature (15 ~ 25 ° C).

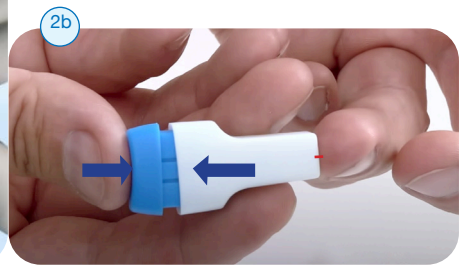
First read the entire instructions for use and use the kit immediately after opening the protective cover, but no later than 60 minutes after opening the aluminum protective cover.

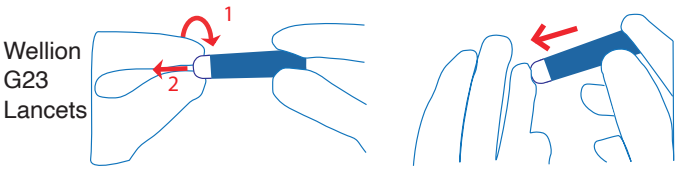


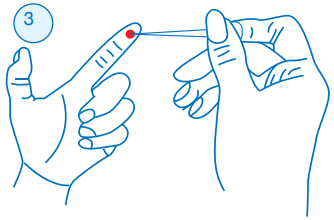
Clean the blood sampling site with a disinfecting pad and let it air-dry.



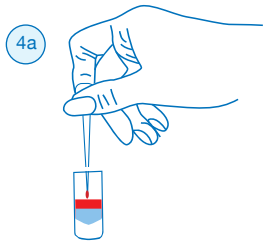
Remove the lancet cap(2a) and press the narrower end at the disinfected site to release the needle (2b). Press the lancet firmly against your finger before releasing the needle! The microneedle is very short and requires close contact with the skin. The lancet is adapted to only one press - the release of the needle.



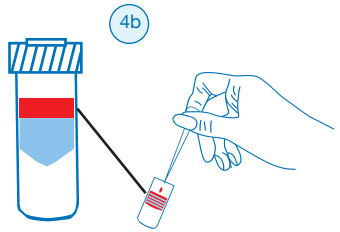




Press the injection site, then collect 2-3 microdrops using the plastic dropper and transfer them into the vial.



By pressing the dropper, transfer the blood into the vial with the reagent. Close the vial tightly with the cap.



Fill in the vial by 2-3 drops! Otherwise the test may be invalid!

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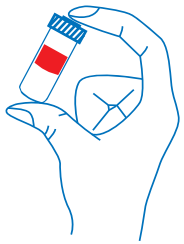

Check whether the vial is closed tighly and mix the mixture well by genlte shaking (for approx. 30 seconds.)

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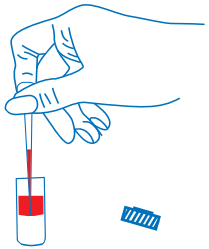

Use a clean dropper and draw the mixed mixture in it use 5-6 drops.

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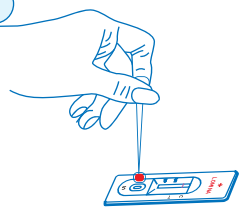

Prepare your watch or stopwatch and drip the mixture into a small hole on test tape, start read the time and watch after how many minutes the IgG band is displayed and whether IgM is also displayed.

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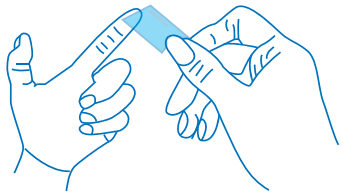


Dry the excess blood, if any, and disinfect the site again. Pack the test remains and dispose them in a prescribed way.

ATTENTION!

Leave the test cassette in a horizontal position at rest.
Do not move or tilt it during the measurement!
Use the test immediately after opening the primary package!
Maintain the required sample volume and use only the droppers provided in the kit - 1 drop = 15 ul.
The control C bar appears within 1 minute.
If it does not appear, the test is always invalid!
Use another cassette and repeat the test!
Detection of long-term antibodies, i.e. an IgG band, appears in the time range from 1 to 45 minutes depending on the concentration of antibodies in the test sample.

[Test results - interpretation of test results]

1. Negative antibody test result:

If the control strip QCC (Quality Control - C) is visible and lines M and G do not stain, the sample is negative because no antibodies were detected.

This test is not intended for early detection of COVID-19, so if you have symptoms or suspicion of COVID-19 and you have been in an infected environment or have been in contact with an infected person, always consult your doctor and condition.

2. Positive test result for antibodies:

2.1. If control strip "C" is displayed together with the "IgM" strip, IgM antibody has been detected and the sample is positive. IgM antibodies indicate an acute reaction of the immune system after an immediate encounter with the virus, but it can also be triggered by a vaccine.

2.2. If the control strip "C" is displayed together with the "IgG" strip, an IgG antibody has been detected and the sample is positive. Depending on the display speed of the IgG band, it is possible to orientatively determine the value of antibodies after infection or after vaccination. The presence of IgG antibodies in the body is desirable to increase protection against COVID-19

2.3. If control strip "C" is displayed together with the "IgG" strip and the "IgM" strip, both IgG and IgM antibodies have been detected and the sample is positive for both types of antibodies.

3. Invalid result:

If the check bar "C" does not appear, the test is invalid in any case and you must repeat it! This can be caused by a long test delay, reagent contamination, temperature degradation of the test, and the like.

[In case of a positive test result]

If the test is positive, you have antibodies to COVID-19 in your body.

After vaccination against COVID-19, it is possible to measure the level of antibodies and their approximate amount after about 14 days. The level of antibodies can be determined also after COVID-19 disease.

The level of IgG antibodies is directly related to the speed of display of the IgG strip(band) on the test cassette. The faster the IgG band is visible, the higher the antibody level.

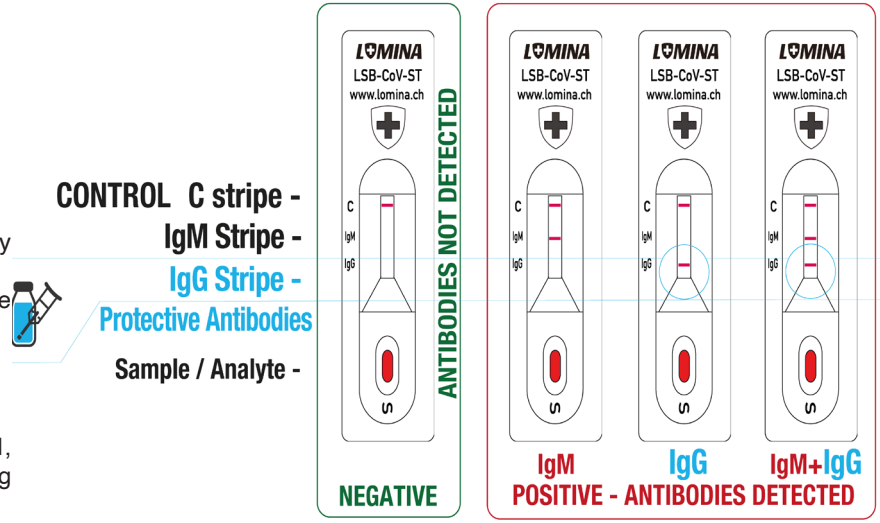
If the IgG band appears within one minute of the test, then the antibody level is> 640 titers. If an IgG band appears after 1-2 minutes the level will be> 320 titers, after 2-3 minutes> 160 titers, after 3-10 minutes> 80 titers.Within 10 minutes after imaging, we consider antibody titers to be high (strong antibodies - see the chart at the bottom of the instructions for use).

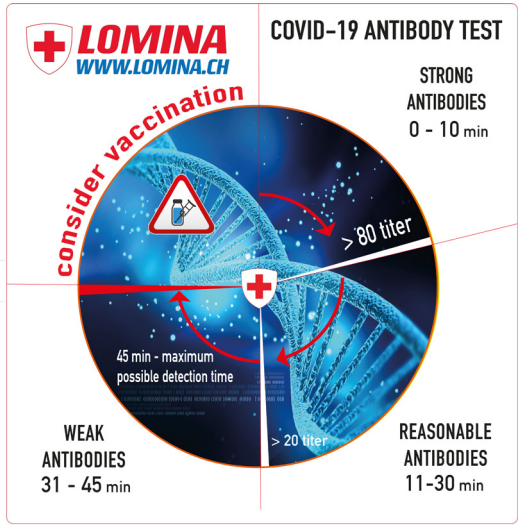
The generally accepted safe level of antibodies providing protection to the organism is about >10 titers.

A titre is a unit expressing the amount of a substance. It usually indicates the lowest dilution of the substance at which the reaction is still taking place, resp. at which the concentration of antibodies can destroy the active virus. The higher the antibody titer, the higher the level of antibody and protection you have.

If you have had a COVID-19 infection or have been vaccinated, and yet the test has not shown any antibodies (repeatedly) within 45 minutes, then you most likely do not have them or it is low. In this case, it is advisable to deal with this situation and inform your doctor.

If a strip of IgM appears during testing, it may be an initial immune response that is related to the body's response to the virus but also to vaccination. However, if you experience this strip, it may be an acute infection and it is advisable to inform your doctor and undergo a PCR or antigen test.





[Cross-reactivity]

Tests for IgG / IgM antibodies to SARS-CoV-2 (whole blood) were analyzed to detect antibodies in positive samples of influenza A, B, adenovirus, mycoplasma, pneumonia, and positive serum samples of ANA, HBV, and HCV. Furthermore, human coronaviruses HCoV-OC43, HCoV-229E, HCoV-NL63 and HCoV-HKU1 were analyzed. The results showed no signs of cross-reactivity.

[Specificity* / Sensitivity**]

IgG – 96,79% (CI 95%: 94,46%-98,33%) / 97,27 %; (CI 95%: 95,86%-98,30%).
IgM – 98,54% (CI 95%: 97,14%-99,37%) / 88,46% (CI 95%: 84,18%-94,92%).

[Disruptive substances]

The following compounds were tested in the SARS-CoV-2 IgG / IgM antibody assay (whole blood) and no interfering effects were found. Triglycerides: 50 mg / dl, ascorbic acid: 20 mg / dl, hemoglobin 1000 mg / dl, bilirubin: 60 mg / dl, total cholesterol: 6 mmol / l The results did not show interfering reactivity.

[Disposal of the used test]

1. Even if the lancet used once has a safety lock against needle ejection, it is important to dispose of the used lancets carefully.
2. Place the used material in a plastic bag with a thickness of at least 0.2 mm, weigh it and disinfect the surface of the bag. If you use thinner material, you need to put two bags and disinfect the outer one.
3. Make sure the bags are really tied.
4. Only throw the waste secured in this way into the black bin (for mixed municipal waste) in the standard way.
5. Under no circumstances should these tied bags be stored outside the containers to avoid endangering the health of the employees of the collection companies.
6. After handling waste, it is always necessary to wash your hands with soap and water.

[PRECAUTION]

1. Serological rapid tests may only be used as ancillary screening tools.
2. Accuracy and detectable rates cannot reach 100% with respect to individual antibody production in specific patients.
3. If positive IgM antibodies without IgG are detected, it is advisable to retest as soon as possible by direct virus detection such as PCR, antigen and the like. The presence of IgM may indicate an active or terminal phase of the disease. In contrast, IgG antibodies indicate a disease and are present in the body for many months after infection or vaccination.
4. The principle of the test works on the basis of antibody detection, not on the detection of the virus itself! The body produces antibodies almost immediately after infection (or vaccination), but detectable levels are usually present as the patient's temperature rises. Because the rate of IgM and IgG production varies between individuals, the patient may become infected even if the test is negative. If you notice flu-like / coronavirus-like symptoms, do not use this test as a tool to detect COVID-19. In the meantime, keep the quarantine for safety. In case of uncertainty, always consult your specialist about your condition.

[Performance of semiquantitative antibody determination]

% the total number of results of compliance with a particular titre:	95,33 %
% the total number of results of the match with a particular quadrant:	100 %

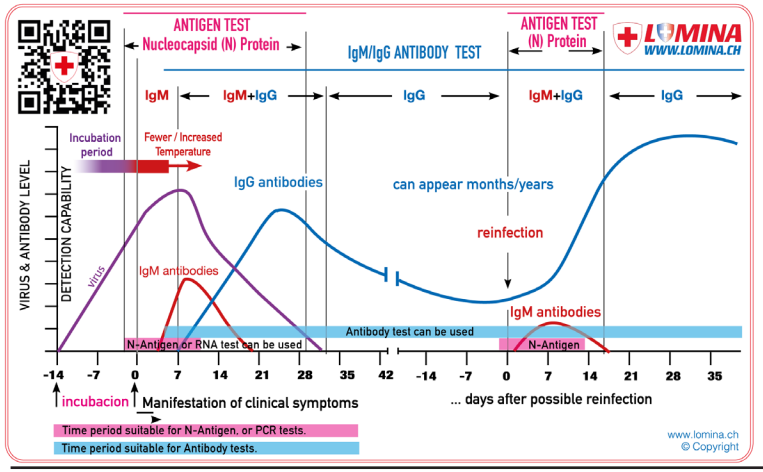
The display time of the antibody detection strip depends on the amount of antibodies. The sooner an antibody detection band appears, the more antibodies a person has.

[Cross-reactivity of semi-quantitative antibody evaluation]

The biochemical values of the tested individuals do not affect the time limit of antibody detection.

General indication of antibodies and protection against Covid-19*

Time to display the IgG line	0 - 10 Minutes	11 - 30 Minutes	31 - 45 Minutes	>45 Minutes
Antibody level	High level of Antibodies	Medium level of Antibodies	Low level of Antibodies	Wery low or none Antibodies detected



* The specificity of the test expresses the ability of the test to accurately select cases in which the marker of interest (test substance) is not present.
** The sensitivity of the test, or the sensitivity of the test, expresses the success with which the test detects the presence of the marker of interest in a given subject.

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REF LSB-CoV-ST

IVD CE 2854 2

	EAN13 - 1 pcs packaging	EAN13 - 2 pcs packaging	EAN13 - pcs packaging
APA/PDK		4586625	4556164
RZPRO		4586625	4556164

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