Instructions for use - Fast COVID-19 IgM/IgG Antibody Detection Kit (Colloidal gold) (Not for internal use)

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IVD CE 2854

[Product name]

Fast COVID-19 IgM / IgG Antibody Detection Kit (Colloidal gold)

REF LSB-CoV-ST

[Package variants]

Variant "A" - 5 pieces tests 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.

[Intended use]

IVD test for self-testing for the detection of IgG and IgM antibodies in the blood, thus demonstrating **active** or **overcome** COVID 19 infection caused by SARS-CoV-2 virus. The product does not serve as a primary tool for early detection of COVID19! For these purposes, it is necessary to use PCR methods, antigen assays and the like.

[Test principle]

This kit works on the principle of immunochromatography using colloidal gold. The test kit contains 1) An antigen labelled 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. To drop the required amount of sample into the hole on the test strip, the sample will flow over the nitrocellulose membrane inside the test strip due to the capillary effect. If the test sample contains SARS-CoV IgM / IgG antibodies, the antibody will bind to the colloidal gold-labelled SARS-CoV-2 antigen and the antibody complex will render monoclonal IgM antibodies, or monoclonal IgG antibodies on the nitrocellulose membrane as purple-red M, or G lines and thus plots whether the samples are positive for IgM or IgG antibodies and thus demonstrates COVID-19 infection, or provides evidence of past infection and active presence of antibodies in the body.

[Content of presentation]

1	Plastic testing strip	
2	2.plastic droppers (1 drop = 20-25 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; Typ Actilance STERILE R)
5	Disinfecting pad	(M.Braun Melsungen AG - product code: 00056-0183)
6	Instructions for use	

[Storage conditions]

1) Store under the temperature of from 4 to 30 °C. Protect from light. The expiry date and the batch number are shown on the primary pack of the test and also on the reagent bottle.

2) Use immediately after opening the primary pack. The test starts degrading due to humidity after the primary pack opening. The test cannot be used 60 minutes after opening; the results will not be valid.

3) Do not use if the primary packaging is broken.

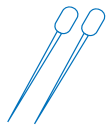
[Usable biological material]

The test is developed and tested for the general public for the use of blood samples taken from a finger.

[Instructions for use]

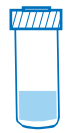
Open the box, take the primary pack out and let it warm/cool to the room temperature (24 °C). At first, read the whole instructions for use and use the kit immediately after you open the primary pack, however, within maximum 60 minutes after you open the aluminium primary pack !

Lancet for blood sample taking (contains a needle)



Plastic droppers

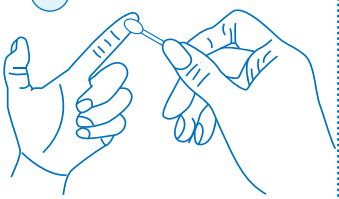
Disinfecting pad



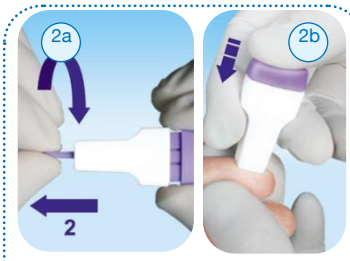
Vial with reagent

Plastic testing strip

1

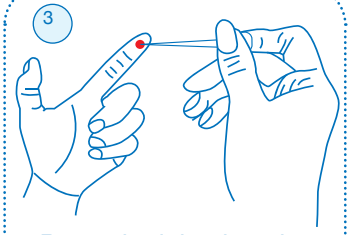


Clean the blood sampling site with a disinfecting pad and let it air-dry.



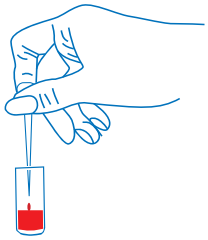
Remove the lancet cap (2a) and press the narrower lancet end at the disinfected site to release the needle(2b).

3



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

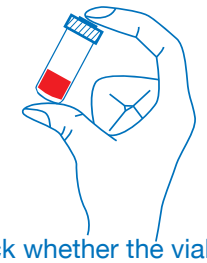
4



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!

5



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

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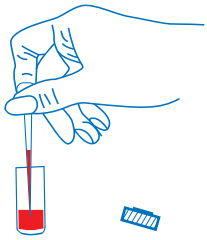
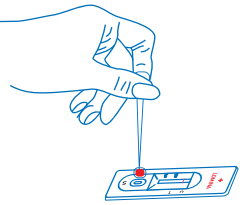


Use a clean dropper and draw the mixed mixture in it use 2 drops.

7



Take a stopwatch and transfer the mixture into the small hole on the testing strip. Start reading the time and read the test result after 3 minutes.

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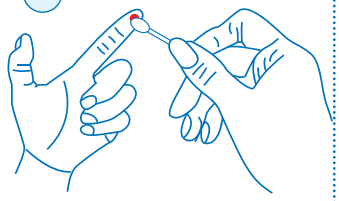


Dry the excess blood, if any, and disinfect the site again. Pack the test remains and dispose them in a prescribed way.

ATTENTION! Do not read the test result after more than 10 minutes! The test result can change due to humidity ! The results are invalid after 10 minutes!

The results are valid only from minute 3 to minute 10 after the mixture dripping on the plastic testing strip. Let the strip remain in a horizontal position at rest. Do not move or tilt it during the measurement! Use immediately after opening the primary pack!

Maintain required volume of samples! Use only droppers supplied in the kit - (1drop = ~20-25ul).

HINT: At 10th minute take a photo of the strip/membrane and read the result by zooming the image.

[Test results / Interpretation of the test result]

1.Negative result:

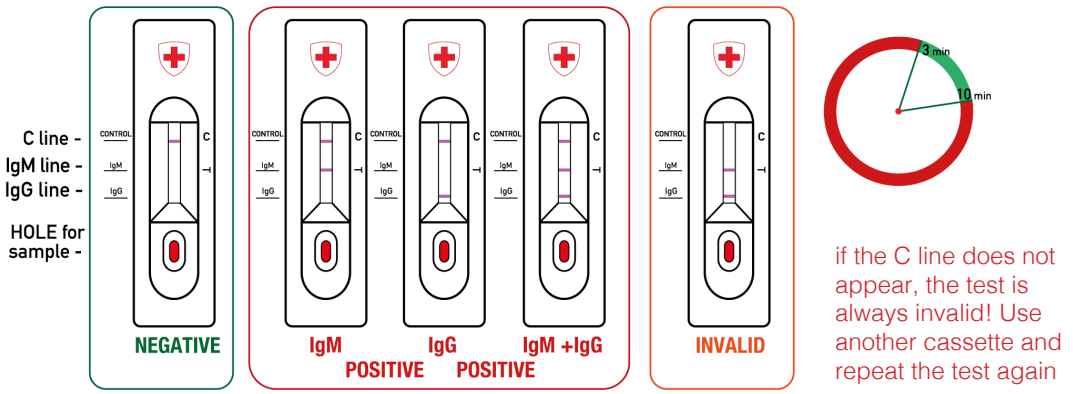
If the QCC (Quality Control – C) control line is visible and the M- and G-lines are not, the sample is negative because no antibodies were detected. However, continue your health condition monitoring. Re-testing 24 hours later is recommended. Do not forget that the amount of antibodies produced in case of a disease is individual and antibodies production is manifested usually by increased temperature.
ATTENTION! The test detects the presence of antibodies, but its accuracy depends on the amount of antibodies, which is individual for each person. Even if the test is negative, continue to monitor your health. If fever and flu-like symptoms persist, repeat the test after 24-48 hours. If you experience breathing or other serious problems, or your condition persists, always consult your doctor. If you have symptoms and you have been in an infected environment or have been in contact with an infected person, always consult your doctor about your condition and procedure.

2.Positive test result:

2.1 If the control C-line appears together with the M-line, IgM antibody was detected and the sample is positive.
2.2 If the control C-line appears together with the G-line, IgG antibody was detected and the sample is positive.
2.3 If the control C-line appears together with both the G- and M-lines, both IgG and IgM antibodies were detected and the sample is positive. Stay calm in all three cases and read the instructions on next page.

3. Invalid result:

If no C-line appears, the test is invalid and must be repeated! It can be due to time delay at testing, reagent contamination, test impairment by temperature, incorrect amount of liquids etc.



[In case of a positive test result]

- First and foremost, keep calm.
- Contact your doctor immediately and tell him the result of the serological test.
- Your doctor will provide you with further information and will also contact the relevant authorities if necessary. Remember presence of antibodies doesn't necessarily mean you are infected by the virus now.
- Do not see a doctor or a hospital - you would endanger yourself and others.
- Observe personal quarantine, if possible stay alone in one room and apply disinfection to all points of contact (handles, ambulance, etc.) until you get future instruction by your doctor.
- Wear a facemask or a respirator.
- Follow a drinking regimen and strive for maximum fluid consumption.

[Cross-reactivity]

Tests for IgG / IgM antibodies to SARS-CoV-2 (whole blood) were analysed 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 analysed. The results showed no signs of cross-reactivity.

[Specificity* / Sensitivity]**

97,32% (CI 95%: 97,12%-97,52%) / 93,54% (CI 95%: 93,12%-93,97%).
(IgG – 95,49% (CI 95%: 95,20%-95,78%) / 94,08 %; (CI 95%: 93,41%-94,75%).
(IgM – 95,81% (CI 95%: 95,51%-96,11%) / 74,52% (CI 95%: 73,09%-77,09%).
* 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, expresses the success with which the test detects the presence of the marker of interest in a given subject.

[Disruptive substances]

The following compounds were tested with the SARS-CoV-2 IgG / IgM antibody test (whole blood) and no interfering effects were found. Triglycerides: 50 mg / dl, ascorbic acid: 20 mg / dl, haemoglobin 1000 mg / dl, bilirubin: 60 mg / dl, total cholesterol: 6 mmol / l

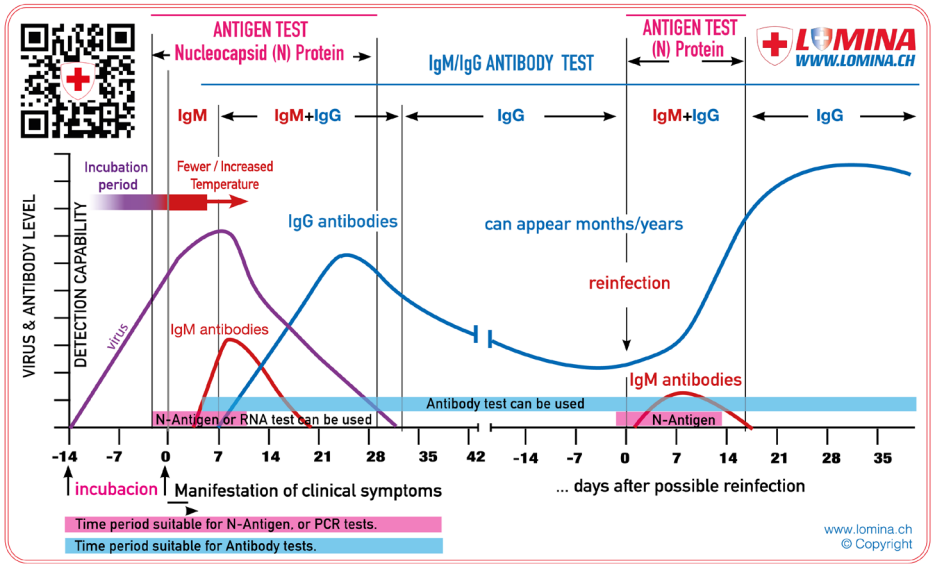
The results did not show cross reactivity.

[Disposal of the used test]

1. Although the used lancet has a safety lock against the needle forwarding, used lancets must be disposed of carefully.
2. Place the used waste in a plastic bag of at least 0.2-mm width, tie the bag and disinfect its surface. If you have thinner bags, use two bags and disinfect the outer one.
3. Check whether the bag is tied well.
4. Place the bag into the black waste container only (intended for mixed municipal waste) in a usual way.
5. The tied bags may never be placed outside the waste containers to avoid putting the waste disposal company employees at risk.
6. Always wash your hands with soap and water after waste handling.

[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 a positive sample is detected, it is necessary to retest as soon as possible by direct virus detection such as PCR.
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, 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, repeat the test after 24-48 hours. In the meantime, keep the quarantine for safety. In case of extreme uncertainty, always consult your specialist about your condition.



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