Instructions for Use (IFU)

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SARS-CoV-2/COVID19 IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)-PROFI

(Not intended for internal use)

IVD CE SÚKL / RZPRO / EUDAMED # 061583-0001 # 061583-0002 GMDN #64756

[Product name]

SARS-CoV-2/COVID19 IgM/IgG Antibody fast detection kit (Colloidal gold) - PROFI

[Package variants]

Variant A - 20 pieces tests package
Variant B - 5 pieces tests package
Variant C - 2 pieces tests package
Each variant contains relative number of testing cassette with colloidal gold + accessories and labels showing the batch code, date of manufacture, and expiry date. (See content of presentation paragraph bellow)

[Intended use]

IVD test for IgM and IgG antibodies in blood, i.e. for proving the Coronavirus SARS-CoV-2 infection/ COVID-19 disease. Edition for Health Care Professionals - IVD Other Category

[Test principle]

This test is based on fluorescent immunochromatography. The testing kit contains 1) an antigen labelled by colloidal gold and a complex of control antibodies; 2) nitrocellulose membranes with two testing lines (M- and G-line) and one qualitative control line (C-line). The required amount of the sample is dripped into a hole on the test strip. Capillary effects helps the sample run down the nitrocellulose membrane inside the test strip. If the tested sample contains SARS-CoV19/COVID-19 IgM/IgG antibodies, they will be bound to the COVID-19-antigen labelled by colloidal gold and the monoclonal IgM or IgG antibodies will appear on the nitrocellulose membrane as violet-red M- or G-lines. The test will show the sample positivity to IgM or IgG antibodies, thus proving the COVID-19 infection.

[Content of presentation]

① Plastic testing strip wrapped in an AL/PE pouch
② 2 plastic droppers (1 micro-drop = 20-25ul)
③ Vial with reagent 100ul
④ Lancet (“vial”) for blood sampling CE STERILE R
⑤ Disinfecting pad
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.

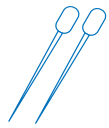
[Usable biological material]

The test has been developed and tested for blood samples (40-60ul), serum or plasma samples (10ul) testing by the medical professionals.
[Additional information for health care professionals: Peripheral blood, serum or plasma samples obtained with clinically used anticoagulants (EDTA, heparin, sodium citrate) can be used for the test. Dont use turbid samples. If turbidity occurs use centrifuge and pippete non turbid analyte only]

[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 ("vial") for blood sample taking (contains a needle)



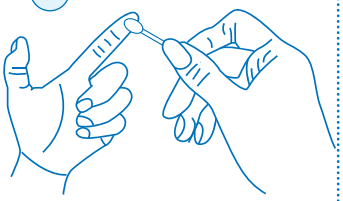
Plastic droppers

Disinfecting pad

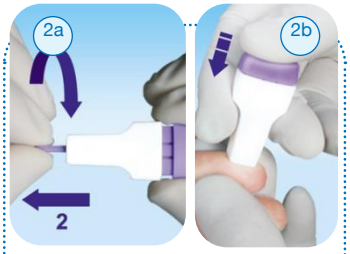
Vial with reagent

Plastic testing strip

1

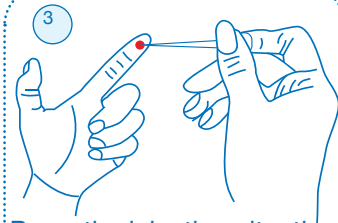


Clean the blood sampling site with a disinfecting swab and let it air-dry.



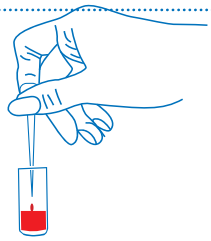
Remove the lancet cap (2a) and press the narrower lancet end at the disinfected site to release the needle(2b).

3

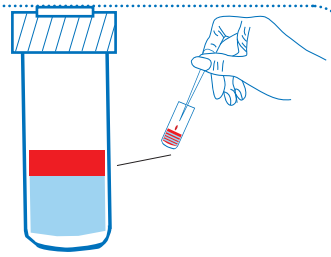


Press the injection site, then collect 2-3 microdrops using the plastic dropper (40-60ul) and transfer them into the vial. (alternatively use 10ul of serum or plasma)

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! (~50-60ul)
Otherwise the test may be invalid!

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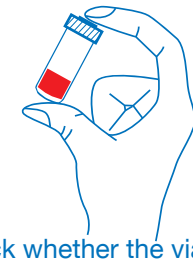

Check whether the vial is closed tightly and mix the mixture well by gentle shaking (for approx. 30 seconds)

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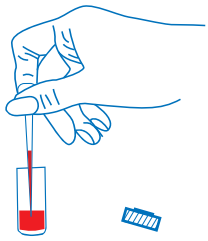
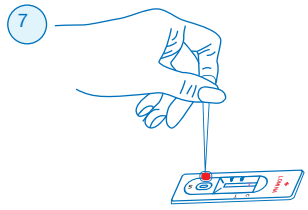


Use a clean dropper and draw the mixed mixture in it use 2 drops = (45-50ul)

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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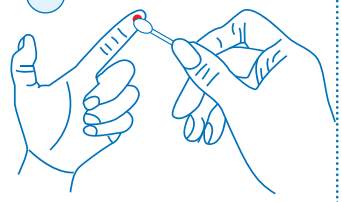


Dry the excess blood, if any, and disinfect the site again. Pack the test remains and dispose them in a prescribed way.

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. Alternatively, use medical precise electronic pipette.
HINT: Take a photo of the strip and then stretch the area of the membrane and read the result.

[Test results reading]

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 precision depends on the amount of antibodies which is individual. Even if the test is negative, please monitor your health condition. If increased temperature and flu-like symptoms persist, repeat the test 24-48 hours later. If respiratory or any other serious complaints occur, or if your health condition does not improve, consult your physician. If you have symptoms and you stayed in infected environment or were in contact with an infected individual, always consult your condition and actions with your physician.

2.Positive test result:

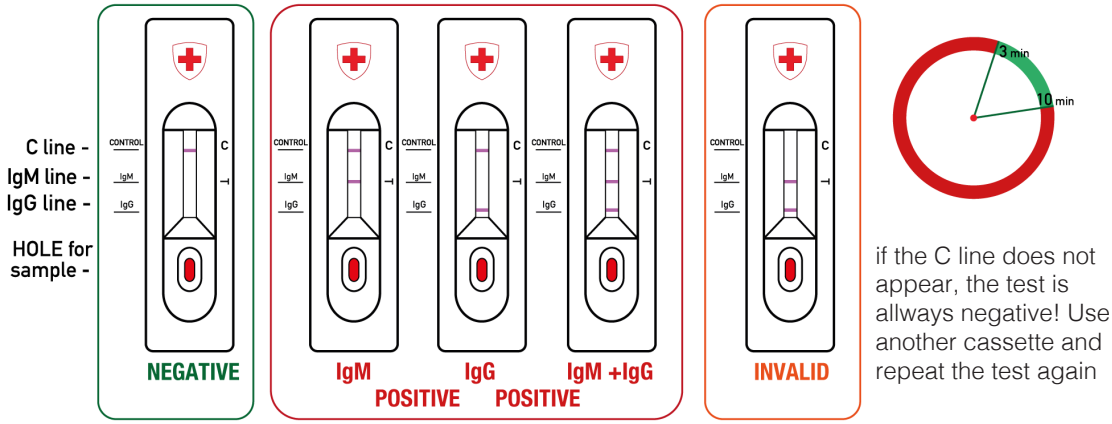
2.1 If the control C-line appears together with the M-line, IgM antibody was detected and the sample is positive.

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 page 4.

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 etc.



[Disposal of the test used]

Dispose of infectious / contaminated material according to standard procedures.

[Cross-reactivity]

Tests for IgG / IgM antibodies against the SARS-CoV-2 virus (whole blood / serum / plasma) were analyzed to detect antibodies in positive samples of influenza virus type A, B, RSV, adenovirus, HBsAg, syphilis, H pylori, HIV and HCV. The results did not show any sign of cross reactivity.

[Disruptive substances]

The following compounds were tested with the SARS-CoV-2 IgG / IgM antibody test (whole blood / serum / plasma) 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 cross reactivity.

[specificity / sensitivity]

97,32% (CI 95%: 97,12%-97,52%) / 93,54% (CI 95%: 93,12%-93,97%).

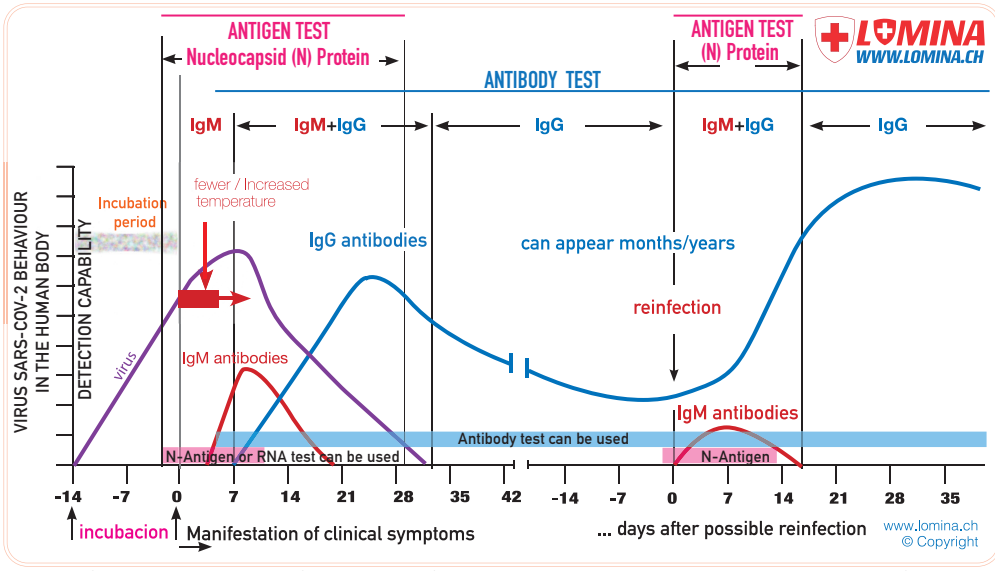
(IgG – 95,49% (CI 95%: 95,20%-95,78%) / 94,08 %; (CI 95%: 93,41%-94,75%).

[PRECAUTION]

1. Fast serological tests can only be used as auxiliary screening tools.
2. Due to individual formation of antibodies in individual patients, the precision and rate of detection cannot reach 100%. IgM antibodies detection rate is allways lower than IgG.
3. If a positive sample is detected, retesting by direct virus detection must be performed as soon as possible.
4. The test is based on antibodies detection, not on the detection of the virus as such. The body products antibodies almost immediately after affliction by an infection but a detectable level is usually found when the patient's temperature is increased concurrently. As the speed of IgM and IgG production differs individually, the patient may be infected even if the test result is negative. If you observe flu-like/coronavirus-like symptoms, repeat the test 24-48 hours later. To be on the safe side, observe the quarantine in the meantime. In extreme uncertainty, consult your health condition with a physician.

[Disposal of the used test in accordance with WHO recommendations]

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.



*reinfection is a condition where the infection in the patient first resolved and the patient has already been tested with a negative result for the presence of the virus and subsequently reinfected with a new infection or reactivation of the virus.

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ISO 13485 MEDICAL DEVICES

UKAS MANAGEMENT SYSTEMS 015

IVD CE GMDN #64756

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