For the love of life.

# Rapid SARS-CoV-2 Antibody (IgM/IgG) Test

**For in vitro diagnostic use only.** IVD

**Please read this package insert carefully prior to use and strictly follow the instructions.**

Reliability of the assay cannot be guaranteed if there are any deviations from the instructions in this package insert. **Strict personal protection is required throughout the test!**

## Intended use

The *Rapid SARS-CoV-2 Antibody (IgM/IgG)* Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of IgG and/or IgM to SARS-CoV-2 in human whole blood (venous and fingerstick), serum or plasma specimens. This test is intended for use by healthcare professionals and trained healthcare workers as an aid in the diagnosis of SARS-CoV-2 infection.

## Summary

In December, 2019, a pneumonia associated with SARS-CoV-2 (also known as 2019-nCoV) emerged.[1] A few patients have developed severe pneumonia, pulmonary oedema, ARDS, or multiple organ failure and have died.[1]
The *Rapid SARS-CoV-2 Antibody (IgM/IgG)* Test is based on immunochromatography for detection of IgG and IgM specific to SARS-CoV-2 in human whole blood (venous and fingerstick), serum or plasma. It is simple, visual qualitative and presents the result within 20 minutes.

Preliminary performance data : sensitivity 94.4%, specificity 98%

## Test principle

On the IgM side of the cassette, the IgM antibody (SARS-CoV-2 specific and non-specific) in the specimen will combine with the gold conjugated mouse anti-human IgM monoclonal antibody pre-coated on the sample pad to form an immune complex. The complex will move forward along the test strip. If the test sample contains SARS-CoV-2 specific IgM and the concentration is above the minimum detection limit, the complex will be captured by the SARS-CoV-2 antigen pre-coated at the test band region, and form a purplish red band. If the specimen does not contain SARS-CoV-2 specific IgM or the concentration is below the minimum detection limit, there will be no purplish red band shown at the test band region.
On the IgG side of the cassette, the IgG antibody (SARS-CoV-2 specific and non-specific) in the specimen will combine with the gold conjugated mouse anti-human IgG monoclonal antibody pre-coated on the sample pad to form an immune complex. The complex will move forward along the test strip.
If the test sample contains SARS-CoV-2 specific IgG and the concentration is above the minimum detection limit, the complex will be captured by the SARSCoV-2 antigen pre-coated at the test band region, and form a purplish red band. If the specimen does not contain SARS-CoV-2 specific IgG or the concentration is below the minimum detection limit, there will be no purplish red band shown at the test band region.
Regardless of whether the analyte exist in the sample, a purplish red band will appear at the both of the two control band regions. Only when the control band appears the correlated result is valid.

## Storage conditions and stability

The *Rapid SARS-CoV-2 Antibody (IgM/IgG)* Test shall be stored at 2-30°C. The shelf life is temporarily set as 6 months. Test cassette should be used immediately upon opening the foil pouch. Sample diluent should be stored capped at 2-30°C and used within 8 weeks after opening.

## Warnings and precautions [2-3]

The warnings and precautions are included, but not limited to the following:

**[Warnings]**

- This product is for in vitro diagnosis of the infection of SARS-CoV-2 only; other diseases cannot be analyzed with any component of this kit
- Specimen with positive results should be retested with other technological method such as RT-PCR under the guidance of local regulations before the clinical diagnosis is made.
- Sample diluents contain sodium azide. Sodium azide can react with copper and lead used in certain plumbing systems to form metal salts which are explosive. The quantity used in this kit is small, however, when disposing sodium azide containing materials, flush with relatively large quantities of water to prevent metal azide build up in plumbing systems.

**[Precautions]**

- Very important! When handling and processing specimens, laboratory practices and procedures that are basic to good microbiological practices and procedures (GMPP) should be followed.[3]
- Wear disposable gloves at all times when handling specimens. Avoid contact of gloved hands with the face. Gloves should always be inspected before use to check they are intact.[3]
- Do not use expired reagents or test cassettes.
- Do not use accessories if the seal or package is broken.
- Do not use test cassette if the foil pouch is damaged or the seal is broken.
- Do not use the provided safety lancets if the cap is already pulled off before use.
- Do not reuse the accessories. All the accessories are for single use.
- Do not reuse the cassette. Each cassette enclosed in a foil pouch is only for single use.
- Do not pipette by mouth.
- Do not eat or smoke while handling specimens.
- Do not store the specimen in dropper; it is only used for specimen collection.Do not use pooled specimens or specimens other than specified (i.e. saliva, urine).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test under environment which leads to rapid evaporation (e.g. >40°C and <40% rH, close to a running fan or air conditioner)
- Ensure the specimen is added correctly prior to the addition of sample diluent.
- Avoid contact between the„S" well of cassette and diluent bottle to prevent contamination of diluent.
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant to control infectious risks.[3]
- Decontaminate and dispose of all specimens, reagents, accessories and other potentially contaminated materials as infectious wastes in a biohazard container. Used lancet should be disposed of in a sharps bin.

## Reagent and materials provided

| Component | 25 tests |
|---|---|
| Test cassette | 25 pieces |
| Dropper | 25 pieces |
| Sample diluent | 4 bottle (2ml) |
| Sterile safety lancet STERILE R | 25 pieces |
| Alcohol swab | 25 pieces |
| Package insert | 1 piece |

Table 1 Reagent and materials provided

**Note: Information of the sterile safety lancet and alcohol swab**

| Accessory | Manufacture | Authorized representative | CE mark |
|---|---|---|---|
| Sterile safety lancet | SteriLance Medical (SuZhou) Inc. No. 68 Litanghe Road, Xiangcheng, Suzhou, China | EMERGO EUROPE Molenstraat 15, 2513 BH, The Hague, The Netherlands | CE 0197 |
| Alcohol swab | | | CE |

## Materials required but not provided

- Disposable gloves
- Timer or stopwatch
- Blood sampling tools (sterile gauze pad, venous puncture device, collection tube with EDTA/heparin sodium/sodium citrate for whole blood or plasma, collection tube with no anticoagulant for serum.)
- Biohazard waste container and sharps bin
- Equipment or reagents for disinfection

## Specimen collection and storage [4]

**Very important!** Blood specimens should be collected under strict personal protection.

***Fingerstick whole blood***

Rub the target finger to stimulate blood flow. Clean the finger with an alcohol swab (Figure I.1) and leave it to dry. Stick the skin of target finger with a safety lancet (a:Twist clockwise the protective cap and remove it, see Figure I.2 for details; b. Place the lancet firmly on the finger to trigger it, see Figure I.3 for details), gently press the bleeding point (avoid excessive bleeding). Wipe away the first drop of blood with a sterile gauze pad (Figure I.4). Allow a new drop of blood to form.
Transfer the blood specimen with the dropper provided. Gently squeeze the bulb of the dropper and touch the tip of the blood. Gently release the bulb to draw up the blood (Figure I.5).

***Venous whole blood***

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Other anticoagulants may lead to incorrect results. Store whole blood specimen at 2-8°C for up to 3 days if it is not used immediately after being sampled. Do not freeze whole blood specimen. Before testing, gently shake the blood tube to obtain a homogeneous specimen.

***Serum***

Collect whole blood specimen into a collection tube which contains no anticoagulant according to standard venous blood sampling process. Leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the serum supernatant.

***Plasma***

Collect whole blood specimen into a collection tube (with specified anticoagulant, namely EDTA, heparin sodium or sodium citrate) according to standard venous blood sampling process. Gently reverse the tube for several times and leave to settle for 30 minutes for blood coagulation, then centrifuge at 3000rpm for at least 5 minutes to obtain the plasma supernatant.

***Notes:***

- Serum or plasma specimens shall be stored at 2-8°C for up to 7 days from time of draw. Store at -18°C or below for long time storage. Multiple freezethaw cycles should be avoided (3 times at most). Frozen specimens shall be equilibrated to room temperature (10-30°C) before testing.
- Serum or plasma specimen containing precipitate may lead to invalid results. Centrifuge the specimen and use the supernatant for the test.

Test procedure

1. Do not open the pouch until ready to perform a test. Use the test under low environment humidity (RH≤70%) within 1 hour.
2. Equilibrate all reagents and specimens to room temperature (10-30°C) before use;
3. Unseal the foil pouch and put the cassette on a clean and dry surface;
4. Mark the specimen ID on test cassette;
5. Add 1 drop of the specimen using the provided dropper (or 10µl by transfer pipette) into„S" well of both the IgM side and IgG side of the cassette;
6. Then add 2 drops of sample diluent into„S" well of both the IgM side and IgG side immediately;
7. Wait for at least 15 minutes (and 20 minutes at most) to interpret the result.

**Step by step**

**I. Fingerstick whole blood**

1.
Clean the finger with alcohol swab and leave it to dry.

2.
Twist the lancet cap for over 180° and remove it.

3.
Place the lancet firmly on side of finger (avoid callus) to trigger it.

4.
Gently massage around the bleeding point. Wipe away the first drop of blood.

5.
Use dropper to collect specimen. Gently squeeze and release bulb to collect blood dropper.

6.
Add 1 drop of the sample using the provided dropper into the"S" well of both the IgM and IgG sides

7.
Add 2 drops of sample diluent into „S" well of both the IgM and IgG sides immediately.

8.
Wait and interpret the result between 15-20 minutes.

## II. Venous whole blood

| | |
|---|---|
|  <br>1a<br>Add 1 drop of specimen using the provided dropper (Gently squeeze the bulb of the dropper fort he blood) into „S“ well both the IgM and IgG sides. |  <br>1b<br>Add 10µl of specimen using transfer pipette into„S“ well of both the IgM and IgG sides. |
|  <br>3.<br>Add 2 drops of sample diluent into „S“ well of both the IgM and IgG sides immediately. |  <br>4.<br>Wait and interpret the result between 15-20 minutes.[3] |

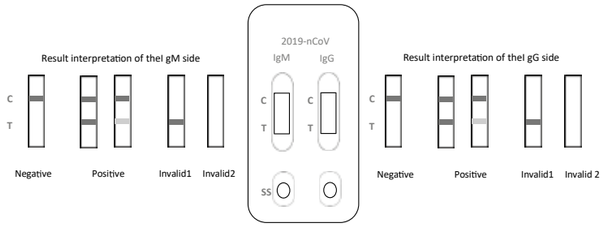
## III. Serum/plasma

| | |
|---|---|
|  <br>1a<br>Add 1 drop of specimen using the provided dropper (Gently squeeze the bulb of the dropper for the blood) into„S“ well of both the IgM and IgG sides. |  <br>1b<br>Add 10µl of specimen using transfer pipette into„S“ well of both the IgM and IgG sides. |
|  <br>3.<br>Add 2 drops of sample diluent into „S“ well of both the IgM and IgG sides immediately. |  <br>4.<br>Wait and interpret the result between 15-20 minutes. |

**Caution:**

- Always apply specimen with a new and clean dropper or pipette tip to avoid cross contamination.
- Negative results cannot rule out the possibility of exposure to or infection of SARS-CoV-2.

## Result interpretation




**Test results on the IgM side and IgG side are uncorrelated, and can be different.**

Interpret the result on each side **separately** according to the definitions below:

**Negative:** Purplish red band only appears on control band area indicates a negative result.

**Positive:** Purplish red bands appear at both the test band area (even though very weak) and the control band area indicates a positive result.

**Invalid 1:** A purplish red band appears only at the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

**Invalid 2:** Purplish red band appears at neither the control band area nor the test band area of the cassette. Repeat the test. Contact the supplier if the control band remains invisible.

## Performance characteristics

***Analytical specificity***

No false result was obtained from cross-reaction samples including MP positive, HIV positiv, HCV positive, TP positive, HBV positive, Flu A positiv, Flu B positive samples with *Rapid SARS-CoV-2 Antibody (IgM/IgG) Test*.

No false result was obtained on endogenous interferant samples including total protein, HAMA, RF, IgM, IgG, hemoglobin, bilirubin, SLE, triglyceride, multiple blood transfusions, and pregnant (multifarious) women samples with *Rapid SARS-CoV-2 Antibody (IgM/IgG) Test*.

***Diagnostic sensitivity and specificity***

Table 2 Diagnostic performance of *Rapid SARS-CoV-2 Antibody (IgM/IgG) Test*

| | | Diagnostic results | | |
|---|---|---|---|---|
| | | Positive | Negative | Total |
| Rapid SARS-CoV-2 Antibody Test | Positive | 51 | 8 | 59 |
| | Negative | 3 | 392 | 395 |
| | Total | 54 | 400 | 454 |

The diagnostic sensitivity of the test is 94,4 % (95% CI: 84.89 ~ 98.10).
The diagnostic specifity of the test is 98% (95% CI: 96.10 ~ 98.98).
Diagnostic performance data will be continuously collected and updated.

***Precision***

To analyze within-run and between-run precision, 5 replicates of three specismens containing different concentrations of antibody were tested at three lab sites.
The negative and positive values were all correctly identified.

## Limitations

- The kit is designed to detect IgG and/or IgM to SARS-CoV-2 in huma serum, plasma, and whole blood. Specimens other than those specified may not supply accurate results and the device will not notify this kind of misuse to the user.
- The intensity of test band does not necessarily correlate to the titer of antibody in specimen.
- The presence of the control band only indicates the flow of the conjugate.
- When a specimen contain high concentration of IgG and/or IgM to SARS-CoV-2 is tested on the device, the correlated control band(s) could be absent due to the test principle. In this case, please perform further analysis according to section of„Test result and interpretation“.
- This product is intended to detect IgG and/or IgM to SARS-CoV-2 from individuals, clinical diagnosis on SARS-CoV-2 infection should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection caused by SARS-CoV-2. A negative result can also occur in the following circumstances:
  - Recently acquired SARS-CoV-2 infection.
  - Low levels of antibody (e.g., early seroconversion specimens) below the detection limit of the test.
  - Neither IgG nor IgM to SARS-CoV-2 in the patient that react with specific antigens utilized in the assay configuration, in exceptional cases this may lead to observation of negative results.
  - Specimens are not properly stored.
  - Extremely high concentration of a particular analyte.
  - Recently discovered type or subtype of SARS-CoV-2.
- For reasons above, care should be taken in interpreting negative results. Other clinical data (e.g., symptoms or risk factors) should be used in conjunction with the test results.
- Specimen with positive results should be retested with other technological method such as RT-PCR under the guidance of local regulations before the clinical diagnosis is made.
- The product is not validated on specimens from infants, children, or patients on anti-retroviral treatment.
- Use of hemolytic specimens, rheumatoid factors-contained specimens, hyperlipemia specimens or icteric specimens may lead to impairment to the test result.
- Only specimens with good fluidity and without hemolysis can be used with this test.

## References


1. Nanshan Chen*, Min Zhou*, Xuan Dong*, Jieming Qu*, Fengyun Gong, Yang Han, Yang Qiu, Jingli Wang, Ying Liu, Yuan Wei, Jia'an Xia, Ting Yu, Xinxin Zhang, Li Zhang Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. LANCET. January 29, 2020.

2. Zhang N, Wang L, Deng X, et al. Recent advances in the detection of respiratory virus infection in humans. J Med Virol. 2020;92. DOI:10.1002/jmv. 5674

3. National Committee for Clinical Laboratory Standards. Protection of laboratory workers from infectious disease transmitted by blood, body fluids, and tissue: Tentative guideline. NCCLS Document M29-T. Villanova, PA.: NCCLS, 1989.

4. Clinical and Laboratory Standards Institute. Procedures and Devices for collection of Diagnostic Capillary Blood Specimens, Approved Standard-Sixth Edition H4-A6.


## Key symbols used

| | |
|---|---|
| Caution | Keep away from sunlight |
| Manufacturer | LOT Batch Code |
| Consult instructions for use | Do not reuse |
| Contains sufficient for 6 Tests | Temperature Limitation (2-30°C) |
| Keep Dry | IVD In vitro diagnostic medical device |
| REF Catalogue number | Use-by date |
| Do not use if package is damaged | STERILE R Sterilized using irradiation |
| CE European Conformity | EC REP Authorised Representative in the European Community |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