SANILABO COVID-19 IgG/IgM Rapid Test

REF R0180C CE

Instructions for Use

INTENDED USE

The SANILABO COVID-19 IgG/IgM Rapid Test is a lateral flow immunoassay for the detection of anti-SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood. It is intended to be used by healthcare professionals as an aid in the diagnosis of infection with SARS-CoV-2 coronavirus.

Any interpretation or use of this preliminary test result must also rely on other clinical findings as well as on the professional judgment of healthcare providers. Alternative test method(s) should be considered to confirm the test result obtained by this device.

SUMMARY AND EXPLANATION OF THE TEST

SARS-CoV-2 belongs to the broad family of coronaviruses which are capable of causing illnesses ranging from the common cold to more severe diseases[1]. SARS-CoV-2 infections cause COVID-19 disease. The infected patients have a wide range of clinical symptoms, from little to no symptoms, to fever, tiredness and dry cough, and possibly leading to severe sickness and death. Most patients recover without special treatment. Around 1 out of every 6 patients who get COVID-19 become seriously ill and develop difficulty breathing. Older people and those with underlying medical problems, like high blood pressure, heart problems or diabetes, are more likely to develop serious illness.

Human-to-human transmission of the virus has been confirmed and occur primarily via respiratory droplets from coughs and sneezes within a range of about 6 feet (1.8 m). Viral RNA has also been found in stool samples from patients. It's possible that the virus can be infectious even during the incubation period, but this has not been proven. WHO stated on February 1, 2020 that at this time, "transmission from asymptomatic cases is likely not a major driver of transmission[2-5].

Currently, the laboratory method for detecting SARS-CoV-2 infection is RT-PCR. However, this method requires sophisticated equipment and highly trained laboratory technicians. Moreover, viral load decreases rapidly 9 or 10 days after onset of symptoms. During the acute phase of infection, the titer of IgM to SARS-CoV-2 rises rapidly and peaks around 2-3 weeks after the infection. SARS-CoV-2 specific IgG antibodies appear shortly after IgM and persist for months[6]. It is unknown if SARS-CoV-2 infection leads to lifetime immunity or come with a 2nd infection. Nevertheless, the SARS-CoV-2 specific antibodies are useful markers for diagnosis and epidemiologic survey.

The SANILABO COVID-19 IgG/IgM Rapid Test detects anti-SARS-CoV-2 IgG and IgM antibodies in human serum, plasma or whole blood. The test can be performed within 15 minutes by minimally skilled personnel without the use of cumbersome laboratory equipment.

TEST PRINCIPLE

The SANILABO COVID-19 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test strip in the cassette consists of: 1) a colored conjugate pad containing SARS-CoV-2 recombinant antigens conjugated with colloidal gold (SARS-CoV-2 conjugates) and a control antibody conjugated with colloidal gold, 2) a nitrocellulose membrane strip containing two test lines (G and M lines) and a control line (C line). The G line is pre-coated with antibodies for the detection of anti-SARS-CoV-2 IgG, the M line is pre-coated with antibodies for the detection of anti-SARS-CoV-2 IgM, and the C line is pre-coated with a control line antibody.

When an adequate volume of specimen is dispensed into the sample well of the test cassette, the specimen migrates by capillary action along the cassette strip. Anti-SARS-CoV-2 IgG, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated anti-human IgG, forming a colored G line, indicating an anti- SARS-CoV-2 IgG positive test result, suggesting a recent infection or a past infection. Anti-SARS-CoV-2 IgM, if present in the specimen, will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated anti-human IgM, forming a colored M line, indicating an anti-SARS-CoV-2 IgM positive test result and suggesting an acute SARS- CoV-2 infection. An IgM and IgG double positive result suggests a late acute infection.

Absence of any of the test lines (G or M) suggests a negative result. Each test contains an internal control (C line) which should exhibit a colored line of the control antibodies regardless of color development on any of the test lines. If the C line does not develop, the test result is invalid, and the specimen must be retested with another device.

REAGENTS AND MATERIALS PROVIDED

1. Individually sealed foil pouches containing:
   a. One cassette device
   b. One desiccant
2. Plastic droppers
3. Detection buffer (REF SB-R0180, 3 mL/bottle)
4. Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

1. Clock or timer
2. Lancing device for whole blood test

WARNINGS AND PRECAUTIONS

For *In Vitro* Diagnostic Use

1. Read these Instructions for Use completely before performing the test. Failure to follow the instructions could lead to inaccurate test results.
2. Do not open the sealed pouch, unless ready to conduct the assay.
3. Once the pouch is opened, it should be used within 30 minutes to avoid failure caused by the moisture absorption.
4. Do not use expired devices or components.
5. Do not use the components of any other type of test kit as a substitute for the components in this kit.
6. Do not use hemolyzed blood specimen for testing.
7. Use only one specimen per device. Do not combine specimens.
8. Wear protective clothing and disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
9. Follow the US CDC Universal Precautions for prevention of transmission of HIV, HBV and other blood-borne pathogens.
10. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
11. Dispose of all specimens and materials used to perform the test as bio-hazardous waste.
12. Handle external controls in the same manner as patient specimens.
13. Read test results 10-15 minutes after a specimen is applied to the sample well of the device. Reading the test result after 15 minutes should be considered invalid and must be repeated.
14. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.

REAGENT PREPARATION AND STORAGE INSTRUCTIONS

All reagents are ready to use as supplied. Store unused test devices unopened at 2-30°C. If stored at 2-8°C, ensure that the test device is brought to room temperature before opening. The test device is stable until the expiration date printed on the sealed pouch. Do not freeze the kit or expose the kit to temperatures above 30°C.

SPECIMEN COLLECTION AND HANDLING

Consider any materials of human origin as infectious and handle them with standard bio-safety procedures.

Plasma/Serum

Step 1: Collect blood specimen into collection tube containing EDTA or citrate **(not Heparin)** for plasma or collection tube containing no anticoagulants for serum by venipuncture.

Step 2: A) To prepare plasma specimen, centrifuge collected specimens and carefully withdraw the plasma into a new pre-labeled tube.

B) To prepare serum specimen, allow blood to clot, then centrifuge collected specimens and carefully withdraw the serum into a new pre-labeled tube.

Test specimens as soon as possible after collecting. If not tested immediately, specimens can be stored at 2-8°C for up to 3 days, or frozen at -20°C for longer storage.

Avoid multiple freeze-thaw cycles. Prior to testing, bring frozen specimens to room temperature slowly and mix gently. Specimens containing visible particulate matter should be clarified by centrifugation before testing.

Do not use specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid possible interference with result interpretation.

Whole Blood

Step 1: Whole blood can be obtained by either fingertip puncture or by venipuncture. Collect venous blood specimen into a collection tube containing EDTA or citrate **(not Heparin).** Do not use hemolyzed blood for testing.

Whole blood specimens should be stored in refrigeration (2-8°C), if not tested immediately. The specimens must be tested within 24 hours of collection.

Note: Do not test specimens demonstrating gross lipemia, gross hemolysis or turbidity in order to avoid interference with result interpretation.

ASSAY PROCEDURE

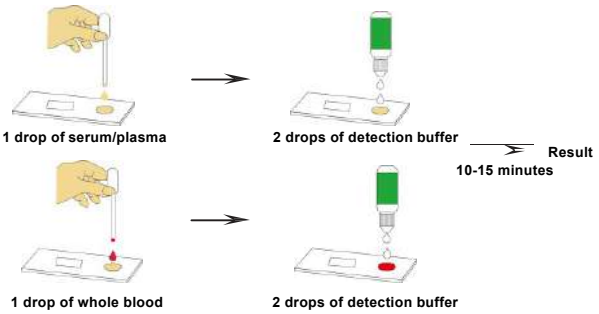
Step 1: Ensure that specimen and test components are equilibrated to room temperature. If frozen, mix the specimen well after thawing, prior to performing the assay.

Step 2: When ready to test, open the pouch at the notch and remove device. Place the test device on a clean, flat surface.

Step 3: Label the device with specimen's ID number.

Step 4: Fill the plastic dropper with the specimen.
Holding the dropper vertically, dispense 1 drop (~10 µL) of serum, plasma or whole blood (~15 µL) into the S well of the test cassette. Ensure there are no bubbles.

Step 5: Immediately add 2 drops (~70-100 µL) detection buffer into the S well of the test cassette. Ensure there are no bubbles.



Step 6: Set up timer.

Step 7: Read results at 10-15 minutes. Positive results may be visible as soon as 1 minute. Negative results must be confirmed at the end of 15 minutes. ***Any results interpreted outside 10-15 minutes window should be considered invalid and must be repeated. Discard used device after interpreting the results following local laws governing the disposal of device.***

QUALITY CONTROL

1. **Internal Control:** This test contains a built-in control feature, the C line. The C line develops after adding specimen extract. Otherwise, review the whole procedure and repeat test with a new device.

2. **External Control:** Good Laboratory Practice recommends using external controls, positive and negative, to assure the proper performance of the assay, particularly under the following circumstances:
   a. A new operator uses the kit, prior to performing testing of specimens.
   b. A new lot of test kit is used.
   c. A new shipment of kits is used.
   d. The temperature used during storage of the kit falls outside of 2-30°C.

e. The temperature of the test area falls outside of 15-30°C.
f. To verify a higher than expected frequency of positive or negative results.
g. To investigate the cause of repeated invalid results.

INTERPRETATION OF ASSAY RESULT

1. **NEGATIVE RESULT:** If only the C line is present, the absence of any color in both test lines (M and G) indicates that there is no SARS-CoV-2 IgG or IgM antibodies detected. The result is negative or non-reactive.

2. **POSITIVE RESULT:** In addition to the presence of the C line, if the G or M line develops, or both G and M lines develop, the test indicates the presence of SARS-CoV-2 IgG and/or IgM antibody. The result is positive or reactive.

Specimens with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnosis decision is made.

3. **INVALID:** If no C line develops, the assay is invalid regardless of any color in the test lines as indicated below. Repeat the assay with a new device.

PERFORMANCE CHARACTERISTICS

1. **Clinical Performance**

A total of 551 specimens were collected from susceptible subjects and tested with the SANILABO COVID-19 IgG/IgM Rapid Test and by a commercial PCR kit. Comparison for all subjects is shown in the following table:

	SANILABO COVID-19 IgG/IgM Rapid Test IgG Results		SANILABO COVID-19 IgG/IgM Rapid Test IgM Results	
PCR Test	**Positive**	**Negative**	**Positive**	**Negative**
Positive	216	7	174	49
Negative	0	328	2	326
Total	216	335	176	375

Relative IgG Sensitivity: 96.86% (95% CI: 93.66%-98.47%), Relative IgG Specificity: 100% (95% CI: 98.84%-100%)

Relative IgM Sensitivity: 78.03% (95% CI: 72.14%-82.96%), Relative IgM Specificity: 99.39% (95% CI: 97.80%-99.83%)

Relative Test Sensitivity: 96.86% (95% CI: 93.66%-98.47%), Relative Test Specificity: 99.39% (95% CI: 97.80%-99.83%), Overall Agreement: 98.37% (95% CI: 96.93%-99.14%)

2. **Cross reactivity**

No false positive anti-SARS-CoV-2 virus IgG and IgM test results were observed on at least 5 specimens from patients negative for COVID-19, but presenting similar clinical symptoms, as well as 2-5 specimens from the following disease states or specific conditions:

HBV	HCV	HIV	Pneumonia mycoplasma
Tuberculosis	Syphilis	Dengue	Pneumonia chlamydia
Zika	Chikungunya		

3. **Interference**

No interference was observed with the potentially interfering substances listed below at the indicated concentration:

Bilirubin	15 mg/dL	Triglycerides	400 mg/dL
Hemoglobin	20 g/dL	Rheumatoid factor	3250 IU/mL

LIMITATIONS OF TEST

1. The SANILABO COVID-19 IgG/IgM Rapid Test is limited to the qualitative detection of anti- SARS-CoV-2 virus IgG and IgM in human serum, plasma and whole blood. The intensity of the test band does not have linear correlation with the antibody titer in the specimen.
2. The Assay Procedure and the Test Result Interpretation must be followed closely when testing the presence of antibodies to SARS-CoV-2 virus in serum, plasma and whole blood from individual subjects. Failure to follow the procedure may lead to inaccurate results.
3. **Heparin potentially affects assay results; therefore, it should not be used as an anticoagulant.**
4. The SANILABO COVID-19 IgG/IgM Rapid Test is not applicable for patients who have received vaccination or have been treated with antibody drug to SARS-CoV-2 coronavirus since the SARS-CoV-2 IgG/IgM antibodies may not be caused by virus infections in those cases.
5. The result is used as an aid to detection of SARS-CoV-2 infection only. A negative or non-reactive test result does not confirm the test subject does not carry the virus. It may be due to a poor immune response, the quantity of antibodies to SARS-CoV-2 virus present in the specimen is below the limits of detection, or if the antibodies are not present during the stage of disease in which a specimen is collected. Infection may progress rapidly. If the symptoms persist, while the result from SANILABO COVID-19 IgG/IgM Rapid is negative or non-reactive, it is recommended to test with an alternative test method.
6. While positive test results only indicate that the test subject was infected before testing, it does not confirm that the test subject carries the virus. The test result must be carefully evaluated in conjunction with other methods. Take clinical symptoms into consideration.
7. It is possible that patients who were exposed to other viruses may show some level of reactivity with this test, due to potential cross-reactivity. Unusually high titer of heterophile antibodies or rheumatoid factor present in some specimens may affect the expected results[7, 8]. Factors, such as operational error can also potentially induce false results.

REFERENCES

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Index of Symbols

	Consult instructions for use	IVD	For *in vitro* diagnostic use only		Use by
REF	Catalog #	LOT	Lot Number		Tests per kit
2°C 30°C	Store between 2-30°C	EC REP	Authorized Representative		Do not reuse
	Manufacturer		Date of manufacture		

CTK Biotech, Inc.
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PI-R0180C Rev. B1.0
Date released: 2020-03-17 English version

For Export Only, Not For Re-sale in the USA.

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