EN Quality approved by SD BIOSENSOR / For *in vitro* diagnostics use only

REF Q-NCOV-01C

STANDARD Q

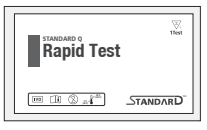
COVID-19 IgM/IgG Combo

STANDARD™ Q COVID-19 IgM/IgG Combo Test

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

KIT CONTENTS



Test device (individually in a foil pouch with desiccant)

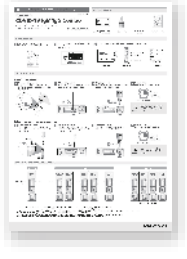
Buffer bottle

Capillary tube (20μl)

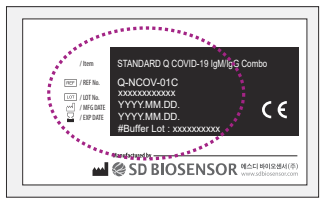
Instructions for use

PREPARATION

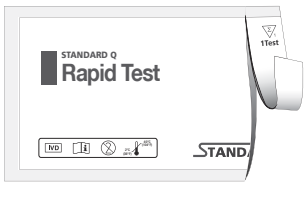
1 Carefully read instructions for using STANDARD Q COVID-19 IgM/IgG Combo Test.



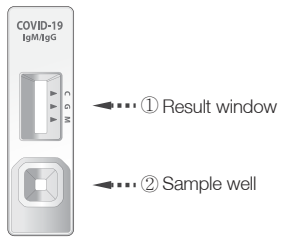
2 Check the expiry date at the back of the foil pouch. Do not use the test device, if expiry date has passed.



3 Check the test device and the silica gel pack within the foil pouch.



<Foil pouch>



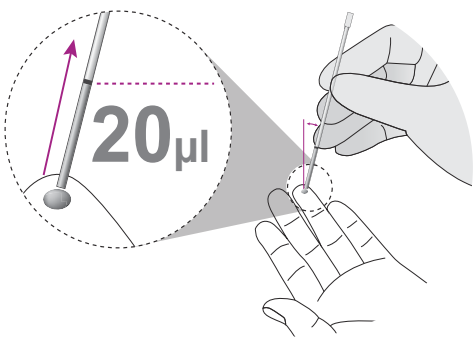
<Test device>

<Desiccant>

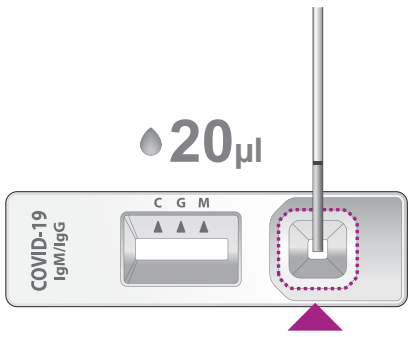
TEST PROCEDURE

Using Capillary whole blood

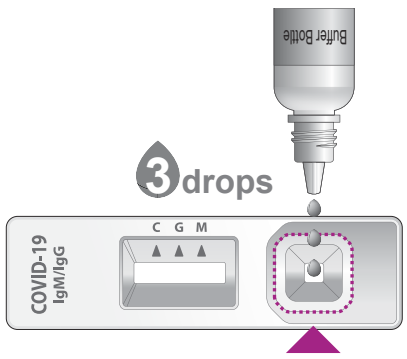
1 **Collecting of Specimen**
Using a capillary tube, collect the 20μl of capillary whole blood to the black line of the capillary tube.



2 **Adding of Specimen**
Add the collected capillary whole blood to the specimen well of the test device.



3 **Dropping of buffer**
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.

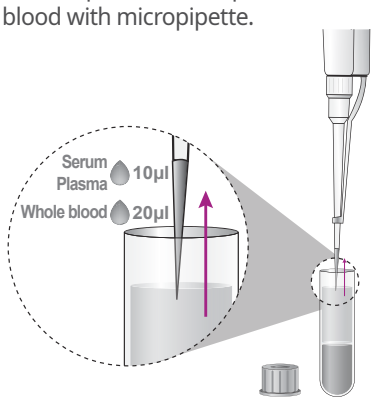


4 **Reading Time**
Read the test result at 10~15 minutes.

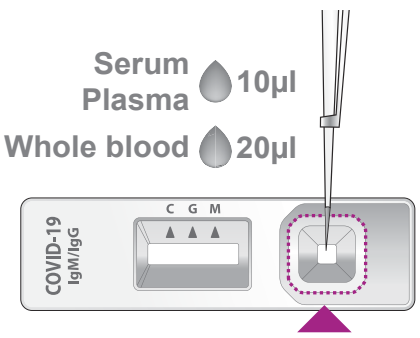
CAUTION
- Do not read test results after 15 minutes. It may give false results.

Using serum/plasma/venous whole blood

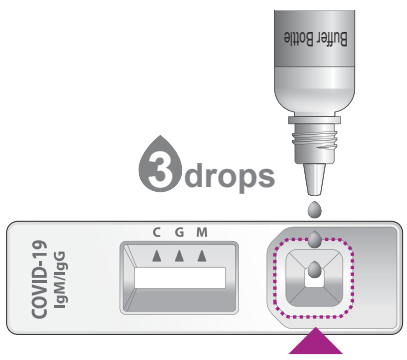
1 **Collecting of Specimen**
Using a micropipette, collect the 10μl of serum, plasma or 20μl of venous whole blood with micropipette.



2 **Adding of Specimen**
Add the collected serum, plasma or venous whole blood to the specimen well of the test device.



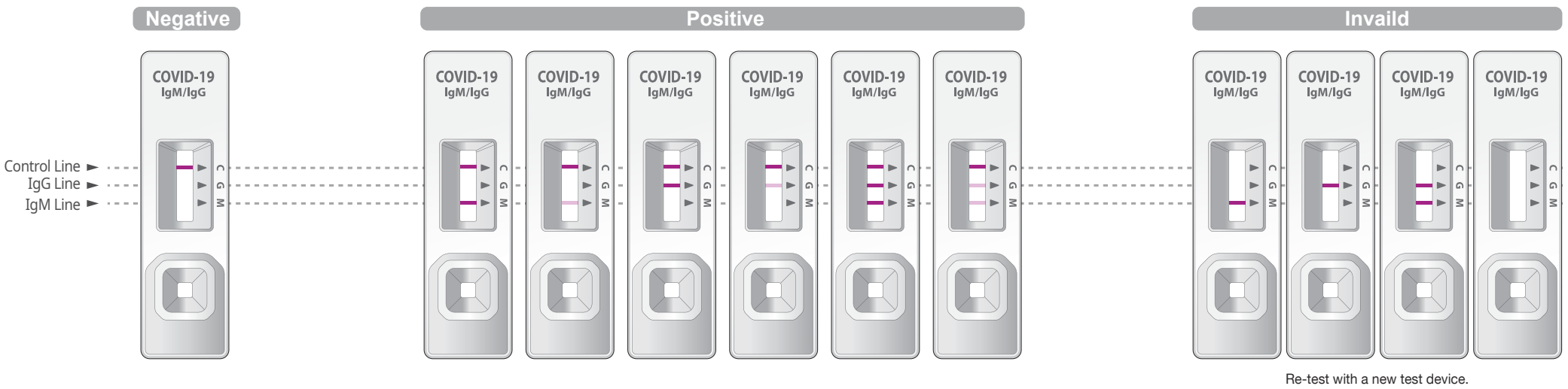
3 **Dropping of buffer**
Add 3 drops (90μl) of buffer vertically into the specimen well of the test device.



4 **Reading Time**
Read the test result at 10~15 minutes.

CAUTION
- Do not read test results after 15 minutes. It may give false results.

INTERPRETATION OF TEST RESULT



1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C).
2. A colored bands will appear in the lower section of the result window. These bands are each test line of IgM/IgG (M, G).
3. Even if the control line is faint, or the test line isn't uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

*** STANDARD Q COVID-19 IgM/IgG Combo Test may cross-react with antibody against SARS-CoV-1.**
*** Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.**
*** Positive results should be considered in conjunction with the clinical history, RT-PCR results and other data available.**

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EXPLANATION AND SUMMARY

[Introduction]

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "COVID-19", was discovered due to Wuhan Viral Pneumonia cases in 2019 and was named by the World Health Organization on January 12, 2020. WHO confirmed that COVID-19 can cause colds, the Middle East Respiratory Syndrome (MERS) and more serious diseases such as severe acute respiratory syndrome (SARS). This kit is helpful for the auxiliary diagnosis of coronavirus infection. The test results are for clinical reference only and cannot be used as a basis for confirming or excluding cases alone.

[Intended use]

STANDARD Q COVID-19 IgM/IgG Combo Test is a rapid chromatographic immunoassay for the qualitative detection of specific antibodies to SARS-CoV-2 present in human serum, plasma or whole blood. This test is for in vitro professional diagnostic use and intended as an aid to diagnosis of SARS-CoV-2 infection in convalescent phase of patient with clinical symptoms with SARS-CoV-2 infection. It provides only an initial screening test result. More specific alternative diagnosis methods should be performed in order to obtain the confirmation of SARS-CoV-2 infection.

[Test principle]

STANDARD Q COVID-19 IgM/IgG Combo Test has three pre-coated lines, "C" Control line, "G" and "M" Test line for the device on the surface of the nitrocellulose membrane. The control line and two test lines in the result window are not visible before applying any specimens. monoclonal anti-nucleocapsid antibody is coated on the control line region and monoclonal anti-human IgG antibody and Monoclonal anti-human IgM antibody is coated on the "G" and "M" test line region. Recombinant COVID-19 nucleocapsid protein conjugated with colloidal gold particles are used as detectors for "M" and "G" test line. During the test, SARS-CoV-2 antibodies in the specimen interact with recombinant COVID-19 nucleocapsid protein conjugated with colloidal gold particles making antibody-antigen gold particle complex. This complex migrates on the membrane via capillary action until the "M" and "G" test line, where it will be captured by the monoclonal anti-human IgG antibody or monoclonal anti-human IgM antibody. A violet test line would be visible in the result window if SARS-CoV-2 antibodies are present in the specimen. The intensity of violet test line will vary depending upon the amount SARS-CoV-2 antibodies present in the specimen. If SARS-CoV-2 antibodies are not present in the specimen, then no color appears in the test line. The control line is used for procedural control, and should always appear if the test procedure is performed properly and the test reagents of the control line are working.

[Kit contents]

① Test device (individually in a foil pouch with desiccant) ② Buffer bottle ③ Capillary tube (20μl) ④ Instructions for use

KIT STORAGE AND STABILITY

Store the kit at room temperature, 2-30°C / 36-86°F, out of direct sunlight. Kit materials are stable until the expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use the buffer of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating desiccant beads change from yellow to green, the test device in the pouch should be discarded.
11. Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

SPECIMEN COLLECTION AND PREPARATION

[Serum]

1. Collect the whole blood into the commercially available plain tube, NOT containing anti-coagulants such as heparin, EDTA, Sodium citrate by venipuncture and leave to settle for 30 minutes for blood coagulation and then centrifuge blood to get serum specimen of supernatant.
2. If serum in the plain tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Plasma]

1. Collect the venous blood into the commercially available anti-coagulant tube such as heparin, EDTA, Sodium citrate by venipuncture and centrifuge blood to get plasma specimen.
2. If plasma in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1 week after collection. Using the specimen in the long-term keeping more than 1 week can cause non-specific reaction. For prolonged storage, it should be at below -40°C/-40°F.
3. They should be brought to room temperature prior to use.

[Whole blood]

• Capillary whole blood

1. Capillary whole blood should be collected aseptically by fingertip.
2. Clean the area to be lanced with an alcohol swab.
3. Squeeze the end of the fingertip and pierce with a sterile lancet.
4. Using a capillary tube, collect the 20μl of capillary whole blood to the black line of the capillary tube.
5. The capillary whole blood must be tested immediately after collection.

• Venous whole blood

1. Collect the venous whole blood into the commercially available anti-coagulant tube such as heparin, EDTA , Sodium citrate by venipuncture.
2. If venous whole blood in an anti-coagulant tube is stored in a refrigerator at 2-8°C/36-46°F, the specimen can be used for testing within 1-2 days after collection.
3. Do not use hemolyzed blood Specimens.

CAUTION

- Use separate disposable materials for each specimen in order to avoid cross-contamination which can cause erroneous results.

LIMITATION OF TEST

1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. This test detects the presence of SARS-CoV-2 IgM/IgG in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.
3. Test results must be considered with other clinical data available to the physician.
4. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
5. Neither the quantitative value nor the rate anti- SARS-CoV-2 IgM/IgG concentration can be determined by this qualitative test.
6. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
7. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by viral culture or an molecular assay or ELISA.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other coronavirus infection except the SARS-CoV-1.
10. Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children.

EXTERNAL QUALITY CONTROL

1. Positive and negative controls are optional contents (STANDARD COVID-19 IgM/IgG Control(Cat No. 10COVC20)) and these controls can be provided as a means on additional quality control to demonstrate a positive or negative reaction.
2. Quality controls should be treated and tested the same as patient specimens.
3. It is recommended that positive and negative controls be run:
   - once for each new lot.
   - once for each untrained operator.
   - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

NOTIFICATION FOR COVID-19 ANTIBODY TESTS

1. This test has not been reviewed by the FDA.
2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
3. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
4. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E or past or present infection with SARS virus (no. 6).
5. Not for the screening of donated blood.
6. The test procedure should be conducted in ambient temperature and pressure.
7. Results of these tests should be appropriately recorded in a test report.

BIBLIOGRAPHY

1. Clinical management of severe acute respiratory infection when novel coronavirus (nCoV) infection is suspected. Interim guidance. WHO.2020
2. Diagnostic detection of Wuhan coronavirus 2019 by real-time RT-PCR.2020
3. Diagnosis and treatment of pneumonia caused by new coronavirus (trial version 4) National Health Commission. 2020

CE IVD

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or you can also contact us through www.sdbiosensor.com

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Issue date: 2020.04

REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
Contains Sufficient for <n> Tests
Caution
To indicate the temperature limitations in which the transport package has to be kept and handled.
Note
Do not re-use.
Use by
LOT Batch code
Manufacturer
Date of manufacture
Indicate that you should keep the product dry
Keep away from sunlight
Do not use if packaging is damaged