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

REF Q-NCOV-01D

## STANDARD Q

# COVID-19 IgM/IgG Duo

STANDARD™ Q COVID-19 IgM/IgG Duo Test

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

SD BIOSENSOR

## KIT CONTENTS

Test device (individually in a foil pouch with desiccant)

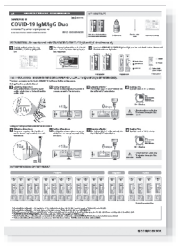
Buffer bottle


Capillary tube (10μl)

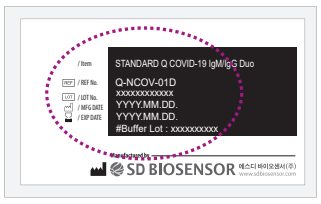

Instructions for use

## PREPARATION - Be sure to test both STANDARD Q COVID-19 IgM and IgG simultaneously.

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

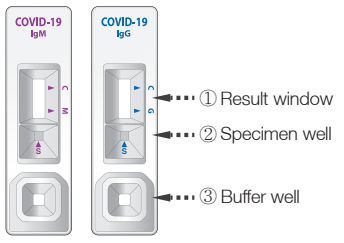


**2** Check the expiry date at the back of the foil pouch. Do not use the test device, if expiry date has passed.




**3** Open **both STANDARD Q COVID-19 IgM and IgG pouches, and check the test devices and the desiccant in each pouches.**

<Foil pouch>



<Test device>

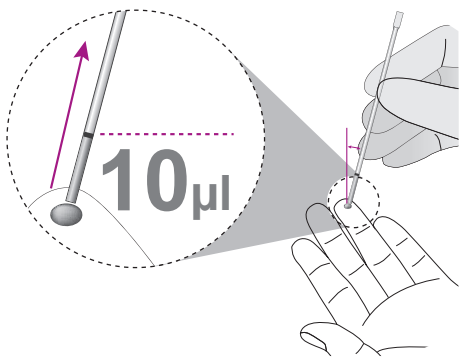
<Desiccant>

## TEST PROCEDURE - Be sure to test both STANDARD Q COVID-19 IgM and IgG simultaneously.

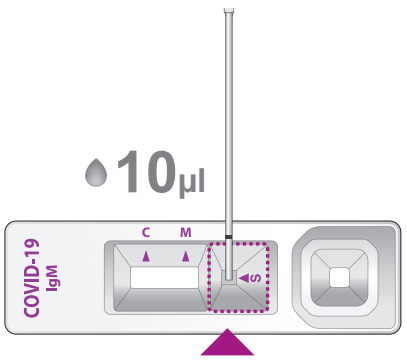
**The test procedures for both COVID-19 IgM and IgG are the same.**

### Using Capillary whole blood

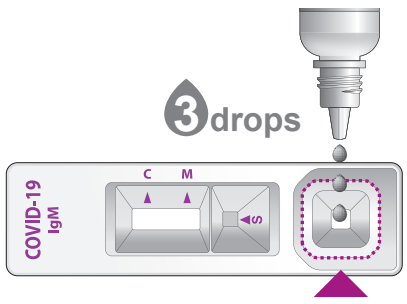
**1 Collecting of Specimen**
Using a capillary tube, collect the 10μl of capillary whole blood to the black line of the capillary tube.




**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 buffer well of the test device.

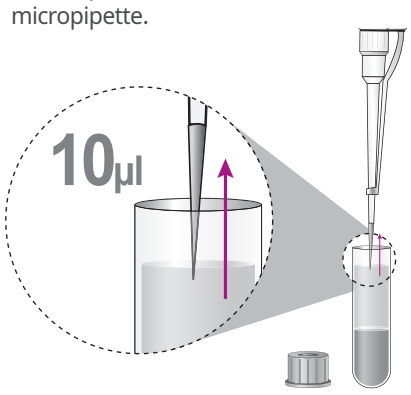



**4 Reading Time**
Read test result at 10~15 minutes.

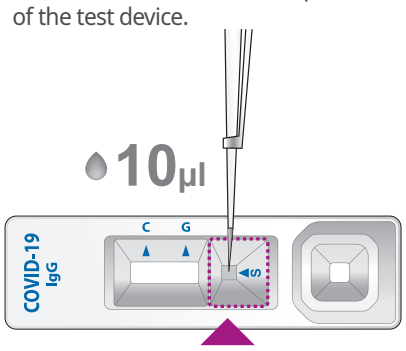

**CAUTION**
- Do not read test results after 15 minutes. It may give false results.

### Using serum/plasma/venous whole blood

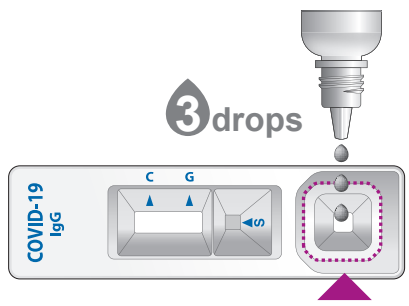
**1 Collecting of Specimen**
Using a micropipette, collect the 10μl of serum, plasma or venous whole blood with micropipette.




**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 buffer well of the test device.

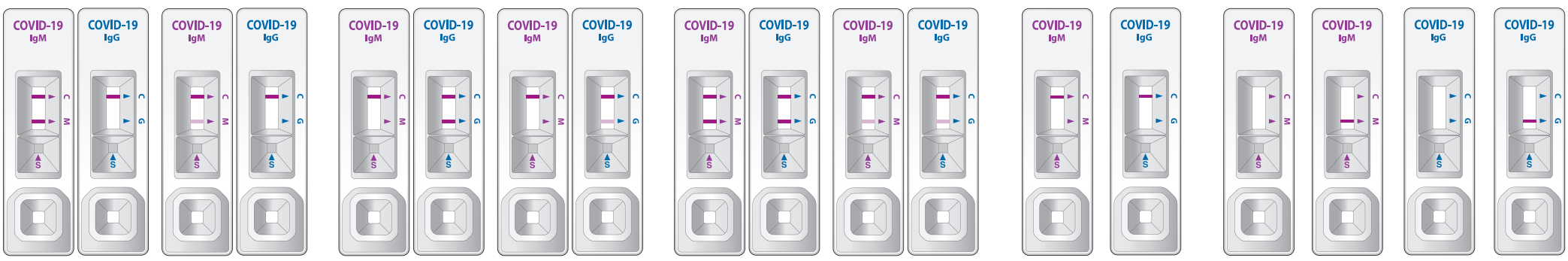



**4 Reading Time**
Read test result at 10~15 minutes.


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

## INTERPRETATION OF TEST RESULT

**Positive** | **Negative** | **Invaild**




Re-test with a new test device.

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 band will appear in the lower section of the result window. These bands are 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 Duo Test may cross-react with antibody against SARS-Corona-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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# STANDARD™ Q COVID-19 IgM/IgG Duo Test

SD BIOSENSOR

## 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 Duo 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 Duo Test has two pre-coated lines, "C" Control line, "G" Test line for the COVID-19 IgG Device and "C" Control line, "M" Test line for the COVID-19 IgM device on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any specimens. Goat polyclonal anti-mouse IgG antibody is coated on the control line region and SARS-CoV-2 recombinant protein is coated on the test line region. Monoclonal anti-human IgG antibody conjugated with colloidal gold particles are used as detectors for COVID-19 IgG Device and Monoclonal anti-human IgM antibody conjugated with colloidal gold particles are used as detectors for COVID-19 IgM Device During the test, SARS-CoV-2 antibodies in the Specimen interact with Monoclonal anti-human IgG antibody conjugated with colloidal gold particles or Monoclonal anti-human IgM antibody conjugated with colloidal gold particles making antibody-antibody gold particle complex. This complex migrates on the membrane via capillary action until the test line, where it will be captured by the SARS-CoV-2 recombinant protein. 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 (10μl) 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 10μl 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**

- As known relevant interference, hemolytic Specimen, rheumatoid factors-contained Specimen and lipemic, icteric Specimen can lead to impair the test results.
- Use separate disposable materials for each Specimen in order to avoid cross-contamination which can cause erroneous results.

## PERFORMANCE CHARACTERISTICS

### [Clinical evaluation]

Test were performed according to instructions for use of 'STANDARD Q COVID-19 IgM/IgG Duo Test' with residual serum from 33 positive patients confirmed by real-time PCR (2019-nCoV Real-time PCR kit) method and 30 healthy donors.

#### • Positive specimens

| No. | Onset of Symptom date | Confirmation Test date | Blood collection date | Days after symptom onset | STANDARD Q COVID-19 IgM/IgG Duo Test result | |
|---|---|---|---|---|---|---|
| | | | | | IgM | IgG |
| 1 | Unknown | Feb. 09, 2020 | Feb. 17, 2020 | Unknown | Positive | Pos weak |
| 2 | Unknown | Jan. 30, 2020 | Feb. 17, 2020 | Unknown | Positive | Positive |
| 3 | Unknown | Feb. 02, 2020 | Feb. 17, 2020 | Unknown | Positive | Positive |
| 4 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 23, 2020 | 8 | Pos weak | Pos weak |
| 5 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 27, 2020 | 12 | Pos weak | Positive |
| 6 | Feb. 15, 2020 | Feb. 23, 2020 | Mar. 03, 2020 | 17 | Pos weak | Positive |
| 7 | Feb. 06, 2020 | Feb. 09, 2020 | Feb. 13, 2020 | 7 | Negative | Negative |
| 8 | Feb. 06, 2020 | Feb. 09, 2020 | Feb. 21, 2020 | 15 | Pos weak | Positive |
| 9 | Feb. 06, 2020 | Feb. 09, 2020 | Mar. 03, 2020 | 26 | Pos weak | Positive |
| 10 | Feb. 18, 2020 | Feb. 19, 2020 | Feb. 19, 2020 | 1 | Negative | Negative |
| 11 | Feb. 18, 2020 | Feb. 19, 2020 | Feb. 26, 2020 | 8 | Negative | Positive |
| 12 | Feb. 19, 2020 | Feb. 19, 2020 | Feb. 23, 2020 | 4 | Negative | Negative |
| 13 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 23, 2020 | 8 | Positive | Positive |
| 14 | Feb. 6, 2020 | Feb. 9, 2020 | Mar. 03, 2020 | 26 | Positive | Positive |
| 15 | Jan. 30, 2020 | Feb. 1, 2020 | Feb. 09, 2020 | 10 | Negative | Negative |
| 16 | Jan. 25, 2020 | Feb. 1, 2020 | Feb. 12, 2020 | 18 | Positive | Positive |
| 17 | Feb. 25, 2020 | Feb. 25, 2020 | Mar. 03, 2020 | 7 | Negative | Positive |
| 18 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 25, 2020 | 10 | Positive | Positive |
| 19 | Feb. 6, 2020 | Feb. 9, 2020 | Feb. 21, 2020 | 15 | Positive | Positive |
| 20 | Jan. 30, 2020 | Feb. 1, 2020 | Feb. 13, 2020 | 14 | Positive | Positive |
| 21 | Jan. 25, 2020 | Feb. 1, 2020 | Feb. 09, 2020 | 15 | Trace | Positive |
| 22 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 26, 2020 | 11 | Positive | Positive |
| 23 | Feb. 6, 2020 | Feb. 9, 2020 | Feb. 17, 2020 | 11 | Positive | Positive |
| 24 | Jan. 30, 2020 | Feb. 1, 2020 | Feb. 06, 2020 | 7 | Negative | Negative |
| 25 | Feb. 18, 2020 | Feb. 21, 2020 | Feb. 26, 2020 | 8 | Negative | Negative |
| 26 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 27, 2020 | 12 | Positive | Positive |
| 27 | Feb. 6, 2020 | Feb. 9, 2020 | Mar. 01, 2020 | 24 | Positive | Positive |
| 28 | Jan. 25, 2020 | Feb. 1, 2020 | Feb. 17, 2020 | 23 | Positive | Positive |
| 29 | Feb. 25, 2020 | Feb. 25, 2020 | Mar. 02, 2020 | 6 | Negative | Positive |
| 30 | Feb. 15, 2020 | Feb. 23, 2020 | Feb. 29, 2020 | 14 | Positive | Positive |
| 31 | Feb. 22, 2020 | Feb. 24, 2020 | Mar. 06, 2020 | 13 | Negative | Positive |
| 32 | Feb. 4, 2020 | Feb. 4, 2020 | Feb. 20, 2020 | 16 | Negative | Positive |
| 33 | Feb. 4, 2020 | Feb. 4, 2020 | Feb. 20, 2020 | 16 | Negative | Positive |

#### • Negative specimens

| No. | Blood collection date | STANDARD Q COVID-19 IgM/IgG Duo Test result | |
|---|---|---|---|
| | | IgM | IgG |
| 1 | Mar. 6, 2020 | Negative | Negative |
| 2 | Feb. 20, 2020 | Negative | Negative |
| 3 | Mar. 4, 2020 | Negative | Negative |
| 4 | Mar. 5, 2020 | Negative | Negative |
| 5 | Mar. 9, 2020 | Negative | Negative |
| 6 | Mar. 7, 2020 | Negative | Negative |
| 7 | Mar. 11, 2020 | Negative | Negative |
| 8 | Mar. 5 2020 | Negative | Negative |
| 9 | Mar. 11, 2020 | Negative | Negative |
| 10 | Mar. 7. 2020 | Negative | Negative |
| 11 | Mar. 9, 2020 | Negative | Negative |
| 12 | Mar. 6, 2020 | Negative | Negative |
| 13 | Mar. 4, 2020 | Negative | Negative |
| 14 | Feb. 20, 2020 | Negative | Negative |
| 15 | Feb. 19, 2020 | Negative | Negative |

| No. | Blood collection date | STANDARD Q COVID-19 IgM/IgG Duo Test result | |
|---|---|---|---|
| | | IgM | IgG |
| 16 | Feb. 18, 2020 | Negative | Negative |
| 17 | Feb. 25, 2020 | Negative | Negative |
| 18 | Feb. 20, 2020 | Negative | Negative |
| 19 | Feb. 25, 2020 | Negative | Pos weak |
| 20 | Feb. 17, 2020 | Negative | Negative |
| 21 | Feb. 20, 2020 | Negative | Negative |
| 22 | Feb. 20, 2020 | Negative | Negative |
| 23 | Feb. 20, 2020 | Negative | Negative |
| 24 | Feb. 19, 2020 | Negative | Negative |
| 25 | Feb. 13, 2020 | Negative | Negative |
| 26 | Feb. 10, 2020 | Negative | Negative |
| 27 | Feb. 10, 2020 | Negative | Negative |
| 28 | Feb. 2, 2020 | Negative | Negative |
| 29 | Feb. 12, 2020 | Negative | Negative |
| 30 | Feb. 6, 2020 | Negative | Negative |

- Due to the differing inter-patient time response to the virus, any individual positive result of IgM or IgG should be read as a positive result for SARS-CoV-2 and the combined positive test results are used to calculate total Duo test sensitivity.

Combined positive test results are used to calculate total Duo test sensitivity

| | | PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| STANDARD Q COVID-19 IgM+IgG | Positive | 27 | 1 | 28 |
| | Negative | 6 | 29 | 35 |
| Total | | 33 | 30 | 63 |

Sensitivity : 81.8%, Specificity : 96.6%

- STANDARD Q COVID-19 IgM + IgG showed 81.8% of sensitivity and 96.6% of specificity.
- Test results of the specimens collected after 8 days and 10 days from the date of symptom onset below.

Test result of the specimens collected after 8 days from the date of symptom onset

| | | PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| STANDARD Q COVID-19 IgM+IgG | Positive | 25 | 1 | 26 |
| | Negative | 2 | 29 | 31 |
| Total | | 27 | 30 | 57 |

Sensitivity : 92.6%, Specificity : 96.6%

Test result of the specimens collected after 10 days from the date of symptom onset

| | | PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| STANDARD Q COVID-19 IgM+IgG | Positive | 23 | 1 | 24 |
| | Negative | 1 | 29 | 30 |
| Total | | 24 | 30 | 54 |

Sensitivity : 95.8%, Specificity : 96.6%

- Based on result of test with positive specimens, it was found that IgM antibody diagnosis with STANDARD Q COVID-19 IgM/IgG Duo Test was effective for diagnosis COVID-19 from the time when after about 7 days from the date of symptom onset. And STANDARD Q COVID-19 IgM/IgG Duo Test showed a high specificity in the test with negative specimens.

## ANALYTICAL PERFORMANCE

1. **Limit of Detection:** IgM-0.02 mg/ml, IgG-0.02 mg/ml
2. **Cross-Reactivity:** No cross-reactivity for HIV positive plasma, Japanese Encephalitis positive plasma, Zika virus positive plasma, Chikungunya positive plasma, Dengue IgM positive plasma, Salmonella typhi IgM positive plasma, Rubella IgM, CMV IgG/IgM, Tick borne encephalitis IgM positive plasma, West Nile Virus positive plasma, Treponema palladium, HAV IgM positive plasma, HAV IgG positive plasma, HBV Ab positive plasma, HCV Ab positive plasma, Influenza vaccine positive plasma, Leishmania positive plasma, Brucella IgM positive plasma, Chagas positive plasma, Toxoplasma positive plasma and Filariasis positive plasma for IgM and IgG
3. **Interference study:** No Interference for Respiratory Specimens (Mucin: bovine submaxillary gland type I-S, Blood (human), EDTA anticoagulated, Biotin), Nasal sprays (Neo-Synephrine, Afrin Nasal Spray, Saline Nasal Spray), Homeopathic allergy relief medicine (Homeopathic Zicam Allergy Relief Nasal Gel, Sodium Cromoglycate, Olopatadine Hydrochloride), Anti-viral drugs (Zanamivir, Oseltamivir, Artemether-lumefantrine, Doxycycline hyclate, Quinine, Lamivudine, Ribavirin, Daclatasvir), Anti-inflammatory medication (Acetaminophen, Acetylsalicylic acid, Ibuprofen), Antibiotic (Mupirocin, Tobramycin, Erythromycin, Ciprofloxacin), Human anti-mouse antibody, Pregnant woman, Elevated levels of C-reactive protein for IgM and IgG
4. **High-dose Hook Effect:** No hook effect at the concentration of 1.25 mg/ml for IgM and 0.3 mg/ml for IgG
5. **Matrix Equivalency:** The difference of Matrix (Capillary whole blood, Venous whole blood, Plasma, Serum) and anticoagulant (EDTA, Heparin, Sodium citrate) does not affect the result.

| Sort | Matrix | Anticoagulant | Spiked Concentration | Agreement to expected result |
|---|---|---|---|---|
| COVID-19 IgG antibody spiked | Serum | NA | 0.04 mg/ml | 100%(25/25) |
| | Plasma | Heparin | 0.04 mg/ml | 100%(25/25) |
| | | EDTA | 0.04 mg/ml | 100%(25/25) |
| | | Sodium Citrate | 0.04 mg/ml | 100%(25/25) |
| | Venous whole blood | Heparin | 0.04 mg/ml | 100%(25/25) |
| | | EDTA | 0.04 mg/ml | 100%(25/25) |
| | | Sodium Citrate | 0.04 mg/ml | 100%(25/25) |
| | Capillary whole blood | EDTA | 0.04 mg/ml | 100%(25/25) |
| COVID-19 IgG antibody spiked | Serum | NA | 0.04 mg/ml | 100%(25/25) |
| | Plasma | Heparin | 0.04 mg/ml | 100%(25/25) |
| | | EDTA | 0.04 mg/ml | 100%(25/25) |
| | | Sodium Citrate | 0.04 mg/ml | 100%(25/25) |
| | Venous whole blood | Heparin | 0.04 mg/ml | 100%(25/25) |
| | | EDTA | 0.04 mg/ml | 100%(25/25) |
| | | Sodium Citrate | 0.04 mg/ml | 100%(25/25) |
| | Capillary whole blood | EDTA | 0.04 mg/ml | 100%(25/25) |
| N/A | Serum | NA | N/A | 100%(25/25) |
| | Plasma | Heparin | N/A | 100%(25/25) |
| | | EDTA | N/A | 100%(25/25) |
| | | Sodium Citrate | N/A | 100%(25/25) |
| | Venous whole blood | Heparin | N/A | 100%(25/25) |
| | | EDTA | N/A | 100%(25/25) |
| | | Sodium Citrate | N/A | 100%(25/25) |
| | Capillary whole blood | EDTA | N/A | 100%(25/25) |

6. **Stability schedule for 24months of claimed shelf life**
   1) Accelerated Aging Test: February, 2020 ~ August, 2020 (for 19 weeks)
   2) Real time stability Test: February, 2020 ~ May, 2022 (for 26 months)

## 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.

## 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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L23COV1ENR3
Issue date: 2020.03


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