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***For Medical Professional Use Only***

# SARS-CoV-2 IgM/IgG Duo Test (Colloidal Gold)

## INTENDED USE

The SARS-CoV-2 IgM/IgG Duo Test is a lateral flow chromatography immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in serum, plasma (EDTA, sodium citrate and lithium heparin) or fingerstick whole blood, venous whole blood specimens from patients suspected of COVID-19 infection by a healthcare provider. The SARS-CoV-2 IgM/IgG Duo Test is an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the SARS-CoV-2 IgM/IgG Duo Test should not be used as the sole basis for diagnosis.

Testing is limited to qualified laboratories. Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the SARS-CoV-2 IgM/IgG Duo Test early after infection is unknown.

False positive results for IgM and IgG antibodies may occur due to cross-reactivity from pre-existing antibodies or other possible causes.
At this time, it is unknown for how long IgM or IgG antibodies may persist following infection.
For prescription use only. For in vitro diagnostic use only.

## GENERAL INFORMATION

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV). SARS- CoV-2 is a new strain that has not been previously identified in humans. The novel “Coronavirus Disease 2019” (COVID-19) is caused by infection with the virus “SARS- CoV-2”. Patients with SARS-CoV-2 report a mild (including some with no reported symptoms) to severe. Symptoms of COVID-19 are fever, fatigue, dry cough, shortness of breath and other symptoms which can rapidly develop into severe pneumonia, respiratory failure, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc. which can be life-threatening. There is an urgent need for rapid tests to manage the ongoing pandemic.
The SARS-CoV-2 IgM/IgG Duo Test is intended for qualitative detection of antibodies indicative of SARS-CoV-2 infection and is to be used as an aid for diagnosis of SARS-CoV-2 infection.

## PRINCIPLE OF THE TEST

The test cassette contains (1) mixed recombinant sars-cov-2 antigens labeled and quality control protein labeled conjugates and (2) two Test lines (T1 and T2, pre-coated with anti-human IgM and IgG antibody, respectively) and a Control line (Pre-coated with an antibody to quality control protein).When the sample is applied to the test strip, the gold-labeled recombinant SARS-CoV-2 proteins will bind with SARS-CoV-2 IgM and/or IgG antibodies present in sample and form antigen-antibody complexes. These complexes move along with the test strip and then will be captured on T1 line by anti-human antibody IgM and/or on T2 line by anti-human IgG antibody, resulting in purplish red band on the test region, indicating a positive result. If antibodies against SRAS-CoV-2 are not present or are present at very low levels in the sample, there is no red line appears in “T1 and T2”. The “Control Line” is used for procedural control. Control line should always appear if the test procedure is performed properly and the test reagents of control line are working.

## REAGENTS PROVIDED

Each kit contains:

| Item | Component | Specification/Qty. | |
|---|---|---|---|
| | | 1 Test/kit<br>R042-01 | 20 Tests/kit<br>R042-02 |
| 1 | Test device individually foil pouched with a desiccant | 1 pc | 20 pcs |
| 2 | Sample diluent (Tris buffer, detergent, preservative) | 1 mL | 5 mL |
| 3 | Instructions for use | 1 | 1 |

## MATERIALS REQUIRED BUT NOT PROVIDED

1. Sterile Safety Lancets
2. Disposable 20 µL Transfer Pipet
3. 20µL-, 50µL-, 100 µL- micro-pipets and tips
4. Bandages
5. Timer
6. Disposable gloves, Biohazard disposal container, Collection devices (for venous whole blood, serum, plasma)
7. Antiseptic wipes (for fingerstick whole blood specimens)

## STORAGE AND STABILITY

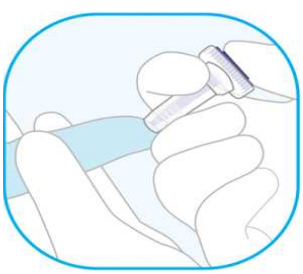
1. The test device is sensitive to humidity and as well as to heat.
2. Store kit components at 2-30°C and do not use after the expiry date on the box outer label.
3. Perform the test immediately after removing the test device from a foil pouch.
4. Do not freeze.
5. Do not store the test kit in direct sunlight.

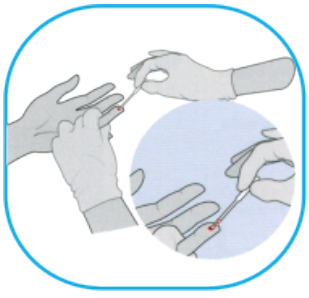
## SPECIMEN COLLECTION AND PREPARATION

1.Sample should be ***human serum, plasma and fingerstick whole blood, venous whole blood only,*** other body fluid samples are not tested and may cause incorrect or inaccurate results.

2. **Fingerstick Whole Blood Collection**

- Clean the finger of the tested person with an antiseptic wipe. Allow the finger to dry thoroughly.
- Using a sterile lancet, puncture the skin just off the center of the finger. Avoid squeezing the fingertip to accelerate bleeding as this may dilute the blood with excess tissue fluid.
- Collect the sample by laying the disposable 20µl Transfer Pipet against the drop of blood until the Pipet is full.
- Fingerstick specimens must be tested immediately after collection.





3. **Venous whole blood, serum or plasma collection**

- Collect specimens using standard procedures [1].
- Follow the instructions provided with your collection device for use and processing of the sample [2].
- Samples should be thoroughly separated from all cellular material. Failure to do so may lead to an erroneous result.

4. If venous whole blood, serum, or plasma specimens are not tested immediately, they should be refrigerated at 2~8°C. For storage period longer than 1 week, freezing is recommended for serum, or plasma. They should be brought to room temperature prior to use.

5. Specimens containing a precipitate may yield inconsistent test results. Such specimens must be clarified prior to assaying.

6. Repeated freezing and thawing may give erroneous results.

7. The use of hemolytic, lipemic or bacterially contaminated specimens should be avoided.

## PRECAUTIONS

1. For in vitro diagnostic use only.

2. Do not eat or smoke while handling specimens.

3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.

4. Clean up spills thoroughly using an appropriate disinfectant.

5. Decontaminate and dispose of all specimens, used kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.

6. Do not use the test kit if the pouch is damaged or the seal is broken.

## TEST PROCEDURE

Read this instructions for use carefully before operating to avoid incorrect results.

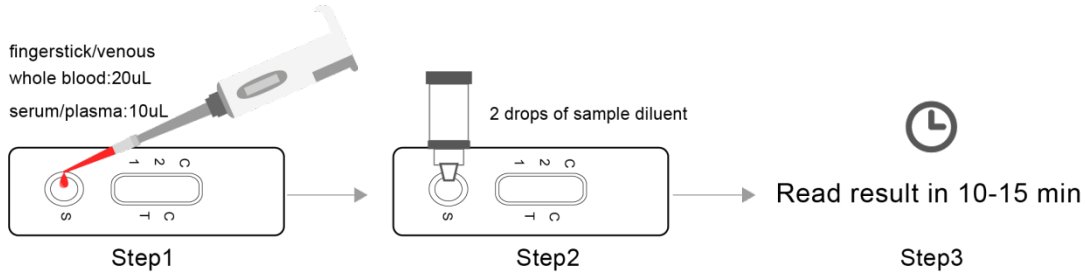
1. All reagents have to be brought to room temperature (18 to 25 °C) before performing the test.

2. Remove the test device from the foil pouch, and place it on a flat, dry surface.

3. Step1: Add **10 µL** of **serum/plasma or 20 µL of fingerstick whole blood or venous whole blood** into the sample well with pipette or with Transfer pipet.

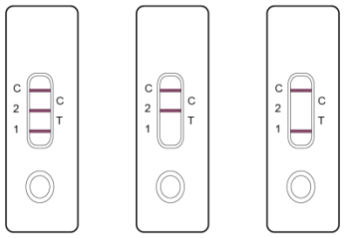
4. Step2: Add 2 drops (60µL) of sample diluent into the sample well immediately.

5. Step3: As the test begins to work, you will see red color move across the reaction window in the center of the test device. Interpret the test results in 10-15 minutes.




## INTERPRETATION OF RESULTS

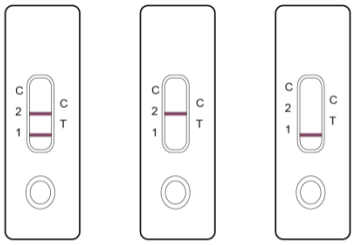
**Positive (+)**

| | |
|---|---|
|  IgM/G Positive IgG Positive IgM Positive | 1. The presence of 3 red lines (T1, T2 and C) within the reaction window, no matter which band appears first, indicates presence of both SARS-CoV-2 IgM and IgG antibodies.<br>2. The presence of 2 red lines (T1 and C) within the reaction window, no matter which band appears first, indicates presence of SARS-CoV-2 IgM antibody.<br>3. The presence of 2 red lines (T2 and C) within the reaction window, no matter which band appears first, indicates presence of SARS-CoV-2 IgG antibody. |

**Negative (-)**

| | |
|---|---|
|  Negative | 1. The presence of “C” line (control line) only within the reaction window indicates that no SARS-CoV-2 antibodies are detected. The results is negative. |

**Invalid**

| | |
|---|---|
|  Invalid Invalid Invalid | 1. If the control(C) line is not displayed in 10-15 min, regardless of whether T1 and/or T2 line is present, the test result is invalid. It is recommended that the specimen should be re-tested.<br>2. The test result is invalid after 15 min. |

**PERFORMANCE CHARACTERISTICS.**

**1. Cross-Reactivity**

Cross-reactivity of the SARS-CoV-2 IgM/IgG Duo Test was evaluated using serum or plasma samples which contain antibodies to the pathogens listed below. No false positivity or false negativity was found with the following Table 1:

Table 1 Cross-reactivity of the SARS-CoV-2 IgM/IgG Duo Test

| Organisms/Conditions | Number of Samples | SARS-CoV-2 IgM/IgG Duo Test | | | |
|---|---|---|---|---|---|
| | | IgM | | IgG | |
| | | POS | NEG | POS | NEG |
| HBV | 9 | 0 | 9 | 0 | 9 |
| HCV | 10 | 0 | 10 | 0 | 10 |
| Influenza A | 10 | 0 | 10 | 0 | 10 |
| Influenza B | 7 | 0 | 7 | 0 | 7 |
| Chlamydia pneumoniae | 4 | 0 | 4 | 0 | 4 |

| | | | | | |
|---|---|---|---|---|---|
| Mycoplasma pneumoniae | 6 | 0 | 6 | 0 | 6 |
| Streptococcus pneumoniae | 3 | 0 | 3 | 0 | 3 |
| Mycobacterium tuberculosis | 5 | 0 | 5 | 0 | 5 |
| EB Virus | 7 | 0 | 7 | 0 | 7 |
| Respiratory syncytial virus | 4 | 0 | 4 | 0 | 4 |
| Adenovirus | 6 | 0 | 6 | 0 | 6 |
| Enterovirus 71 | 5 | 0 | 5 | 0 | 5 |

**2. Potentially Endogenous Interfering Substances**

One of the following Potential interfering substances were spiked into weakly positive or negative specimens for SARS-CoV-2 IgM or IgG antibodies, and specimens moderately positive for SARS-CoV-2 IgM or IgG antibodies. And tested in multiple replicates. No false positivity or false negativity was found with the following Table 2:

Table 2: Potential interfering substances tested with SARS-CoV-2 IgM/IgG Duo Test

| Substance | Concentration | Substance | Concentration |
|---|---|---|---|
| Hemoglobin | 10 mg/ml | Zanamivir | 140 ng/ml |
| Bilirubin | 0.4 mg/ml | Ritonavir | 50 μg/ml |
| Triglycerides | 15 mg/ml | Tramadol | 12 μg/ml |
| Cholesterol | 4 mg/ml | Azithromycin | 5 μg/ml |
| Human Anti-mouse Antibody (HAMA) | 100 IU /ml | Meropenem | 10 mg/ml |
| Rheumatoid Factor | 1500 IU/ml | Oseltamivir | 1000 ng/ml |
| Human Serum Albumin | 60 mg/ml | Mupirocin | 10 mg/ml |
| α-interferon | 2 ng/ml | benzocaine | 1.5 mg/ml |
| Lopinavir | 2 μg/ml | Peramivir | 20 μg/ml |
| Tobramycin | 10 mg/L | Epinephrine | 500 pmol/L |
| Ribavirin | 40 mg/L | | |

**3. Clinical Performance**

A total of 276 samples were tested which included plasma, serum, fingerstick whole blood and venous whole blood.

| | | | PCR Kit | | Total |
|---|---|---|---|---|---|
| | | | Pos | Neg | |
| SARS-CoV-2 IgM/IgG Duo Test | Pos | IgG+/IgM+ | 116 | 0 | 116 |
| | | IgG+/IgM- | 8 | 2 | 10 |
| | | IgG-/IgM+ | 3 | 1 | 4 |
| | Neg | IgG-/IgM- | 11 | 105 | 116 |
| Total | | | 138 | 108 | 246 |

**Positive Percent Agreement (PPA) =92.03% (127/138)** (95% CI: 86.51%-93.85%).

**Negative Percent Agreement(NPA) =97.22% (105/108)** (95% CI: 91.38%-98.09%).

**Overall Rates of Agreement (ORA) = 94.31% ((127+105/(138+108))** (95% CI: 88.65%-95.12%).

**LIMITATIONS**

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1. This kit is for **in vitro diagnosis** and **medical professional** use only.

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 excludeSARS-CoV-2 infection or to inform infection status.

4. Positive results may be due to past or present infection with non-SARS-CoV-2coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

**REFERENCES**

1. CLSI. Collection of Diagnostic Venous Blood Specimens. 7th ed. CLSI standard GP41. Wayne, PA: Clinical and Laboratory Standards Institute; 2017.

2. CLSI. Tubes and Additives for Venous and Capillary Blood Specimen Collection; Approved Standard-Sixth Edition. CLSI document GP39-A6. Wayne, PA: Clinical and Laboratory Standards Institute; 2010.

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| SYMBOL | DESCRIPTION | SYMBOL | DESCRIPTION |
|---|---|---|---|
| | Manufactured By | CE | CE Mark |
| EC REP | Authorized Representative | REF | Catalog Number |
| IVD | InVitro Diagnostic Medical Device | | Potential Biological Hazards After Use |
| LOT | Batch Code | | Do Not Reuse |
| | Expiration Date in Year-Month-Day Format | | Date of Manufacture |
| | Temperature Limitation | | Consult instructions for use |
| | caution | | Keep away from sunlight |