STANDARD Q
COVID-19 IgM/IgG Duo
STANDARD™ Q COVID-19 IgM/IgG Duo Test
SD BIOSENSOR

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.

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.

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.

INTERPRETATION OF TEST RESULT

Positive

Negative

Invalid

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-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.

CAUTION

• Do not read test results after 15 minutes. It may give false results.
**STANDARD™ Q COVID-19 IgM/IgG Duo Test**

**Kits Storage and Stability**

- Store the kit at room temperature (15–30°C) in a dry environment.
- Kits are stable until the expiration date printed on the product label.

**Warnings and Precautions**

- Do not freeze the kit.
- Do not freeze the test if the pouch is damaged or the seal is broken.
- Do not re-use the buffer of another lot.
- Do not use the test kit if the pouch is damaged or the seal is broken.

**Clinical Evaluation**

- **1.** Venous whole blood
  - Collect the venous whole blood into a commercially available anti-coagulant tube such as heparin, EDTA, Sodium Citrate by venipuncture.

**Preparation of Specimens**

- **Serum**
  - **1.** The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
  - **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.

**SPECIMEN COLLECTION AND PREPARATION**

- **Serum**
  - **1.** The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.

**Analytical Performance**

- **Sensitivity:** 92.6%
- **Specificity:** 96.6%

**Performance Characteristics**

- **Sensitivity:** 81.8%
- **Specificity:** 96.6%

**Limitation of Test**

- Do not use the test kit if the pouch is damaged or the seal is broken.
- Do not use the buffer of another lot.

**Bibliography**

- CDC: https://www.cdc.gov
- WHO: https://www.who.int
- ICMR: https://www.icmr.org.in

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**Explanation and Summary**

- **Introduction**
  - SARS-CoV-2 is a single-stranded negative-sense RNA virus that is an enveloped virus of about 60 to 120 nm in diameter. In general, most of the largest of all RNA viruses is an internal polyprotein that encodes spikes, nucleoproteins, and virion envelope proteins. It is a cause of acute and chronic diseases. Common signs of a person infected with SARSCoV-2 include respiratory symptoms, fever, cough, shortness of breath, and fatigue. In severe cases, ARDS can cause pneumonia, severe acute respiratory syndrome, shivering, hypotension, and 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.

- **Test Principle**
  - STANDARD™ Q COVID-19 IgM/IgG Duo Test has two color zones: the **Control Line** (C) and the **Test Line** (T). The test is positive if the **Test Line** (T) appears. When tested positive, the test line is captured by the SARS-CoV-2 recombinant protein. A visible test line appears in the result window if SARS-CoV-2 antibodies are present in the Specimen. The control line appears in the window to indicate that the test was performed properly and the test reagents of the control line are working.

- **Negative Specimens**
  - **1.** Venous whole blood
  - **2.** Capillary whole blood
  - **3.** Standard Q COVID-19 IgM/IgG Duo Test result

- **Performance Characteristics**
  - **Sensitivity:** 81.8%
  - **Specificity:** 96.6%

- **Limitation of Test**
  - **1.** The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
  - **2.** In clinical evaluation, the test was performed with blood specimens that were collected after 8 days from the date of symptom onset.
  - **3.** The test results are not intended to be used as the sole criteria for the diagnosis of SARS-CoV-2 infection.

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**Bibliography**

- CDC: https://www.cdc.gov
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