KHB® IVD

DIAGNOSTIC KIT FOR SARS-CoV-2 IgM/IgG ANTIBODY (COLLOIDAL GOLD)

Instructions for use

REF R-423-25-C-CE (25 Tests)

⚠ ***PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE***

【Product Name】

Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold)

【Package Size】

25 Tests/Kit

【Intended Use】

The Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) from KHB adopts the solid phase colloidal gold immunochromatographic technology for the qualitative determination of IgM/IgG antibodies against SARS-CoV-2 in human serum, plasma, and whole blood.

The 2019 novel coronavirus, recently named SARS-CoV-2 (originally called 2019-nCoV) is identified as the causative agent of an outbreak of viral pneumonia, COVID-19.

SARS-CoV-2 belongs to the β-coronavirus genus and is similar with the SARS in 2003 and MERS in 2012. The genome of Coronavirus encodes four structural proteins including Spike (S) protein, Envelope (E) proteins, Membrane (M) protein and Nucleocapsid (N).

The body's immune system produces specific antibodies in general 1 to 2 weeks after the 2019 novel coronavirus infection for the first time.

【Principles of Procedure】

The Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) from KHB adopts the solid phase colloidal gold immunochromatographic technology for the qualitative determination of IgM/IgG antibodies against SARS-CoV-2 in human serum, plasma, and whole blood. The gold SARS-CoV-2 antigen conjugate and the gold chicken IgY conjugate are coated to the conjugate pad in advance. The test line T1 (antibodies against human IgM), the test line T2 (SPA) and the control line (chicken IgY antibodies) are pre-coated on the surface of Nitrocellulose (NC) membrane.

When the specimen is added to the sample pad, it migrates through the conjugate pad, the gold SARS-CoV-2 antigen conjugate - IgM antibodies against SARS-CoV-2- antibody against human IgM complex is formed and test line T1 will be visible in the strip if there are enough IgM antibodies against SARS-CoV-2 (IgM Positive) in the specimen; the gold SARS-CoV-2 antigen conjugate - IgG antibodies against SARS-CoV-2 – SPA complex is formed and test line T2 will be visible in the strip if there are enough IgG antibodies against SARS-CoV-2 (IgG Positive) in the specimen. If the specific IgM/IgG antibodies are absent, or present at a very low level, no test line appears (Negative).

【Materials Provided】

• SARS-CoV-2 IgM/IgG antibody test cassette with desiccant	1×25 cassettes	Cassette
• Sample diluent	4 ml ×1 bottle	Sample Diluent
• Instructions for use	1 piece	

Accessories		Manufacturer	EC-Representative	CE mark	Classification
• Safety lancet	25 pieces	Ningbo Medsun Medical Co., Ltd. No.55, Jinxi Road, Zhenhai, 315221, Ningbo, P.R.China	Shanghai International Holding Corp. GmbH (Europe) Eiffestraβe 80 20537 Hamburg, Germany	CE_{0123}	MDD93/42/EEC, AnnexV, Class IIa
• Alcohol pad (70% Isopropyl alcohol)	25 pieces	Lights Medical Manufacture Co., Ltd. No.19, Quanda Road, Wuqing Development Area, Tianjin, 301700, P.R.China	Welkang Ltd., t/a Welkang Tech Consulting Suite B, 29 Harley Street, London W1G 9QR, England, United Kingdom	CE	MDD93/42/EEC, Annex Ⅶ, Class I
• Disposable transfer pipette	25 pieces	Zhejiang Sorfa Life Science Research Co., Ltd. No.148 Longshan Road, Zhongguan Town, Deqing county, Huzhou City, 313220, Zhejiang, P.R.China	Sungo Certification Company Limited. RM101, Maple House,118 High Street, Purley, London, England, United Kingdom	CE	98/79/EC, Annex III, Other Devices

【Storage Requirements and Shelf-life】

The test cassettes and the sample diluent must be stored at 4-30℃ until expiration date. The shelf-life is 24 months temporarily.

Do not use frozen and expired devices.

Production date and expiry date please refer to packing label

【Specimen types】

（1）Human serum, plasma, and whole blood specimens are validated to be used with this assay.

（2）Serum and plasma specimens may be stored at 2-8℃ for up to 7 days from time of draw, store at -20℃ or below for long time storage. Several freeze-thaw cycles should be avoided. Whole blood specimens should be used freshly.

（3）Plasma specimens can be prepared with EDTA, heparin or sodium citrate as anticoagulant.

【Specimen Collection and Storage Requirements】

[Whole Blood]

- Collection by venipuncture

Collect the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture. Venous whole blood specimens can be stored up to 8 hours at 18-24°C or up to 7 days at 2-8°C if not tested at the same day of specimen collection, and should not be frozen.

Whole blood specimens should be brought to room temperature(18-28°C) prior to use. Haemolytic or turbid whole blood specimens should not be used.

- Collection by fingerstick[6]

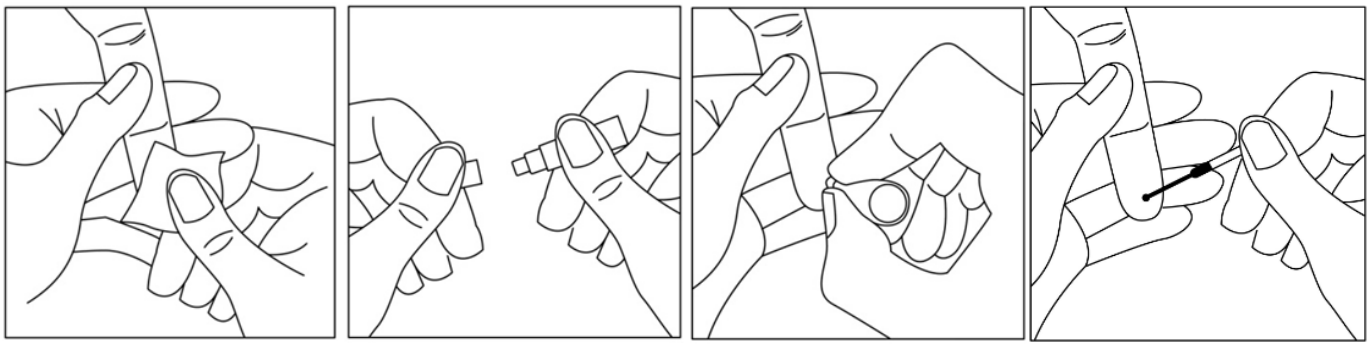


Figure a Figure b Figure c Figure d

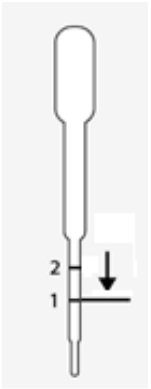


Figure e

1. Choose the ring finger of the patient.
2. Open the alcohol pad and clean the fingertip (Figure a). Allow the fingertip dry.
3. Remove the cap of the safety lancet. (Figure b)
4. Place the lancet on the fingertip, press the lancet against the finger and puncture the skin. (Figure c)
5. Discard the lancet into a bio-hazard waste container immediately.
6. Squeeze the fingertip to form a bulb and use the disposable transfer pipette to collect the drop of the blood. (Figure d)
7. Allow the blood to reach the first graduation and the specimen volume will be 20μL. (Figure e)
   Avoid formation of bubbles during the collection of specimen. Disposable transfer pipette is used for fingerstick only.
8. Transfer the specimen to the sample well immediately after collection. Avoid formation of bubbles.
9. Discard the disposable transfer pipette into a bio-hazard waste container immediately.

[Plasma or Serum]

- Plasma

Draw the whole blood into the collection tube (containing anticoagulants such as heparin, EDTA or sodium citrate) by venipuncture and lightly mix, then centrifuge blood to get plasma supernatant.

- Serum

Draw the whole blood into the collection tube by venipuncture, leave to settle for 2 hours for blood coagulation and then centrifuge blood to get serum supernatant.

Serum and plasma specimens may be stored at 2-8°C for up to 7 days from time of draw, store at -18°C or below for long time storage. Several freeze-thaw cycles should be avoided.

Plasma or serum specimens should be brought to room temperature prior to use.

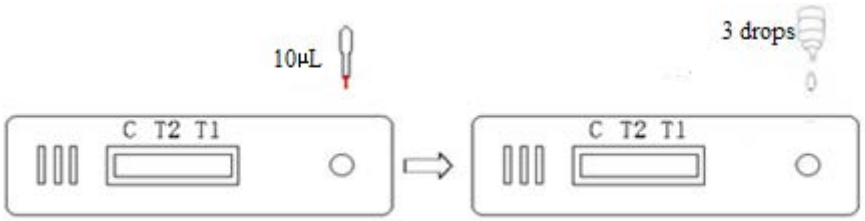
Plasma or serum specimens with visible bio-contamination should not be used.

【Test Procedure】

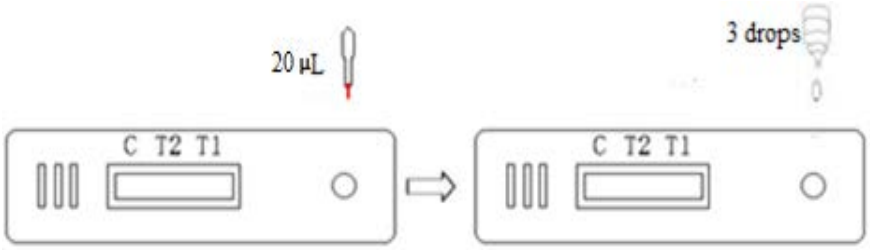
PLEASE USE IN STRICT ACCORDANCE WITH THE INSTRUCTIONS FOR USE.

Equilibrate all specimens and the devices to room temperature before testing.

1. Take out a test cassette from the foil pouch, and place it on a horizontal surface. Test cassette should be used immediately upon opening the pouch.
2. Add 10μL of plasma and serum specimen or 20μL whole blood specimen to the sample area firstly, then slowly add 3 drops of sample diluent (120μL) to the same area.
3. Incubate the cassette and read the result after 15 minutes but not more than 20 minutes.

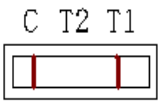
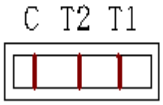
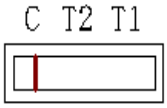
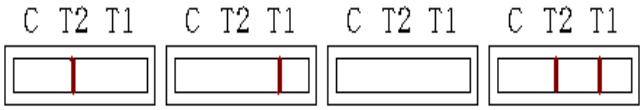


Add 10μL of Plasma and Serum specimen



Add 20μL whole blood specimen

【Interpretation of Results】

Positive	1 IgM Positive/IgG Negative: Visible reddish-purple bands appear both at the control line (C-line) and the test line 1 (T1) of the cassette.	
	2 IgG Positive/IgM Negative: Visible reddish-purple bands appear both at the control line (C-line) and the test line 2 (T2) of the cassette.	
	3. IgM Positive/IgG Positive: Visible reddish-purple bands appear at the control line (C-line), both the test line 1 (T1) and the test line 2 (T2) of the cassette.	
Negative	A reddish-purple band appears only at the control line (C-line) of the cassette	
Invalid Result	Reddish-purple band appears at neither the control line nor the test line of the cassette. Or a reddish-purple band appears only at the test line (T-line) of the cassette	

Interpretation of Results：

1）When the test results show the "negative", but still with associated symptoms, suggestions to further check in time.

2）When the test results show the "positive", suggestion to immediately further diagnoses.

【Limitations of the Procedure】

1. The kit is designed to detect IgM/IgG antibodies against SARS-CoV-2 in human serum, plasma, and whole blood. Specimens other than the specified ones may not supply accurate results.

2. The Diagnostic Kit for SARS-CoV-2 IgM/IgG Antibody (Colloidal Gold) adopts the solid phase colloidal gold immunochromatographic technology for the qualitative determination
3. Please use in strict accordance with the INSTUCTION FOR USE.
4. The test results obtained by other methods and this product have no direct comparison.
5. This product is intended for detection of antibodies against SARS-CoV-2 from individuals to aid in the diagnosis of COVID-19 infection. The assay can be used for clinical reference and should not be the only basis for the diagnosis and treatment. The clinical management of patients should be considered in combination with patients' symptoms and medical history, other laboratory tests, treatment response, epidemiology and other information.
6. Due to the operation and the sample collection, the result may be suspected, at this time repeated testing should be done to ensure consistent results.

【Warning】

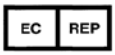
1. This product is only used for in vitro diagnostic, please read this manual in detail before use.
2. Do not use the test cassette if the pouch is damaged or the seal is broken.
3. The kit assay should be considered as infectious. Please follow the infection disease laboratory inspection procedure.
4. Please ensure the accurate quantity of samples for testing, too little/too much sample size may lead to incorrect results.
5. This product is a visual reading, in order to ensure the correct interpretation results, please do not read in the dark place.
6. The kit is suitable for screening in patients with suspected novel coronavirus. The final results should be combined with clinical symptoms by clinical doctors and other laboratory testing index.
7. Negative results with the antibody tests do not preclude SARS-CoV-2 infection and such results must be combined with clinical observations, patient history, and epidemiological information.

【Reference】

1. National health committee "new coronavirus infection pneumonia diagnosis and treatment plan"(fifth edition)
2. World Health Organization: Clinical management of severe acute respiratory infection when Novel coronavirus (nCoV) infection is suspected: Interim Guidance

Key to symbols used

	**Caution**		**Temperature limitation (4-30 °C)**
	**Batch code**		**Date of manufacture**
	**In vitro Diagnostic use Medical device**		**Consult instructions for use**
	**Catalogue number or order number**		**Do not use if package is damaged**
	**Use by**		**Sufficient for "n" use**

	**Do not reuse**		**Biological risks**
	**Manufacturer**		**Authorised representative in the European Community**
	**CE marking**		**Sterilized using Ethylene Oxide**
	**Sterilized using irradiation**		

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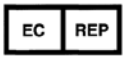

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