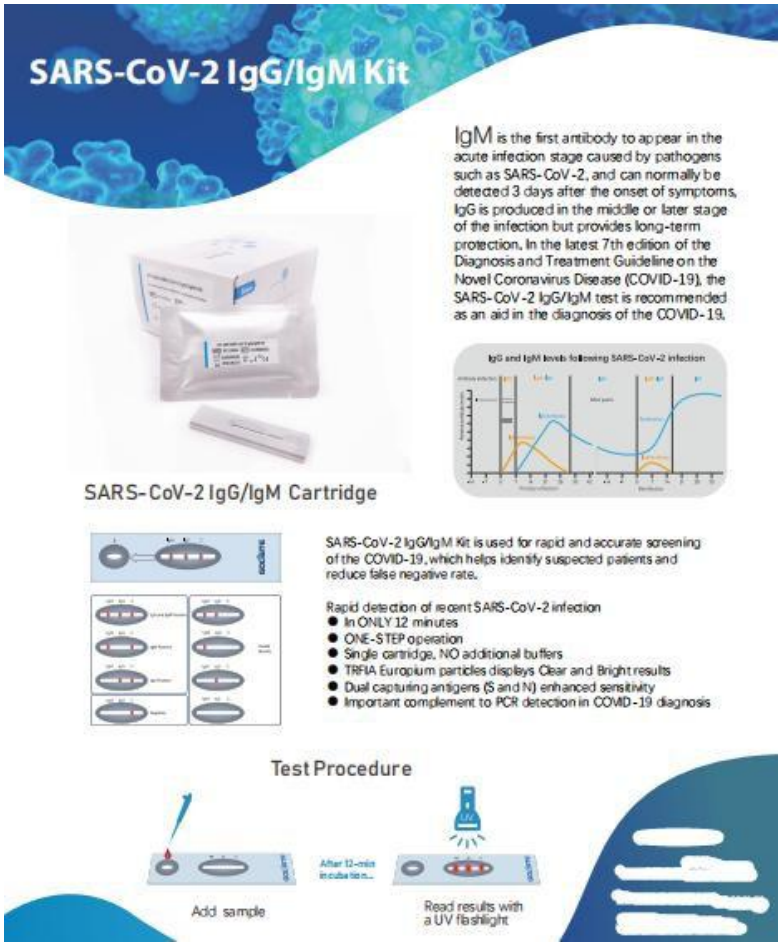
GT-100-SARS-CoV-2IgG/IgM Kit

1.Product pictures

2.Product introduction



After the 12-minute incubation. Illuminate the inspection region with the UV flashlight and read the results.

3.Product specification:

Goldsite Diagnostics Inc.

SARS-CoV-2 IgG/IgM Kit

For determination of SARS-CoV-2 IgG and IgM antibodies

Catalog No.	GT122025

1. Intended Use

This kit is used for qualitative determination of the IgG and IgM antibodies to the novel coronavirus SARS-CoV-2 in human whole blood or serum or plasma as an aid in the diagnosis of coronavirus disease 2019 (COVID-19).

2. Test Principle

Time-resolved fluorescence immunoassay is applied. Briefly, the SARS-CoV-2 IgM and IgG in the sample binds with the fluorescent labeled antigens in the cartridge to form the immunocomplexes. When the complexes migrate to IgM line (coated with mouse anti-human IgM), the complexes that contain the SARS-CoV-2 IgM will be captured. When the complexes migrate to IgG line (coated with mouse anti-human IgG), the complexes that contain the SARS-CoV-2 IgG will be captured. Similarly, the fluorescent labeled chicken IgY antibody will be captured in the C (control) line (coated with goat anti-chicken IgY). These captured complexes will produce fluorescence signal that are proportional to the concentration of each analyte (i.e., SARS-CoV-2 IgM and IgG). Upon excitation by UV light (wavelength = 365 nm), the complexes containing SARS-CoV-2 IgM and IgG will emit lights forming light bands in the IgM and IgG line regions, respectively. Similarly, a light band will also appear in the control line region indicating the correct operation procedure has been taken and the assay is providing reliable results. The presence of the lines at the IgM and IgG line regions indicates whether the sample is positive for the SARS-CoV-2 IgM and/or IgG antibodies, respectively. When the kit is used in conjunction with the GT-100 Time-resolved Fluoroimmunoassay Analyzer, the floresecence signals of the light bands will be read and compared with the preset cut-off values. The sample is considered to be positive for SARS-CoV-2 IgM and/or IgG if the signals are greater than the cut-off values.

3. Reagent Components

3.1 25 reagent cartridges packaged separately with a bag of desiccant.
- Each cartridge is for a single test and consists of the nitrocellulose membrane, absorbent paper, sample pad, coupling pad and PVC board.
- The nitrocellulose membrane is coated with mouse anti-human IgM, mouse anti-human IgG and goat anti-chicken IgY. The coupling pad contains fluorescent labeled SARS-CoV-2 antigen and chicken IgY.

3.2 1 Package insert

3.2 1 ID card (for analyzer mode)

4. Material Required but Not Supplied

4.1 Result reading devices

Use either of the following devices to read the results:
- **A. Analyzer mode**: GT-100 Time-resolved Fluoroimmunoassay Analyzer
- **B. Flashlight mode**: UV flashlight (wavelength = 365 nm)

4.2 Devices for sample collection (pipette)

5. Storage and Stability

Store the cartridges at 2 – 30°C in a dry place and avoid direct sunlight. The unopened packages are stable until the expiry date labeled on the labels. Once opened, they should be used immediately.

6. Sample Collection and Preparation

6.1 Fresh whole blood, serum and plasma samples can be used.

6.2 Avoid test with highly lipemic, turbid and haemolyzed samples.

7. Test Procedure

A. Analyzer mode

7.1 Power on the GT-100.

7.2 Let the sample reach the room temperature.

7.3 Remove the cartridge from its package.

7.4 From the home screen, select **Setting**. Select **Register**. Insert the ID card at the top of the analyzer and click **Register**. After successful registration, the lot number of the assay will be saved. Check in Query Screen to ensure that the registered lot number is correct. Click **Back** to return and select **Sample Test** to enter the Sample Test screen. The instrument door will open automatically.

7.5 Add 30 µL of whole blood sample or 20 µL of serum/plasma sample to the sample well of the cartridge by a pipette.

7.6 Leave the sample-loaded cartridge at room temperature for 12 minutes.

7.7 While waiting, input the sample ID, select the sample type. Insert the cartridge holder into the instrument. After the 12-minute incubation, insert the cartridge into the holder. The instrument door will close.

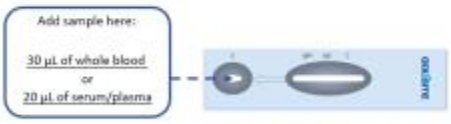
7.8 After the reading is completed, the result will be displayed and printed out. Remove and discard the used cartridge.

B. Flashlight mode

7.1 Let the sample reach the room temperature.

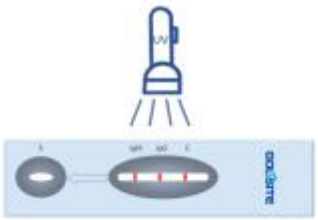
7.2 Remove the cartridge from its package.

7.3 Add 30 µL of whole blood sample or 20 µL of serum/plasma sample to the sample well of the cartridge by a pipette.



7.4 Leave the sample-loaded cartridge at room temperature for 12 minutes.

7.5 After the 12-minute incubation. Illuminate the inspection region with the UV flashlight and read the results.

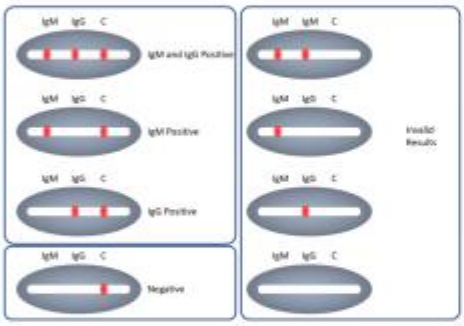


8. Interpretation of Results

A. For analyzer mode:

By comparing with the preset cut-off fluorescence values, the sample result will be displayed as Positive/Negative/Intermediate for SARS-CoV-2 IgM and/or IgG. When an intermediate result is obtained, it is recommended to repeat the test with a new cartridge and examined the result carefully.

B. For flashlight mode:



Note: failure to observe the control line indicate the results are not reliable. When this occurs, check the operation procedure carefully, and test again with a new cartridge.

9. Troubleshooting (for analyzer mode)

9.1 When the fluorescence signal in the control line falls outside the acceptable range, the analyzer displays messages "Invalid Control 1" (the quality control line cannot be found) or "Invalid Control 2" (the quality control signal is lower than the preset value).

9.2 If no chromatographic migration appears in the observation window after 6 minutes of incubation. Discard the cartridge and test again.

9.3 When an expired cartridge is used, the analyzer terminates the test and displays "Expired cartridge".

10. Limitations

10.1 Diagnosis and treatment of SARS-CoV-2 infection should not depend on determination of SARS-CoV-2 IgG/IgM alone. The clinical symptoms, medical history and other laboratory findings of patients should always be taken into consideration.

10.2 With the application of mouse McAb in immunoimaging and immunotherapy, human anti-mouse antibody (HAMA) was produced in patients. The HAMA effect makes the immune analysis easy to produce false positive. The kit has taken measures to eliminate these disturbances as far as possible. The effect of 5% HAMA serum on the test results is within ±15%.

10.3 Interference: hemolysis, jaundice, lipid blood and rheumatoid factors may interfere with the test results. Hemoglobin up to 5 g/L, bilirubin up to 0.1 g/L, triglyceride up to10 g/L, rheumatoid factor up to 150 IU/mL do not interfere the SARS-CoV-2 IgG/IgM assayed.

10.4 Dilution of the sample for testing is not recommended.

11. Performance

11.1 Positive agreement rate: the kit shows a 5/5 agreement with the factory positive reference material.

11.2 Negative agreement rate: the kit shows a 20/20 agreement with the factory negative reference material.

11.3 Repeatability: Two positive reference materials are tested for ten times each. All results should be positive.

12. Caution and Warning

12.1 This reagent is used only for scientific research and should be used in strict accordance with the instructions.

12.2 If the package has been damaged, the label cannot be seen clearly or if the cartridge has expired, do not use the cartridge.

12.3 The test cartridge is for single test and cannot be reused.

12.4 Do not eat the desiccant.

12.5 The reagents can be used only by trained personnel with good laboratory practice and the stated procedure should be followed strictly. The samples, used reagents and consumables are medical waste which are potentially hazardous and should be disposed of in accordance with national and local regulations.

13. Symbols

	Use-by date	REF	Catalogue number
	Date of manufacture		Temperature limit 2 - 30℃
LOT	Lot number		Avoid sunshine

Goldsite Diagnostics Inc.

Goldsite Diagnostics Inc.

Address of Manufacturer
No. 103C, 503C & 504D, Technology Building &
No. 3A & 4A, Technology Building Annex,
Zhaoshang Sub-District, Nanshan District,
Shenzhen, China, 518067
Manufacturing Site
No. 103C Technology Building &
No. 3A & 4A, Technology Building Annex,
Zhaoshang Sub-District, Nanshan District,
Shenzhen, China, 518067
Tel: 86 755 26890807
Fax: 86 755 26890799

EC REP

CMC MEDICAL DEVICES & DRUGS, S.L.
C/ Horacio Lengo No 18, CP 29006, Málaga-Spain

CE

4.Product packing information

25 reagent cartridges packaged separately with a bag of desiccant.

44BoxsX25pcs **1100 small boxes per carton**

CTN:50X40X29cm --- Air freight weight:11.6KG ,

Shipping weight :9.7KG

80BoxsX25pcs **2000 small boxes per carton**

CTN:59X42X19.6cm --- Air freight weight: 19.6KG ,

Shipping weight :16.3KG