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REF **CPA73531**
CPA73530
CPA73532
CPA73534

SARS-CoV-2 IgG Antibody Detection Kit based on Chemiluminescence Immunoassay Platform

For In Vitro Diagnostic Use

Instruction For Use

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Version: V2.0 English
Effective Date:2021-04

Product Name

SARS-CoV-2 IgG Antibody Detection Kit based on Chemiluminescence Immunoassay Platform.

Package Specification

Specification 1 (CPA73531): 50 tests / kit

Specification 2 (CPA73530): 100 tests / kit

Specification 3 (CPA73532): 50 tests / kit (including calibrator and quality control)

Specification 4 (CPA73534): 100 tests / kit (including calibrator and quality control)

Intended Use

This kit is used for *in vitro* semi-quantitative detection of anti-SARS-CoV-2 IgG antibodies in human serum, and it is used for the auxiliary diagnosis of clinical COVID-2019 infection.

SARS-CoV-2 is a novel coronavirus strain found in humans in 2019. This coronavirus strain belongs to the β-type coronavirus coated within a capsule with diameters varying from 60 to 140mm. These coronavirus particles are polymorphic, often round or oval when observed under microscopes. The genetic characteristics of SARS-CoV-2 are significantly different from SARS-CoV and MERS-CoV. The current epidemiological study of SARS-CoV-2 shows that the incubation period of this virus varies from 1 to 14 days, and most patients manifest clinical symptoms in about 3 to 7 days. The major clinical manifestations include fever, fatigue, and dry cough. A few patients have symptoms such as nasal congestion, runny nose, sore throat, and diarrhea. Some critically ill patients may develop dyspnea and/or hypoxemia one week after the onset of the disease, and subsequently, these mild manifestations may evolve into severe conditions, such as acute respiratory distress syndrome, septic shock, metabolic acidosis, and coagulation dysfunction. This coronavirus has evident human-to-human transmission characteristic. The most common transmission route of SARS-CoV-2 is through respiratory droplets, and this route is infectious even when the affected patient is in his incubation period. Novel coronavirus nucleic acids can be detected in nasopharyngeal swabs, sputum, lower respiratory tract secretions, blood, and faeces. However, there are certain inevitable factors may deteriorate the nucleic acid detection accuracy, including a) sampling methods, b) various infection states among affected patients, and c) insufficient sensitivity of specific nucleic acid detection reagents.

The detection of the SARS-CoV-2 antibody in the serum can serve as a complementary method to the nucleic acid detection in terms of improving the accuracy of the coronavirus detection. It is applicable to use specific IgG and IgM antibodies of the novel coronavirus (SARS-CoV-2) in the serum to determine the status of infection of a patient. A solely IgM positive state implies that this patient was infected the coronavirus recently or he/she got a secondary active infection, whereas an exclusively IgG positive state implies that this patient infected the coronavirus previously. The double-positive testing result of both IgG and IgM shows that this patient has developed a repeated or recurrent infection.

Test Principle

This kit employs an indirect method for semi-quantitative detection of anti-SARS-CoV-2 IgG antibodies in human serum. Firstly, the sample was mixed and incubated with SARS-CoV-2 antigen-coated magnetic microspheres. The SARS-CoV-2 antibodies present in the sample can be combined with the captured antigen on the microspheres to form an antigen-antibody immunocomplex; after washing, we can subsequently add acridine-labelled anti-human IgG antibody to form a (magnetic microsphere-coupling antigen) specific acridyl ester-labelled anti-human IgG antibody complex; After a second washing step, the pre-trigger solution and the trigger solution were added to that sandwich complex, and the intensity of the chemiluminescence reaction was measured. By comparing the chemiluminescence signal in the reaction with the cut-off signal obtained from the initial project calibration, we can determine whether the sample has the anti-SARS-CoV-2 IgG antibody.

Materials Provided

Name	Specification 1	Specification 2	Specification 3	Specification 4
Solid phase reagent	1 bottle, 3.5 mL / bottle	1 bottle, 6.0 mL / bottle	1 bottle, 3.5 mL / bottle	1 bottle, 6.0 mL / bottle
Luminescent reagent	1 bottle, 3.5 mL / bottle	1 bottle, 6.0 mL / bottle	1 bottle, 3.5 mL / bottle	1bottle，6.0 mL/bottle
Sample dilution buffer	1 bottle, 12 mL / bottle	1 bottle, 22 mL / bottle	1 bottle, 12 mL / bottle	1 bottle, 22 mL / bottle
Calibrator	/	/	1 tube, 80 μL / tube	1 tube, 80 μL / tube
Negative / positive controls	/	/	1 tube each, 80 μL / tube	1 tube each, 80 μL / tube

Name	Main Components
Solid phase reagent	Magnetic microspheres coated with SARS-CoV-2 antigen
Luminescent reagent	Acridine ester-labelled anti-human IgG antibody
Sample dilution buffer	Phosphate buffer
Calibrator	Negative matrix serum, recombinant antibody
Positive control	Negative matrix serum, recombinant antibody
Negative control	Negative matrix serum

Remarks:

1. Reagent components in different batches cannot be interchanged.
2. Reagents needed but not provided:

   Pre-trigger solution: contains 1.32% (w / v) hydrogen peroxide;

   Trigger solution: contains 0.35N sodium hydroxide;

   Washing buffer: contains phosphate buffer, preservative.

Storage and Stability

- Validity period: Stored at 2 ~ 8 ℃ from light for 12 months.
- Opening stability: Store at 2 ~ 8 ℃ after opening and use within 7 days.
- On-board stability: If the detection system is covered with a soft cover or a replacement cover, then it can be stored for up to 14 days.
- Transportation stability: It is verified that all indicators of the kit meet the product technical requirements within 4 days under the simulated transportation according to factory requirements.
- See product label for production date and usage period.

Applicable Instruments

- Automatic Chemiluminescence Analyzer SMART 6500
- Automatic Chemiluminescence Immunoassay Analyzer TESMI i100

Specimen Requirements

- The test sample type of this kit is serum.
- Collect no less than 1 mL of venous blood, store it in non-anticoagulation collection tubes (including serum separation tubes), and take serum for testing. Avoid severely hemolyzed, obvious microbial contaminated samples.
- Serum samples should be stored at 2~8℃ after collection and processing, and should not be stored for more than 7 days. If you would like to save the serum sample for a long time, place it under -18℃, and the maximum number of freeze-thaw is 5 times.

Testing Procedure

1. Reagent processing

Invert the solid-phase conjugate suspension reagent bottle and observe whether the magnetic microspheres are resuspended. If the magnetic microspheres are still attached to the reagent bottle, continue to flip them to fully suspend.

2. Detection

For setting test samples, calibrators, quality controls, and general operating instructions, referencing with the operating instructions for the applicable instrument.

3. Calibration

It is recommended to recalibrate under the following conditions: a) use a new batch of kits; b) quality control values are out of range; c) use a new batch of the stimulating solution, d) pre-trigger solution.

The calibrator required to perform dilutions from sample diluent in a ratio of 1:20. For instance, pipette 25 μL calibrator in 500 μL sample diluent.

4. Quality control

The quality control required to perform dilutions from sample diluent in a ratio of 1:20. For instance, pipette 25 μL positive/ negative control in 500 μL sample diluent.

The recommended quality control frequency is about 24 hours/testing period. Meanwhile, quality control is also preferred to be performed after using a new batch of kits or calibration. Each laboratory can set their preferred quality control requirements according to their own circumstances.

Positive Value Criteria

- The mean cut-off (CO) value of the reagent is calculated and stored in the system in terms of the mean reaction chemiluminescence signals (RLUs) when performing the two repeated tests for the calibrator.
- The SARS-CoV-2 IgG antibody detection system uses the following formula to calculate the project cut-off (CO) value:

  Cut-off value (CO) = Mean RLUs of the calibrator × Calibration coefficient in the bar code

  S/CO = signal value (RLUs) / Cut-off value of the test sample

  The new cut-off value will be stored in the system after each calibration.

Interpretation of Results

- If the sample S/CO value < 1.00, the test result of the SARS-CoV-2 IgG antibody is considered to be non-reactive (negative).
- If the sample S / CO value ≥1.00, the test result of SARS-CoV-2 IgG antibody can be considered as reactive (positive).
- Factors that may affect the test results and conditions that need to pay attention: a) Negative results generally indicate that the patient has

not been infected with the SARS-CoV-2, but early infection cannot be ruled out. b) The test results of SARS-CoV-2 IgM antibody and the SARS-CoV-2 nucleic acids detection should be combined altogether to make a clinical judgment.

Limitations

1. There are certain limitations for the detection sensitivity in accordance with the serological testing methodology. The testing results of this product are for clinical reference only and should not be used as the sole supporting evidence for making clinical diagnosis and treatment. A comprehensive consideration for the clinical management of patients should combine patient's clinical symptoms/signs, medical history, epidemiology and other laboratory tests.
2. Patients who have been treated with mouse monoclonal antibodies therapy may develop anti-mouse antibodies in their serum which will further influence the serum testing results. So, it is important to consider the patient's medical records and other information to make an appropriate diagnosis.

Performance Characteristics

1. Limit of Detection (LoD)

Tested with a standardized minimum detection limit reference, all results should be positive.

2. Precision

Tested with standardized precision reference products, results should all be positive, and the coefficient of variation CV≤10% (n = 10).

3. Cross-reactivity

The cross-reactivity study compared sample serum of which infected virus such as pneumoniae, influenza, syncytial virus, etc. with the sample serum infected with SARS-CoV-2, and all the test results show that there is no cross-reaction.

4. Negative Reference Compliance Rate

Tested with a standardized negative reference, the results should be negative.

5. Positive Reference Compliance Rate

Tested with a standardized positive reference, the results should be positive.

6. Calibrators and Quality Controls

The calibrator and quality control in the kit can be stored in the environment at 2~8℃ until the expiration date; store at 2 ~ 8℃ after initial opening for 7 days. The deviation between the measured and target value of calibrator accuracy should be within the range of ± 10.0%, and the within-run variation (CV) should not be greater than 15.0%. Positive QC test should show positive results, while negative QC test should show negative results, and the between-run variation (CV) should be no greater than 15.0%.

7. Interference

Common factors which interfere the serological testing results are hyper triglycerides, hyperbilirubinemia, and hemolysis of the sample (elevated haemoglobin). The serum samples were added with high concentrations of the above-mentioned interferences (bilirubin 12mg/dL, haemoglobin 1500mg/dL, triglyceride 3000mg/ dL) and then tested by the kit, the results showed there was no significant interference.

Notes

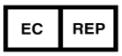
1. This kit is utilized only for *in vitro* diagnosis.
2. The calibrators and negative-positive quality controls in the kit contain human-derived components. Although they have passed the tests of HBs-Ag, HIV1/2-Ab, HCV-Ab, etc., but so far, there is no single test could ensure absolute safety, so these components should still be treated as potential sources of infection.
3. Please avoid direct contact with liquid components of the product.
4. Before using the reagent, please confirm the reagent is in their validity period. While utilizing the reagent, do not mix reagent components from different batches.
5. Prevent reagent evaporation and contamination and ensure the integrity of reagents.
6. Waste may include biohazards or viral vectors and is recommended to be disposed as a potential carrier and transmitter of disease in accordance with local regulators.

References

[1] Novel Coronary Virus Pneumonia Diagnosis and Treatment Plan (Trial Version 6). National Health Office Medical Letter [2020] No. 145

Explanation of Symbols

No.	Symbols	Explanation of Symbols
1		Manufacturer
2		*In Vitro* Diagnostic Medical Device

3		Use By
4		Batch Code
5		Reference Number
6		Date of Manufacture
7		Temperature Limitation
8		Sufficient for
9		Consult Instructions for Use
10		Authorized Representative in the European Community
11		CE Mark
12		Biological Risks