# Evaluation of the Performance Characteristics for SARS-CoV-2 S-RBD IgG Antibody Rapid Test Cassette (Finger Stick Whole Blood) by Comparing CLIA Test

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**ABSTRACT**

**Background:** SARS-CoV-2, a branch of coronavirus, is a positive-strand RNA virus with four major proteins and several auxiliary proteins wrapped with genetic material. It mediates the invasion of the virus mainly through the binding of the S protein to host cell receptors and determines the organization of virus and host tropism. Human coronaviruses are one of the fastest-developing viruses due to their high genomic nucleotide substitution rate and recombination ability. Human coronaviruses are associated with a variety of respiratory diseases of varying severity, such as colds, pneumonia, and bronchitis. On January 30 2020, the World Health Organization (WHO) declared that the COVID-19 outbreak caused by SARS-CoV2 constituted a public health emergency of international concern (PHEIC) and characterized as a pandemic on March 11 2020.

In an effort to expedite the availability of in vitro diagnostics (IVDs) needed in public health emergencies, the WHO has opened the development of an emergency use checklist process, which aims to assist procurement agencies and Member States in deciding whether a specific IVD is suitable for use based on a minimum set of available quality, safety and performance data. IVDs with guaranteed quality, safety and performance are a key component of the overall strategy to control the pandemic.

**Objective:** The main purpose of this evaluation report is to investigate the sensitivity of the SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) for diagnosis during COVID-19.

**Method:** The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is a rapid chromatographic immunoassay intended for the qualitative detection of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human fingerstick whole blood approximately 10 days after vaccination.

**Result:** Through the clinical evaluation of vaccinated, unvaccinated, and virus-uninfected populations, the results show that the overall relative sensitivity of SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is 97.7%, the relative specificity is 99.0%, and the relative accuracy is 98.5%.

**Conclusion:** CITEST SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Fingerstick Whole Blood) is a rapid test that is a qualitative membrane-based immunoassay intended to detect IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in fingerstick whole blood. The product is simple to operate and has been validated against an industry leading commercial CLIA test to give results within 10 minutes of the sample being tested. A comparison of 1257 samples showed an accuracy of 98.5% and an excellent sensitivity of 97.7%. People can use the test kits to get accurate results and determine if they have antibodies in their bodies after they have been vaccinated.

**Keywords:** In vitro diagnostics; IVD; SARS-CoV-2 S-RBD; Sensitivity; Antibody

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## INTRODUCTION

**About SARS-CoV-2:** Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus. Coronaviruses infect many species of animals including humans, causing acute and chronic diseases [1]. COVID-19 is an acute respiratory infectious disease. Currently, patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, but mostly between 3 to 7 days.

Most people infected with COVID-19 will experience mild to moderate respiratory illnesses and recover without requiring special treatment. However, some will become seriously ill and require medical attention. Elderly people and those with underlying medical conditions like cardiovascular disease, diabetes, chronic respiratory disease, or cancer are more likely to develop serious illness.

**The devastating harm caused by SARS-CoV-2 to the human body:** Lymphocytopenia is a common feature of patients infected with SARS-CoV-2, but the mechanism of this depletion is unclear. Studies have shown that SARS-CoV-2 can directly infect secondary lymphoid organs to induce cell death. Immunohistochemistry showed that ACE2, the receptor of SARS-CoV-2, was expressed on CD169+ macrophages in spleen and lymph nodes. Immunofluorescence confirmed that SARS-CoV-2 infection caused severe tissue damage, including lymph follicular depletion, splenic nodule atrophy, histiocytosis and lymphocytopenia. Viral infection leads to severe lymphocyte apoptosis, which triggers macrophages to produce IL-6, a proinflammatory factor that directly promotes lymphocyte necrosis. Thus, SARS-CoV-2 can be said to directly affect the human spleen and lymph by infecting tissues [2].

**Prevention and Diagnosis for SARS-CoV-2 Control:** Vaccines are still an effective means of preventing the SARS-CoV-2 virus. At present, the global epidemic is still in the pandemic stage, and the new crown pneumonia epidemic has the characteristics of multiple points, wide areas, and frequent outbreaks. Building a solid immune barrier is the fundamental strategy to defeat the epidemic.

For the new coronavirus variant(Omicron, Delta, Alpha and so on), relevant scientific studies and epidemic prevention and control practices at home and abroad have shown that the existing vaccine can reduce the risk of virus transmission in the population, reduce the transmission power of infected people, and effectively reduce the incidence of severe illness and death after infection. The WHO issued a statement to maintain the momentum of increasing access to COVID-19 vaccines, and continue to support countries in providing vaccines, and increase people's awareness to vaccination at this stage.

In addition, WHO has encouraged countries to expand vaccination coverage from high-risk, priority groups to the general population, from people over 60 years of age to children aged 3 to 11 years, as an important part of mass immunization efforts? With the global pandemic and ongoing spread of New Coronary Pneumonia, infection rates are rising and vulnerable groups such as children and the elderly also need protection through vaccination, which can reduce or even stop the disease epidemic by creating an immune barrier.

## DIAGNOSTIC METHODS

Diagnosis of COVID-19 has been difficult because laboratory tests and radiographic imaging are not always consistent with a patient's clinical features and exposure history. The current routine detection includes four methods: RT-PCR, genome sequencing, ELISA, and immune colloidal gold technique. Imaging can also be used for diagnosis in the clinic, but the method for early detection and assessment of the severity of the disease needs to rely on the experience of the observer. This is because the manifestations of the new coronary pneumonia are diverse and volatile [3].

**Real-time RT-PCR Method:** Real-time RT-PCR is one of the most widely used laboratory methods for the detection of new coronaviruses.
Real-time RT-PCR is a nuclear-derived method for detecting the presence of specific genetic material in any pathogen (including viruses). Initially, the method used radioisotope markers to detect the target genetic material, but subsequent improvements have led to the replacement of isotope markers with special markers, most commonly fluorescent dyes. This technique allows scientists to see results almost immediately while the process is underway, whereas traditional RT-PCR only provides results at the end of the process [4].

**ELISA Method:** The basis of enzyme-linked immunoassay (ELISA) is the immobilization of antigen or antibody and the enzymatic labeling of antigen or antibody. The antigen or antibody bound to the surface of the solid phase carrier still retains its immunological activity, and the enzyme-labeled antigen or antibody retains both its immunological activity and enzymatic activity. During the measurement, the sample to be tested reacts with the antigen or antibody on the surface of the solid phase carrier. The antigen-antibody complex formed on the solid phase carrier is separated from other substances in the liquid by washing. Then the enzyme-labeled antigen or antibody is added, and it is also bound to the solid phase carrier through the reaction. At this point, the amount of enzyme on the solid phase is proportional to the amount of the tested substance in the sample.

After adding the substrate of the enzyme reaction, the substrate is catalyzed by the enzyme into a colored product, and the amount of the product is directly related to the amount of the tested substance in the sample, so qualitative or quantitative analysis can be carried out according to the color depth.

Due to the high catalytic efficiency of the enzyme, the results of the immune reaction are indirectly amplified, and the assay method achieves high sensitivity.

**Immune Colloidal Gold Technique:** Immune colloidal gold technique is a new type of immunolabeling technique that uses colloidal gold as a tracer marker to apply to antigen and antibody. The colloidal gold chromatography antigen-antibody reacts on the cellulose membrane, so that the colloidal gold-labeled antibody aggregates on the detection line and the quality control line, thereby forming a red band that can be observed with the naked eye.

## EVALUATION OF CITEST SARS-COV-2 S-RBD IGG ANTIBODY RAPID TEST (FINGER STICK WHOLE BLOOD)

**Materials and Directions for Using:** Materials provided included a test cassette, buffer, droppers, sterile lancets, alcohol pads, a biosafety bag and a package insert.

The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Finger stick Whole Blood) is a qualitative membrane-based immunoassay intended to detect IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in finger stick whole blood.

The test sample used in this test is finger stick whole blood, and the bag is brought to room temperature (15-30°C) before opening. Remove the test cassette from the sealed bag and use it within one hour.

**For Finger stick Whole Blood:** Use an alcohol pad to clean the fingertip of the middle finger or ring finger as the puncture site and allow the wiped site to dry for 10 seconds. Carefully rotate and remove the lancet cap for testing and press the sterile lancet firmly against the tip of the middle or ring finger. To increase blood flow, use the thumb and forefinger to gently apply pressure around the puncture site. Without squeezing the dropper, put it in contact with the blood. Draw the blood to the line indicated on the dropper. Put the end of the dropper in contact with the center of the specimen well (S) and release all the blood immediately after collection, then add 2 drops of buffer to the sample (S) and start the timer. Do not move the test during test development.

**Performance Characteristics**: A clinical evaluation was conducted from vaccinated, unvaccinated and uninfected people, comparing the results obtained using the SARS-CoV-2 S-RBD IgG Antibody Rapid Test with SARS-CoV-2 Antibody CLIA test results (Table 1).

The clinical trial included 1257 specimens. The results demonstrated 99.0% specificity and 97.7% sensitivity with an overall accuracy of 98.5%.

| | CLIA confirmed sample number | Correct Identified | Rate | 95% CI (Confidence interval) |
|---|---|---|---|---|
| **Positive Sample** | 553 | 521 | 97.7% (Sensitivity) | 96.1% - 98.8% |
| **Negative sample** | 724 | 717 | 99.0% (Specificity) | 98.0% - 99.6% |
| **Total** | **1257** | **1238** | **98.5% (Total Accuracy)** | **97.7% - 99.1%** |

**Table 1:** Performance Characteristics of SARS-CoV-2 S-RBD IgG Antibody Rapid Test.

## SUMMARY

The SARS-CoV-2 S-RBD IgG Antibody Rapid Test (Finger stick Whole Blood) is used for the qualitative detection of IgG antibodies to SARS-CoV-2 spike (S) protein receptor binding domain (RBD) in human finger stick whole blood approximately 10 days after vaccination. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2. Results are for the detection of SARS-CoV-2 S-RBD IgG antibodies.

In the clinical evaluation of 1257 vaccinated, unvaccinated and uninfected people, compared with the SARS-CoV-2 antibody CLIA test results, the accuracy of the SARS-CoV-2 S-RBD IgG Antibody Rapid Test Cassette (Finger stick Whole Blood) developed by CITEST Diagnostics Inc reached 98.5%. This test kit can therefore be used to obtain accurate results and determine whether antibodies are present in the body after vaccination.

Although vaccination is safe and effective, the success rate of vaccination is not 100%, with a small number of vaccinated people becoming infected during the epidemic. On the other hand, in the absence of an immune barrier, the new coronavirus still spreads easily which require communities to continue to take personal protective measures.

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