The Anti-SARS-CoV-2 Rapid Test Kit

FAQ

What does Anti-SARS-CoV-2 Mean?
It is the name for antibodies against the virus that causes Covid-19 infections.

- **Anti** – antibody test
- **SARS** – Sudden Acute Respiratory Syndrome
- **CoV** – Corona Virus
- **2** – second outbreak strain of its kind

What is COVID-19?
It is the name of the disease that the virus causes.

- **CO** – Corona
- **VI** – Virus
- **D** – Disease
- **19** – first identified in 2019

Is this kit EUA Approved?
Yes, authorization was granted by the FDA on April 24, 2020.

What is the Emergency Use Authorization (EUA) Program?
The EUA is an expedited clearance process in order to release medical devices while they are being reviewed by the FDA.

Does the kit have any other certifications?
Yes, the kit is CE-IVD Marked. The kit is widely used in China and Europe. It is manufactured by Autobio, the largest and most well-known microbiology supplier in China.

Are external controls or standards available?
Not at this time. Autobio plans on releasing external controls in the near future. External controls can be prepared by the user with known positive and negative plasma or serum patient specimens. Internal controls are built into the test cassette.
What are the best applications of this test?
There are several:

1. The test has a valuable epidemiological capability; it gives an indication of who currently has the disease and who had the disease previously and has recovered.

2. The test can be used for rapid screening of carriers of the virus that are symptomatic or asymptomatic. Recent studies suggest that a high percentage (up to 80%) of patients show no or little clinical symptoms of the virus, therefore screening patients is vitally important. The test is ideally suited for hospitals, reference labs, and public health labs.

3. The Anti-SARS-CoV-2 Rapid Test can be used to screen patients suspected of having been infected by the novel coronavirus. However, results of this test should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods such as a nucleic acid rt-PCR test, which detects RNA in the virus.

4. Serological assays are of critical importance to determine sero-prevalence in a given population, to define previous exposure. Sensitive and specific identification of coronavirus (SARS-Cov-2) antibody titers will also support the screening of healthcare workers in order to identify those who are already immune and can be deployed to care for infected patients, thereby minimizing the risk of viral spread to colleagues and other patients.

5. It is important to know that IgM antibodies are formed initially by the patient at about the time that symptoms first appear (after the 2 to 14 day incubation period). The IgM antibodies will dissipate after about one month. IgG antibodies are second to appear in the body, about one week after symptoms appear. They will continue to be present in the blood stream for prolonged periods of time. When the kit shows a positive for IgM antibodies, it is indicative of an active infection. A positive for IgG antibodies indicates that the patient either has an active case or has previously been infected with the SARS-CoV-2 virus and has recovered. If the patient has symptoms and the antibody kit is negative, then an additional molecular test for the viral RNA should be considered.

Is this test confirmatory for COVID-19 disease?
The kit is designed to determine whether the patient is producing IgM and/or IgG antibodies to the SARS-CoV-2 virus. The test can be used for rapid screening of carriers of the virus that are symptomatic or asymptomatic. A diagnosis is made by combining clinical symptoms, the patient history, epidemiological studies, and laboratory testing. The Anti-SARS-CoV-2 Rapid Test should not be the sole source of information when making a diagnosis.
What is the typical immune response for IgM and IgG, when someone becomes infected by SARS-CoV-2?
The chart below shows a likely response over time for antibody production. However, it is not known at this time how long the IgG antibodies will be prevalent in the bloodstream; nor is it known how effective those antibodies would be in preventing a re-infection.

![Antibody Levels Chart](chart.png)

What is the Sensitivity and Specificity?

**Sensitivity at ≥15 days after onset of symptoms.**
Note: Sensitivity decreases as the patient is tested closer to the first day that symptoms appear.
- IgM - 95.7%
- IgG - 99.0%

**Specificity**
- IgM - 99%
- IgG - 99%

These tests have been performed in China and were compared to RT-PCR molecular tests.

What are the acceptable specimen types?
Serum or plasma from anti-coagulated blood samples. Whole blood is not approved at this time.

How long does it take to get test results?
The run time on the test is 15 minutes after the specimen is applied to the cassette. The results cannot be read out after 20 minutes.

What is the kits shelf life?
Six months from the date of manufacture.
Can the test be performed in a doctor’s office?
This kit has been deemed not to be used for Point of Care. It is only to be used by CLIA licensed clinical labs. Even though the test is simple to perform, it is considered “Moderate Complexity” by the FDA, and thus needs to be performed in a licensed laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests.

What is the CPT Code for this test?
CPT 86328 – Immunoassay for infectious agent antibody(ies), qualitative or semiquantitative, single step method (e.g., reagent strip); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]).

Additional CPT Code resources can be found here:
1. AMA announces expedited updates to CPT for COVID-19 antibody tests
2. COVID-19 coding and guidance

In addition to the long descriptors, short and medium descriptors can be accessed on the AMA website.

IMPORTANT - this information is for reference only and is not a recommendation or endorsement of use in any way. Hardy Diagnostics is not responsible for determining the appropriate CPT when processing patient test reimbursements.