

Information on Antibody Test for Novel Coronavirus “COVID-19”

I. About the PCR/Antibody Tests

The PCR Test for COVID-19, which directly observe the presence of novel coronavirus in the body, is currently the gold standard for diagnosis.

The Antibody Test for COVID-19, on the other hand, detects the presence of substances (antibodies) produced by the body's immune system against COVID-19.

Although the advantage of this antibody test is that it can be performed quickly (about 15 minutes), the test has not been well established for the novel coronavirus due to insufficient data accumulation and its validity has not yet been established. Thus, the meaning and significance of the antibody test for COVID-19 is still insufficient and the results are not absolute. It is important to consider the degree of accuracy and limitations of the antibody test when looking at their test results.

However, the antibody test for COVID-19 has already been used overseas (in the United States and China) for the purpose of investigating the extent to which antibodies are found in the general population. The antibodies also gradually decay within about a month. Continued preventive measures are necessary.

Currently, this test cannot be used for the definitive diagnosis of COVID-19 in Japan and is not covered by the Japanese National Health Insurance system.

The Antibody Test for COVID-19 is available and scheduled for:

- Those who have been healthy and had no flu like signs and/or symptoms but want to know if infected by COVID-19 in the past.
- Those who recently (with in the few months) have had flu like symptoms, disorder with taste and/or smell but recovered want to know if infected by COVID-19 before.
- Those who want to test for if infected or established immunity for COVID-19 before going out to the public.

II. About the Antibody Test Kits Used at Our Clinic

The Antibody test kit for COVID-19 used at Tokyo Clinic ICVS Incorporated is the 2019-nCoV IgM/IgG antibody test kit (gold colloid method).

Manufactured by: Shandong ThinkLab Biotechnology Co., Ltd
Imported by: Takesho Corporation

This test kit is CE certified by the European Union, certified by the Chinese Ministry of Commerce as an overseas standard, and registered on the list of medical supply enterprises.

It has been applied for the Emergency Use Authority (EUA) by the U.S. FDA and is already available in Europe, the US and other countries around the world. The product has been available in Japan since May 21, 2020. The results of clinical trials can be determined as positive/negative with 96.53% accuracy.

When humans are first infected with the novel coronavirus, the immune system defends against the virus and produces specific antibodies; IgM antibodies are usually produced after 3 to 7 days and rise a few days later with the appearance of IgG antibodies; the duration of IgM antibodies is relatively short and is mainly seen during the acute infection phase, but IgG antibodies generally suggest a previous infection, and if the rise in IgG antibody titers is progressive, it is likely to be a recent infection. This kit is a combined IgM + IgG test to detect early, mid and late stage infections.

1. Use only 10 μ L of blood samples (serum, plasma, or peripheral blood is acceptable).
2. Take less than 15 minutes for the entire testing process, and the results can be obtained in a short time.
3. Measure and determine both IgM and IgG whether they are negative, by early or late infection.

※ The results have high coding rate with the results of PCR test in many medical institutions.

III. Testing Procedures

1. Place a drop of blood sample to the testing plate, then add the diluent reagent.
2. Leave the tested sample on the plate for 10 minutes, and then visually evaluate the result.

IV. Test Results

The test results and the statement (interpretation) of the test results will be provided in documents at the clinic.

V. Summary (from Application to Delivery of Results)

In order to shorten the time and reducing the total number of visitors in the clinic to less the possible infection, the testing applicants are recommended to: 1) contact the clinic and make a reservation for pre-creating medical records; 2) visit the clinic for testing and its results.

Providing personal information:

- 1) Family Name and Given Name in English spelling (also with pronunciation if the name is in Chinese characters),

- 2) Gender,
- 3) Date of Birth with Age
- 4) Address and Contact Phone Number.

Scheduling:

Desired date and time of the testing. Please provide the second and third preferred date and time in case the first preferred date and time are not available. The testing are available from Monday to Friday, from 9:30 AM to 4:30 PM.

Conditions for Visit:

The tests will not be available for those who with the following conditions for the in house-infection prevention: fever at 37.5°C or more in the past 2 weeks, cough, shortness of breath, sore throat, or strong lethargy, or having been returned from overseas within 14 days.

If a fever, cough, or poor health on the day of the testing scheduled, please re-schedule the appointment as such applicants are not allowed to visit the clinic for the infection prevention.

All the visitors are mandated to wear masks in the clinic at all time for the infection prevention purpose. For those who do not have the mask, masks are available for purchase at the clinic.

Process Summary:

1. Please complete the testing application via email (clinic@icv-s.org) or fax (03-3222-0566).
2. Visit the clinic: the applicant's temperature will be checked at the reception counter for the admittance clearance to the clinic.
3. Make the payment after the clearance (no fever):
 - For the applicants who has never been examined at ICVS Tokyo Clinic before: **JPY 8,000.**
 - For the repeated applicants and the applicants who have examined at ICVS Tokyo Clinic before: **JPY 6,000.**
4. The testing room is next to the reception.
5. Leave the clinic (should be 20 min after the admittance) with the test results.