



SARS-CoV-2 (COVID-19) Detection Methods

SARS-CoV-2 Nucleic Acid Detection

COVID-19 IgG/IgM Rapid Test

COVID-19 Antigen Rapid Test

SARS-CoV-2 (COVID-19) Detection

COVID-19 is an acute respiratory infectious disease caused by novel coronavirus (SARS-CoV-2), and people are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days.

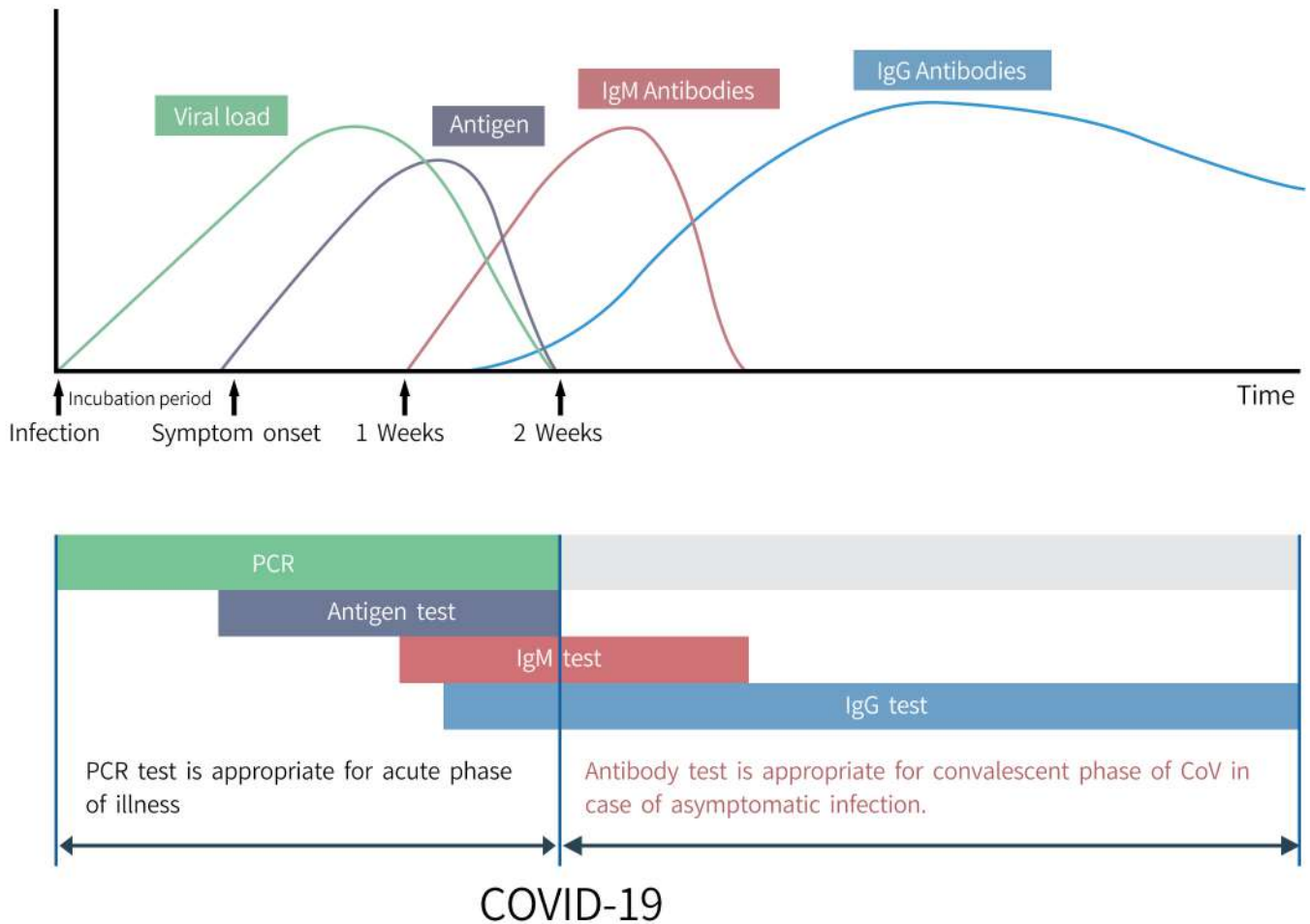


Figure1. Time of appearance of Nucleic Acid/Antigen/Antibody after SARS-CoV-2 infection and applicable detection methods

Different types of COVID-19 test reagents can detect the presence of the SARS-CoV-2 virus or the human body's response to infection. The SARS-CoV-2 Nucleic Acid Detection, COVID-19 Antigen Rapid Test and COVID-19 IgG/IgM Rapid Test are important methods to confirm the SARS-CoV-2 infection.

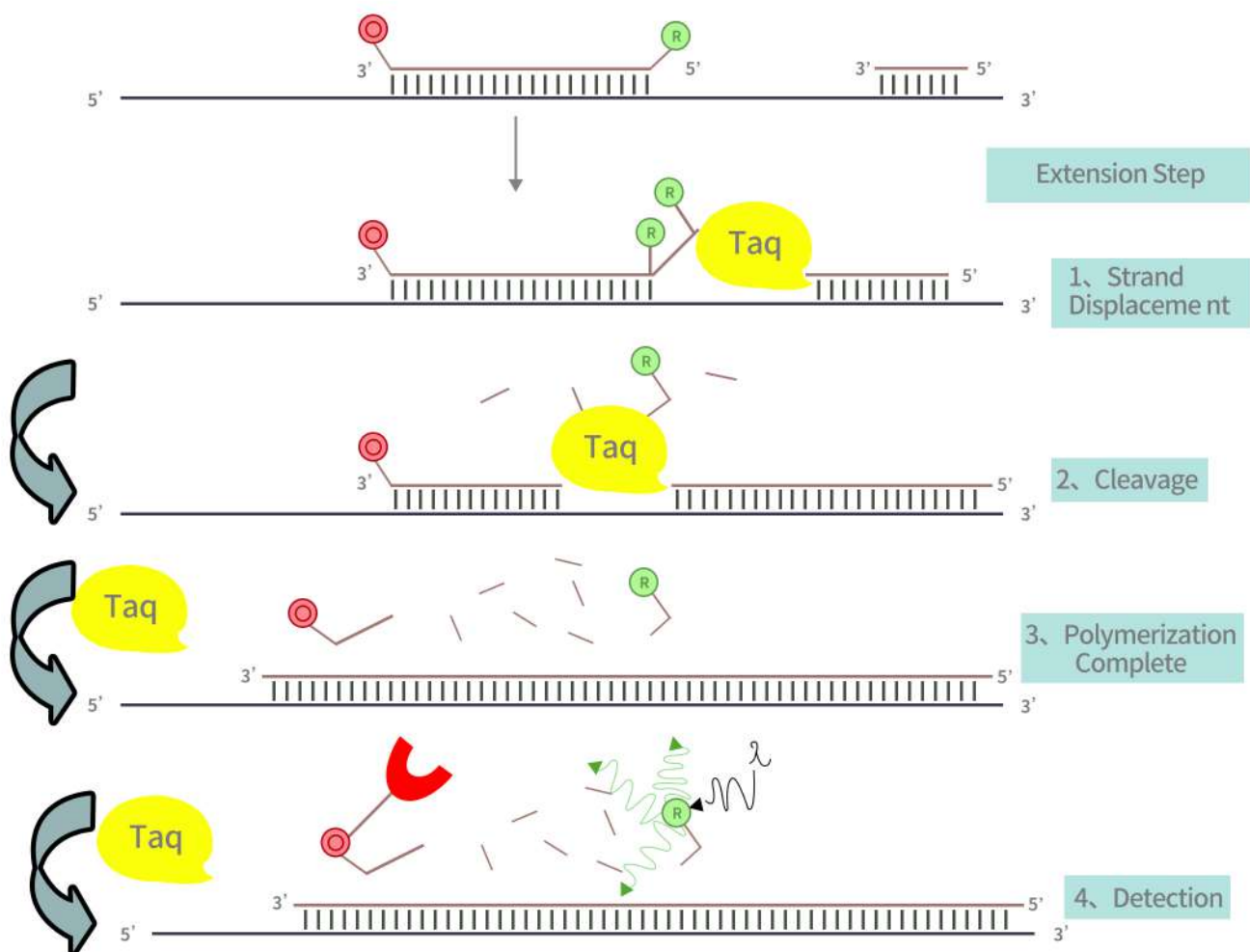
Clongene has developed the SARS-CoV-2 Nucleic Acid RT-PCR Test Kit (dry powder), COVID-19 Antigen Rapid Test Cassette, COVID-19 IgG/IgM Rapid Test Cassette and COVID-19/Influenza A+B Antigen Combo Rapid Test Cassette, which have obtained the CE certification. The products have the characteristics of strong universality, high sensitivity and convenient detection, which can help to improve the detection rate of COVID-19 disease and conducive to the control of the epidemic.

SARS-CoV-2 Nucleic Acid Detection

Nucleic acid detection has the characteristics of early diagnosis high sensitivity and high specificity, which is the "gold standard" for diagnosing COVID-19. Currently, RT-PCR is the most widely used technology

■ Principle

Nucleic acid detection is to determine whether there is SARS-CoV-2 nucleic acid in the sample by detecting the accumulation of fluorescent signal. The SARS-CoV-2 ORF 1ab and the specific conserved sequence of nucleocapsid protein N gene were used as the target area for dual-target gene detection by the RT-PCR. Only when the same sample meets the requirement of dual-target positive or repeated detection as single-target positive that can confirm the SARS-COV-2 nucleic acid positive.



■ Sample Types

Nucleic acid detection samples include nasal swabs, throat swabs, nasopharyngeal swabs, sputum, bronchial lavage fluid, alveolar lavage fluid and others.

SARS-CoV-2 Nucleic Acid RT-PCR Test Kit of Clongene



Product Features



CE Marked



Strong Universality



Fast and Easy to Use



High Safety



High Reproducibility



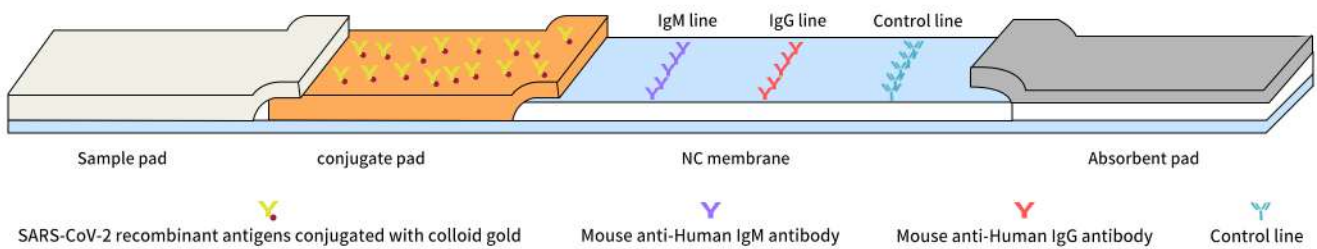
High sensitivity

COVID-19 IgG/IgM Rapid Test

The target of Antibody Detection is not against the virus itself, but the specific antibody produced by the human immune response after the SARS-COV-2 infected. Specific antibodies in the serum are gradually produced at 5-7 days after the human body is infected with SARS-COV-2. IgM antibody appears first but lasts for a short time in the body. At 10-15 days, IgG antibodies appear in large numbers and may last for months or even years.

Name	Content	Generate Time	Duration	Affinity	Function
IgM Antibody	Low	Occurs early and quickly when infected	Shorter Usually 2-3 weeks	Lower	Diagnostic indicators of acute infection stage
IgG Antibody	High	Later than IgM antibody	Longer Months or even years	Higher	It is suggested to be in the middle and late stage of infection or previous infection

Principle



The COVID-19 IgG/IgM Rapid Test is a colloidal gold immunoassay (CGIA) that utilizes the specific reaction between antigen and antibody to detect the anti-SARS-CoV-2 antibody in patients' specimen. If the specimen contains IgM antibody, a burgundy colored IgM line would be visible in the result window and indicating the anti-SARS-CoV-2 IgM positive test result. If the IgG antibody present in the specimen, a burgundy colored IgG line would be visible and indicating the anti-SARS-CoV-2 IgG positive test result. Absence of any T lines (IgG and IgM) suggests a negative result.

Sample Type

Antibody detection samples include serum, plasma and whole blood.

COVID-19 IgG/IgM Rapid Test Cassette of Clongene



Product Features



CE, TGA, ANVISA Marked



Instant result at 15 minutes



Detection for both IgG and IgM



Whole blood, serum and plasma can be detected



No equipment required

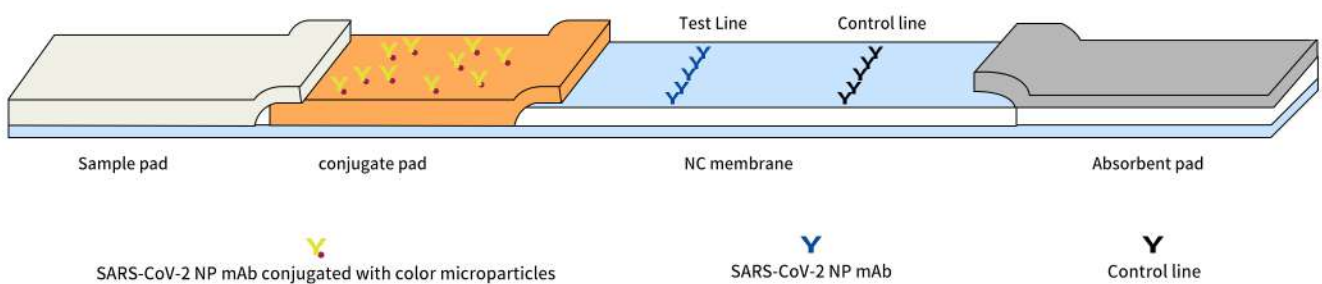


Easy storage, 4-30°C

COVID-19 Antigen Rapid Test

SARS-CoV-2 gene encodes multiple structural proteins such as N protein, E protein and S protein. These proteins contain multiple antigen epitopes. The COVID-19 Antigen Rapid Test can directly prove that the sample contains the virus by using the specific reaction between antigen and antibody. The test has the advantages of fast and convenient, stable sample collection, high throughput, and the result can be interpreted by naked eye.

Principle



The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of the double-antibody sandwich technique. If the specimen contains SARS-CoV-2 antigen, a colored test line (T) would be visible in the result window. Absence of the T line suggests a negative result.

Sample Types

Samples are usually taken from infected sites, such as oropharyngeal swabs and nasopharyngeal swabs.

COVID-19 Antigen Rapid Test Cassette of Clongene



Product Features



CE Marked



Instant result at 15 minutes



Easy to collect samples



Results are clearly visible



No equipment required



Suitable for large-scale rapid screening

Comparison of SARS-CoV-2 (COVID-19) Detection Methods

Kit Type	Detection Time	Sample	Advantage	Disadvantage
Nucleic Acid Detection	1.5-2 hours	Nasal swabs, throat swabs, nasopharyngeal swabs, sputum, bronchial lavage fluid and others	High specificity. "Gold standard" for diagnosing COVID-19.	False negative is likely to result from improper sampling or preservation of samples. High equipment cost. High requirements for operators. Long detection time.
IgG/IgM Rapid Test	15min	Serum, plasma and whole blood	Fast and convenient. Low cost. Results are accurate. Low requirements for equipment and personnel.	False positive is easily caused by rheumatoid factor and heterophilic antibody. False negative was caused by antibody production window period or the different kit sensitivity.
Antigen Rapid Test	15min	Oropharyngeal swabs, nasopharyngeal swabs	Fast and convenient. Low cost. Results are accurate. Low requirements for equipment and personnel.	False negative is likely to result from improper sampling.

SARS-CoV-2 Nucleic Acid Detection, COVID-19 Antigen Rapid Test and COVID-19 IgG/IgM Rapid Test are important methods to confirm the SARS-CoV-2 infection. The three detection methods have differences in the detection window, time-consuming and result accuracy. Therefore, the three detection methods cannot replace each other. Combined application of three detection methods to complement each other can improve detect sensitivity and specificity, effectively shorten the detection window period, increase the positive detection rate and provide double protection for all possible risk groups.



Hangzhou Clongene Biotech Co., Ltd.

Add: No.1 Yichuang Road, Yuhang Sub-district, Yuhang
District, 311121 Hangzhou, China

Tel: +86 (0)571-88262120
400-999-8658

Fax: +86 (0)571-88261752
E-mail: marketing@clongene.com

