

# Clongene

## COVID-19 IgG/IgM RapidTest Cassette

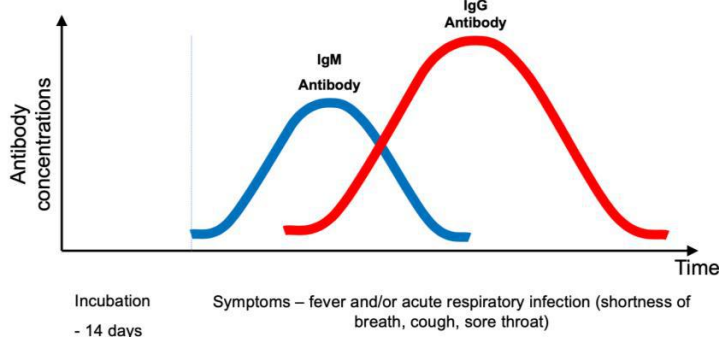
Clongene Rapid Test Cassette provides COVID-19 screening results in 10 – 15 minutes.

SARS-CoV-2 is a new strain of coronavirus infecting humans, with symptoms ranging from a mild respiratory infection to more severe pneumonia with acute respiratory distress. In response to an infection, the human immune system develops antibodies as a defense mechanism. Two important antibodies are IgM and IgG, where IgM is detectable after the onset of symptoms and IgG 1-6 weeks later. Testing for SARS-CoV-2 IgM and IgG antibodies is an effective methodology for the diagnosis and understanding of the progression of a COVID-19 infection.

Detection of the SARS-CoV-2 IgM antibody indicates an earlier stage of the infection, whilst detection of SARS-CoV-2 IgG indicates a later stage of the infection. A sample is positive if there are IgM, IgG or both IgM and IgG antibodies present. Therefore, screening for both SARS-CoV-2 IgM and IgG antibodies gives additional information on the stage of infection.

It should be noted that presence of detectable IgM and IgG antibodies during incubation is neglectable. A negative test may therefore indicate no infection or the infection is still in the incubation time window.

### Window of detection



### Sensitivity and Specificity

167 clinical specimens have been analysed with the Clongene COVID-19 IgG/IgM Rapid Test Cassette and compared with RT-PCR. Sensitivity was calculated as 87.01 % and Specificity as 98.89% (Source: Hangzhou Clongene, clinical study report COVID-19 IgG IgM 20200305).

### Intended use

The Clongene COVID-19 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2 in human Blood/Serum/Plasma.

### Contents

Each Test kit includes:

- Test Cassette, which holds the test strip where detection of the IgM and IgG antibodies take place
- Buffer solution
- IFU/Product insert

### Shelf life & Storage conditions

The Clongene COVID-19 IgG/IgM Rapid Test Cassette offers two years shelf life from date of manufacturing.

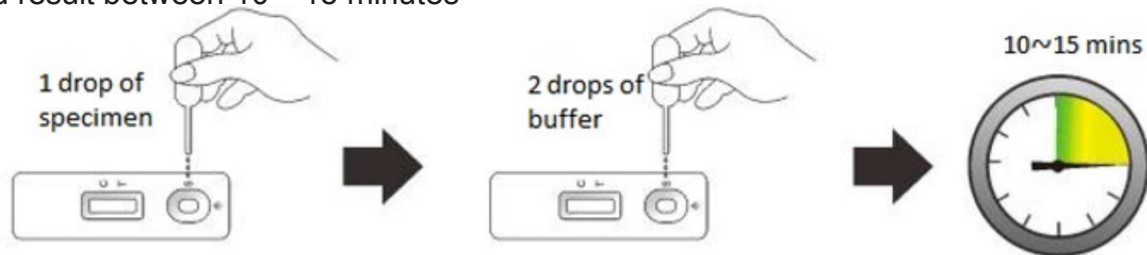
Storage temperature 2°C - 30°C.

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## COVID-19 IgG/IgM Rapid Test Cassette

### Easy to use

1. One droplet of blood/Serum/Plasma is added to the sample well of the Test Cassette
2. Cassette
3. Add 2 drops of Buffer Solution to the same sample well of the Test Cassette  
Read result between 10 – 15 minutes



### Interpretation of results

Results are read from the window of the Test Cassette, which is marked from top to bottom with

C, IgG and IgM;

C is a control line, which must always be present at the time of analysis. No C-line means that the test is invalid

and a new test should be performed.

IgG is a Test line indicating the presence of the IgG SARS-CoV-2 antibody. A line should be read as a positive test.

No line should be interpreted as a negative test.

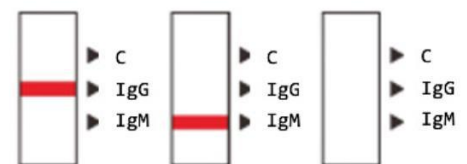
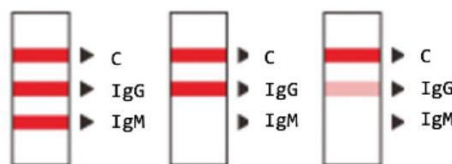
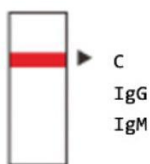
IgM is a Test line indicating the presence of the IgM SARS-CoV-2 antibody. A line should be read as a positive test.

No line should be interpreted as a negative test.

Negative

Positive

Invalid



Dropper/Pipette

