



COVID-19, it is a novel coronavirus with new strain that has not been previously identified in humans, belongs to Coronaviruses (CoV) such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV).

## **Specification**

• Sample Volume: 10µl

• Fast Reaction: 15 minutes

• For professional use only

Product Name	Specimen	Format	Kit size
SARS-CoV-2 IgM/IgG Ab Rapid Test	WB/S/P	Cassette	25T/Box

#### **Intended Use**

Used to detect the IgM and IgG antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in human serum, plasma or whole blood sample qualitatively. It is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2.

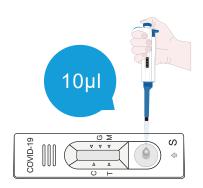
#### **Performance**

Sensitivity	94.15%
Specificity	93.91%
Total consistent	94%

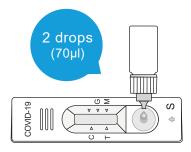
<sup>\*</sup> Note: Results compared to Molecular testing.

### Test procedure and Read result

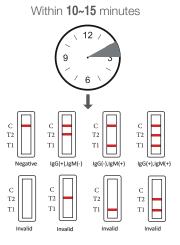
# Serum/Plasma



1. Add 10µl of serum or plasma vertically into the sample well.

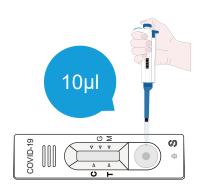


2. Add two (2) drops (70µl) of sample buffer into the sample well.

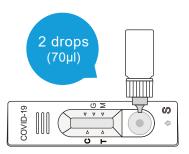


3. Read results within 10~15 minutes, the result is invalid over 20 minutes.

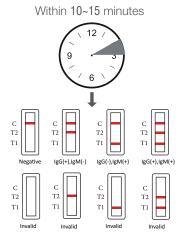
# Whole Blood



1. Add 10µl of whole blood vertically into the sample well.



2. Add two (2) drops (70µl) of sample buffer into the sample well.



3. Read results within 10~15 minutes, the result is invalid over 20 minutes.

