

# MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test



Offers rapid and convenient PoCT  
(Point of Care Testing) for COVID-19



Detects anti-SARS-CoV-2 IgG and  
IgM antibodies



Allows for detection of acute to  
convalescent phase



Specimens: Human serum, plasma  
or whole blood



Fast test result: 15 minutes



Learn more at [www.mpbio.com](http://www.mpbio.com)



MP Bio Americas

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# MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test

Cat. No. 0743140020 (CE) & 0743142020 (RUO)<sup>1</sup> / 20 devices

The World Health Organization (WHO) recommends serological testing to supplement the diagnosis in cases where NAAT assays are negative and there is a strong epidemiological link to COVID-19 infection<sup>1</sup>.

Serological diagnosis is especially important for patients with mild to moderate illness who may not be subjected to PCR testing within the first 2 weeks of illness onset. Serological diagnosis is also an important tool for understanding the prevalence of COVID-19 in the community, as well as to identify individuals who are immune and potentially "protected" from becoming infected.

The MP Diagnostics ASSURE® SARS-CoV-2 IgG/IgM Rapid Test is a qualitative in vitro immunochromatographic test intended to detect and differentiate IgG/IgM antibodies against SARS-CoV-2 in human plasma, serum, and whole blood. The detection of these antibodies facilitates better screening (before further confirmatory testing) and surveillance/contact tracing efforts.



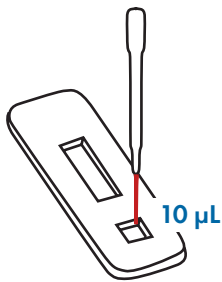
- Control Line  
- Test Line: IgG  
- Test Line: IgM

- Sample well

<sup>1</sup> United States availability is Research Use Only (RUO).

<sup>2</sup> WHO (2 Mar 2020) Interim guidance: Laboratory testing for coronavirus disease 2019 (COVID-19) in suspected human cases

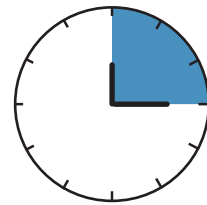
## Simple Assay Procedure



- 1 With a capillary pipette, add 10 µL of serum/plasma/whole blood sample into the sample well.



- 2 Add 3 drops of chase buffer to the sample well.



15 mins

- 3 As the test progresses, a pink-purplish color will move across the result window in the center of the test device. Interpret test results at 15 minutes.

Analytical sensitivity  
**100%**

Analytical specificity  
**99.41%**

Accuracy  
**99.47%**

Diagnostic sensitivity  
**99%**

Diagnostic specificity  
**95%**

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