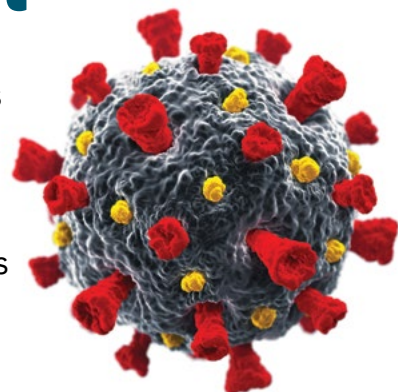




## COVID-19 IgG / IgM Rapid ICT Test

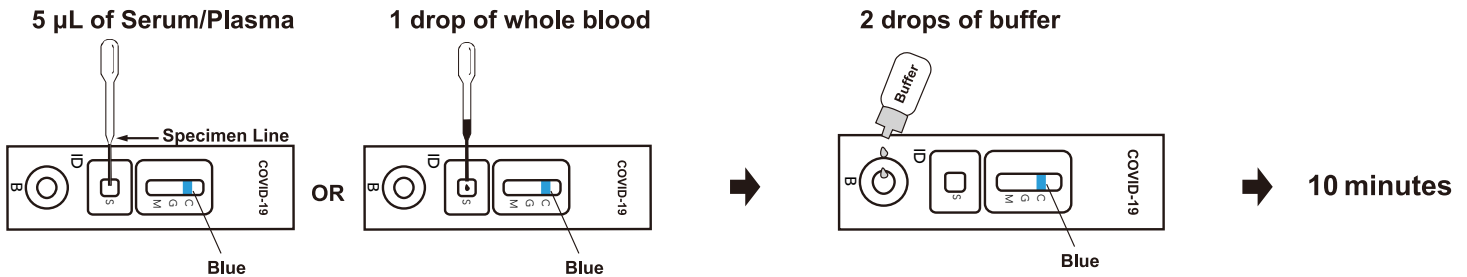
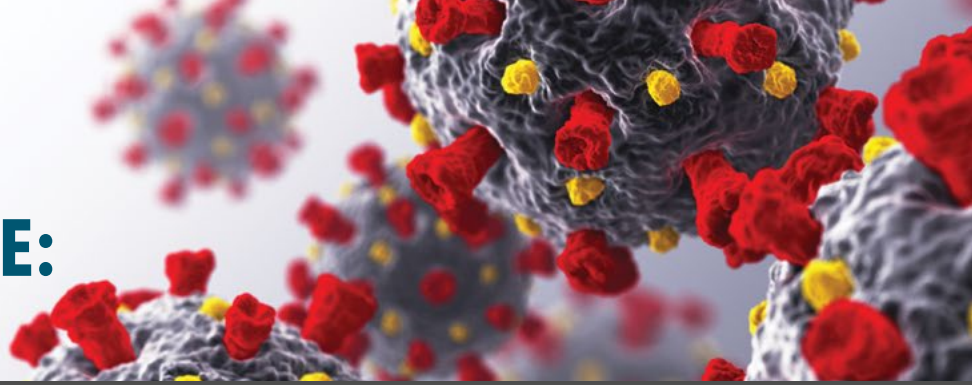
- Qualitative detection of IgM and IgG antibodies to SARS-CoV-2 virus
  - 86.7% IgM Sensitivity and 99.0% Specificity compared to RT-PCR
  - 96.7% IgG Sensitivity and 98.0% Specificity compared to RT-PCR
- Readily identify adaptive immune response in as little as 10 minutes
- Uses venous whole blood, serum, or plasma samples



COVID-19 IgG / IgM Rapid ICT Test

# ASSAY PROCEDURE:

(less < 1 minute hands on time)



### STEP 1:

Unwrap individual test kit.

### STEP 2:

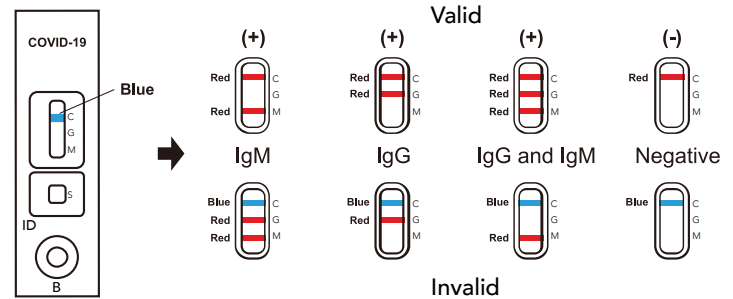
Pipette 5µL or 1 drop of sample into sample port.

### STEP 3:

Add two drops of buffer into buffer port.

### STEP 4:

Observe and interpret results within 10 minutes.



The COVID-19 IgG/IgM Rapid Test Cassette is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

See Package Insert for complete performance data

### Catalog Information

**COVID-19 IgG / IgM Test EUO** (25 Test Kits) ..... 100598

### Warning/Limitations

This test has not been FDA cleared or approved.

This test has been authorized by FDA under an EUA for use by authorized laboratories.

This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens.

This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

This product is intended for professional use and not for home use.

Not for the screening of donated blood.

### References

<sup>1</sup> Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency. 2020.



MedCareGlobal

Medcare Global  
8400 E. Prentice Avenue, Suite: PH  
Greenwood Village CO 80111

303-790-2300