PRIMA

COVID-19 IgG/IgM RAPID TEST

A rapid test for the qualitative detection of IgG and IgM antibodies against COVID-19 in human whole blood, serum or plasma specimens.

For professional in vitro diagnostic use only.

Biomedical Diagnostics Product Reference
N15-NT04032 (10 x 0,6ml)

Result in 10 minutes

Test your health

CE

COVID-19

Early January 2020, a novel coronavirus (COVID-19) was identified as the infectious agent causing an outbreak of viral pneumonia in Wuhan, China, where the first cases had their symptom onset in December 2019. Coronaviruses are enveloped RNA viruses that are distributed broadly among humans, other mammals, and birds and that cause respiratory, enteric, hepatic, and neurologic diseases. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and even death. Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing and avoid close contact with anyone showing symptoms of respiratory illness such as coughing and sneezing.

TEST PRINCIPLE

The COVID-19 IgG/IgM Rapid Test is a qualitative membrane-based lateral flow immunochromatographic assay for the detection of IgG and IgM antibodies to COVID-19 in whole blood, serum or plasma specimen.

WHO ARE THE INTENDED USERS

Test for healthcare professionals to be used to help in the COVID-19 diagnosis.

WHY-BENEFITS

Assistance to the doctor in the diagnosis of COVID-19:
- High Sensitivity and Specificity
- Rapid test (10 minutes)
- Easy to handle and interpret
- Safe and Accurate

TECH SPEC

	SPECIFICITY	SENSIBILITY	OVERALL ACCURACY
IgG	98%	100%	98.6%

	SPECIFICITY	SENSIBILITY	OVERALL ACCURACY
IgM	96%	85%	92.9%

The COVID-19 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma) was compared to a commercial reference PCR test; the results show high sensitivity and specificity.

CLINICAL EVIDENCES

1. World Health Organization (WHO). WHO Statement Regarding Cluster of Pneumonia Cases in Wuhan, China. Beijing: WHO; 9 Jan 2020. [Accessed 26 Jan 2020]. https://www.who.int/china/news/detail/09-01-2020-who-statement-regarding-cluster-of-pneumonia-cases-in-wuhan-china

2. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164. PMID:22094080 DOI: 10.1016/B978-0-12-385885-6.00009-2

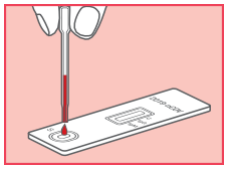
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016; 24:490-502. PMID:27012512 DOI: 10.1016/j.tim.2016.03.003

4. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192. PMID:30531947 DOI:10.1038/s41579-018-0118-9

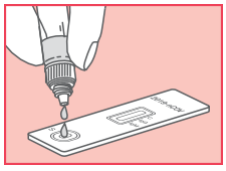
5. World Health Organization (WHO). Coronavirus. https://www.who.int/health-topics/coronavirus

HOW TO USE IT

1) *For whole blood (fingerstick and venous sampling): Fill the blood collecting pipette and transfer 20 µL of whole blood sample into the sample well (S) of the test cassette. As an alternative to the blood collecting pipette, 20 µL of sample from venous sampling can be dispensed with a laboratory micropipette.*
For serum and plasma: Transfer 10 µL of sample to the sample well (S) with a laboratory micropipette.



2) *Add 2 drops of diluent (approximately 80 µL), wait for 10 minutes and read the result.*



100061-P_flyer_02_1.0 - 02/2020

Biomedical Diagnostics
Ahlers House - Noorderlaan 139 - 2030 Antwerpen - Belgium
Tel BE: +32 (0)3 546 39 80 - Tel NL: +31 (0)76 56 55 647 - info@bmd.be - www.bmd.be