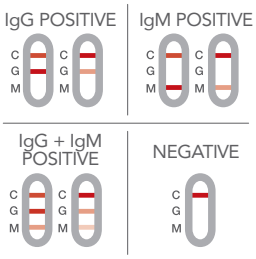
COVID-19 AREA
POST COVID-19 INFECTION

PRIMA HOME TEST

PRIMACOVID®

COVID–19 SEROLOGICAL TEST

Rapid self-test for the qualitative detection of IgG and IgM antibodiesagainst SARS-CoV-2 in human blood specimens



COVID-19 AND SARS-CoV-2

January 2020, the Chinese Centre for Disease Control and Prevention (CDC) identified the Coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) as the causative agent of this first outbreak and the related disease was defined as COVID-19 (Coronavirus Disease 2019). Similarly to other respiratory diseases, SARS-CoV-2 can cause asymptomatic infection, mild symptoms - such as cold, sore throat, cough, fever and loss of sense of smell - or more severe symptoms such as pneumonia and breathing difficulties with even fatal results.

WHO ARE THE INTENDED USERS

COVID-19 SEROLOGICAL TEST is intended to be used by individuals who think that they might have contracted the virus in the past months or that have come into contact with infected people before the past two weeks.

WHY - BENEFITS

COVID-19 SEROLOGICAL TEST is important to help identify people potentially infected with SARS-CoV-2 in addition to, but not as a replacement of, molecular tests.

TEST PRINCIPLE

COVID-19 SEROLOGICAL TEST is a rapid immunochromatographic assay for the qualitative detection of Immunoglobulin G (IgG) and Immunoglobulin M (IgM) against SARSCoV-2 in human blood samples. The Test was evaluated in a number of hospitals and research centers, in comparison with two different commercial reference ELISA tests.

TECH SPECS

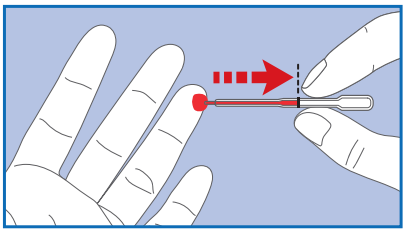
SENSITIVITY IgG	SENSITIVITY IgM	SPECIFICITY IgG and IgM
98,92%	92,98%	98,30%

CLINICAL EVIDENCES

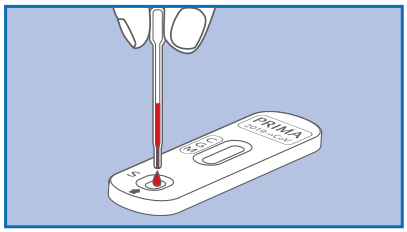
1. European Centre for Disease Prevention and Control, Disease background of COVID-19 (https://www.ecdc.europa.eu/en/2019-ncovbackground-disease)
2. https://www.who.int/emergencies/diseases/novel-coronavirus-2019
3. Valenti L et al. "SARS-CoV-2 seroprevalence trends in healthy blood donors during the COVID-19 Milan outbreak." Submitted to Eurosurveillance, 2020, medRxiv preprint doi: https://www.medrxiv.org/content/10.1101/2020.05.11.20098442v2
4. Long, Q., Liu, B., Deng, H. et al. Antibody responses to SARS-CoV-2 in patients with COVID-19. Nat Med (2020)
5. FIND. Rapid Diagnostic Tests For Covid-19. https://www.finddx.org/wp-content/uploads/2020/05/FIND_COVID-19_RDTs_18.05.2020.pdf
6. Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV2. JAMA. 2020;323(22):2249–2251. DOI:10.1001/jama.2020.8259

HOW TO USE IT

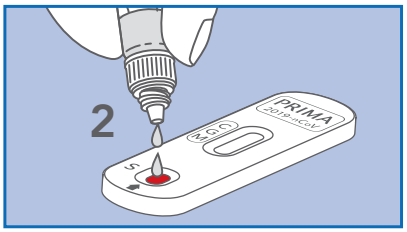
1) Take a blood sample after pricking the finger.



2) Deposit the sample into the specimen well of the cassette.



3) Add 2 drops of diluent and wait 10 minutes before reading the result.



CONTENT: 1 hermetically sealed aluminium pouch containing: 1 test device and a desiccant bag; 1 transparent plastic bag containing a pipette for blood collection; 1 vial with dropper tip containing the diluent required for the test;1 antiseptic skin cleanser gauze; 2 sterile lancets for self-drawing blood; 1 instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
800061-1	COVID-19 SEROLOGICAL TEST	1 TEST	24 MONTHS

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PRIMA

800061-1_LEAFLET_02_1.5 11/2022