COVID-19 AREA
COVID-19 DETECTION

PRIMA HOME TEST

CE 0483

PRIMACOVID®

COVID–19 ANTIGEN SELF-TEST

Rapid self-test for the qualitative detection of SARS-CoV-2 Nucleocapsid protein antigens in human nasal specimens

15 min. | 1-5 test

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

The device is intended for anyone who has recently been exposed to the virus, those with symptoms related to COVID-19 or those who want to monitor their health. The incubation period of the virus is between 1 and 14 days.

WHY - BENEFITS

COVID-19 ANTIGEN SELF-TEST is a rapid and easy way to monitor the positivity to SARS-CoV-2 and to take opportune corrective actions.

TEST PRINCIPLE

COVID-19 ANTIGEN SELF-TEST is a rapid immunochromatographic test for the qualitative detection of SARS-CoV-2 Nucleocapsid antigens from nasal swabs. The extraction buffer is used to extract the viral antigen and allow its detection.

TECH SPECS

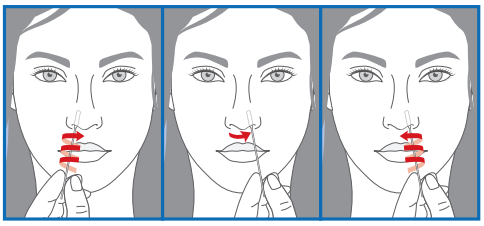
	SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
SYMPTOMATIC	97,20%	99,50%	98,60%
ASYMPTOMATIC	97,80%	99,00%	98,40%

CLINICAL EVIDENCES

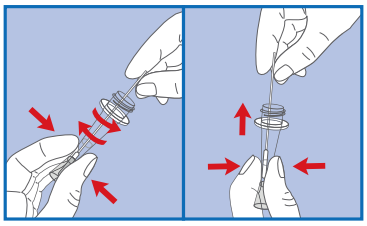
1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine 2020.
2. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020 (https://www.who.int/dg/speeches/detail/who-director-general-s opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020)
3. Centers for Disease Control and Prevention, Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines clinicalspecimens.html)
4. European Centre for Disease Prevention and Control. Options for the use of rapid antigen tests for COVID-19 in the EU/EEA - first update. 2021. https://www.ecdc.europa.eu/en/publications-data/optionsuse-rapid-antigentests-covid-19-eueea-first-update
5. WHO, Advice on the use of point-of-care immunodiagnostic tests for COVID-19 https://www.who.int/ news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19
6. Council of the European Union, Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the E, 20 January 2021

HOW TO USE IT

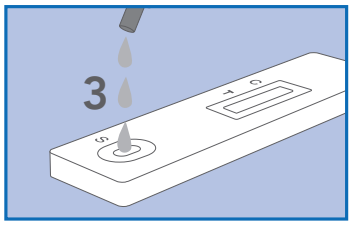
1) Collect the nasal sample by inserting the swab in the nasal cavity and holding it parallel to the palate. Gently rub and roll it and take it out. Repeat the procedure in the other nostril.



2) Insert the swab into the extraction buffer, rotate and remove it while squeezing the sides of the test tube in order to extract as much liquid as possible.



3) Apply 3 drops of the extracted specimen and wait 15 minutes before reading the result.



CONTENT: 1 or 5 sealed aluminium pouches containing each: 1 test device and 1 desiccant bag; 1 or 5 sample collection tubes with dropper containing the extraction buffer; 1 or 5 sterile nasal swabs and instructions for use leaflet.

VIDEO TUTORIAL

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
200063-1	COVID-19 ANTIGEN SELF-TEST	1 TEST	24 MONTHS
200063-5	COVID-19 ANTIGEN SELF-TEST	5 TESTS	

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