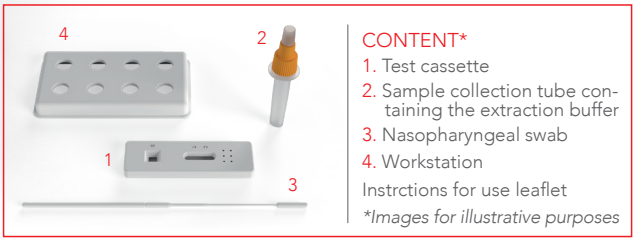
PRIMACOVID®

COVID-19 ANTIGEN RAPID TEST

Rapid test for the qualitative detection of SARS-CoV-2 antigens present in human nasopharyngeal specimens

For professional in-vitro diagnostic use only



TECH SPECS

ACCURACY	SENSITIVITY	SPECIFICITY
99,60%	93,40%	99,90%
(95% CI: 99,20%~99,80%)	(95% CI: 86,90%~97,30%)	(95% CI: 99,60%~>99,90%)

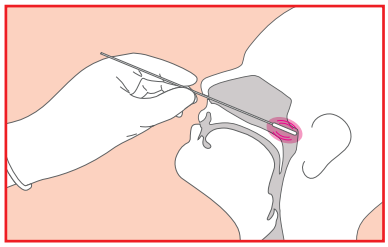
PRINCIPLE OF THE TEST

COVID-19 ANTIGEN RAPID TEST is a rapid immunochromatographic assay, whose target analyte are the SARS-CoV-2 antigens. Pathogen-specific antigens can be used as diagnostic markers to detect the current infection status of an individual.

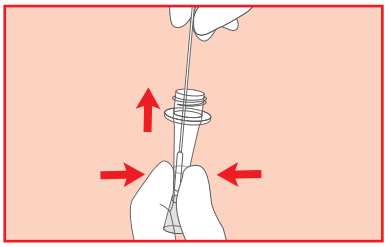
WHO ARE THE INTENDED USERS

The device is intended to be used by healthcare professionals as a first approach in the diagnosis of COVID-19.

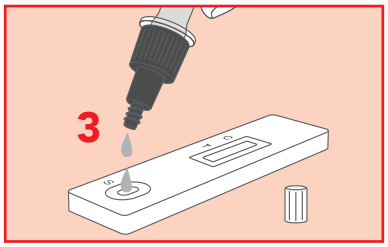
HOW DOES THE TEST WORK?



1. Collect the nasopharyngeal 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.



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.

BIBLIOGRAPHY

1. European Centre for Disease Prevention and Control, Disease background of COVID-19 (https://www.ecdc.europa.eu/en/2019-ncov-background-disease)
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-clinical-specimens.html)
4. European Centre for Disease Prevention and Control. Diagnostic testing and screening for SARS-CoV-2. 2020. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/diagnostic-testing. Accessed January 2022.
5. https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19

REF	DESCRIPTION	NUMBER OF TESTS	SHELF LIFE
200063-20P	COVID-19 ANTIGEN RAPID TEST	20 TESTS	24 MONTHS

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