



PRIMACOVID[®] COVID-19 SALIVA SELF-TEST

Rapid self-test for the qualitative detection of SARS-CoV-2 antigens present in the human oral fluid specimen



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 SALIVA 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 SALIVA SELF-TEST is a rapid immunochromatographic assay which is able to detect SARS-CoV-2 antigens in human oral fluid specimen.

TECH SPECS

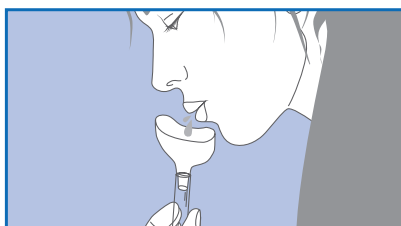
SENSITIVITY	SPECIFICITY	OVERALL ACCURACY
90.1%	99.3%	97%

CLINICAL EVIDENCES

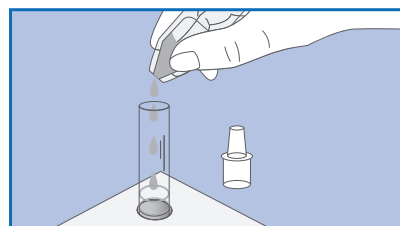
1. BACKINGER, C.L. and KINGSLEY, P.A., Recommendations for Developing User Instruction Manuals for Medical Devices Used in 9 / 57 Home Health Care, Rockville, MD, U.S. Food and Drug Administration, Center for Devices and Radiological Health, HHS Pub. FDA 93-4258.
2. WHO, Advice on the use of point-of-care immunodiagnostic tests for COVID-19 (<https://www.who.int/newsroom/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19>)
3. 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.

HOW TO USE IT

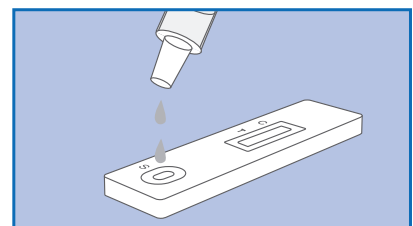
1) Collect oral fluid specimen.



2) Deposit the extraction buffer into the tube containing the specimen and insert the dropper tip.



3) Add 2 drops of the extracted sample 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 vial with dropper containing the extraction buffer; 1 or 5 collection kit with plastic tube, dropper tip and funnel; 1 or 5 Biohazard specimen bag; and instructions for use leaflet.



REF	DESCRIPTION	NUMBER OF TESTS
100371-1	COVID-19 SALIVA SELF-TEST	1 TEST
100371-5	COVID-19 SALIVA SELF-TEST	5 TESTS