Your partner for rapid testing

PRIMA Lab SA
Via Antonio Monti 7
CH-6828 Balerna - SWITZERLAND
+41 91 605 1030
primalabsa.ch

EC REP Qarad EC-REP BV
Pas 257, 2440 Geel
Belgium

REF 200063-20P
200063-20P_IFU_02_5.0 03/2022

IVD for professional use only

PRIMACOVID®

COVID-19 ANTIGEN RAPID TEST

Rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in swab specimen

INSTRUCTIONS FOR USE

15 min. 20 tests

COVID-19 AND ANTIGEN TESTS

In December 2019, cases of pneumonia of unknown aetiology were reported in Wuhan, Hubei Province, China. On January 2020 Chinese Center for Disease Control and Prevention (CDC) identified the newly discovered Coronavirus SARS-CoV-2 (Severe Acute Respiratory Syndrome Coronavirus 2) as the responsible agent of the pneumonia outbreak in China and the related disease was defined as Coronavirus disease 2019 (COVID-19). Symptoms of COVID-19 can vary in severity from being asymptomatic to fever, sore throat, cough, anosmia, general weakness, fatigue and muscular pain. In the most severe cases, the infection can lead to severe pneumonia, acute respiratory distress syndrome, sepsis and septic shock, all potentially leading to death. The incubation period of SARS-CoV-2 ranges between 1 and 14 days, with a median from 5 to 6 days. For initial diagnostic testing of SARS-CoV-2 infection, the US Centers For Disease Control and Prevention (CDC) recommends collecting and testing upper respiratory tract specimens, such as nasopharyngeal specimens. This type of specimens can be analyzed for assessing the presence of genetic material or the antigens of the pathogen. Antigen tests, in particular, detect the proteins which are structural or functional components of the pathogen and are thus very specific for the target microorganism. In the context of COVID-19, antigen tests provide a qualitative answer to the detection of SARS-CoV-2 in the patient sample and can be offered as rapid diagnostic tests to be performed at the point of care.

PRINCIPLE OF THE TEST

PRIMACOVID® COVID-19 ANTIGEN RAPID TEST is a rapid membrane-based lateral flow immunoassay for the qualitative detection of SARS-CoV-2 antigens in human nasopharyngeal and nasal swab specimens. During testing SARS-CoV-2 antigens possibly present in the specimen react with the antibody-coated nanoparticles present in the gold pad of the test. The resulting complex chromatographically migrates upward in the strip membrane by capillary action. If the specimen contains SARS-CoV-2 antigens, they will bind to the SARS-CoV-2 antibodies coated on the Test line region and generate a colored line on the test strip, indicating a positive result. If SARS-CoV-2 antigens are not present in the specimen, no colored line will appear in the Test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the Control line region, indicating that the test procedure has been performed properly and that test components and reagents have operated as intended. If the test is working properly, the background in the result window should be white to light pink, without interfering with results interpretation. The test contains anti-SARS-CoV-2 Nucleocapsid protein antibody as the capture reagent and anti-SARS-CoV-2 Nucleocapsid protein antibody as the detection reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in package insert may yield inaccurate test results.
2. For professional in vitro diagnostic use only. Do not use after expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use test if pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. Please ensure that appropriate amounts of samples are used for testing. Too much or too little sample size may lead to deviation of results.
9. Sterile Swabs for the collection of Nasopharyngeal specimen and Nasal specimen are different, Do not mix the using of the two types of sampling swabs.
10. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
11. The used test should be discarded according to local regulations.
12. Humidity and temperature can adversely affect results.
13. Store as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

CONTENT

THE PACKAGE CONTAINS:

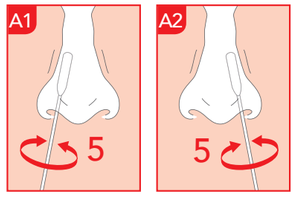
- 20 hermetically sealed aluminum pouches each containing: 1 SARS–CoV–2 ANTIGEN RAPID TEST test cassette and 1 desiccant pouch;
- 20 vials containing SARS–CoV–2 ANTIGEN RAPID TEST extraction buffer
- 20 sterile swabs;
- 1 work station;
- 20 tubes with dropper for sample collection and extraction (Optional);
- 1 instruction manual.

- Required material not supplied: a timer (e.g. timer, watch).

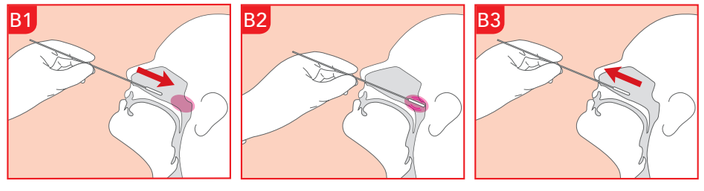
SPECIMEN COLLECTION, TRANSPORT AND STORAGE

NASAL SWAB SPECIMEN COLLECTION

1) Insert the sterile swab less than one inch (about 2 cm) into a nostril (until resistance is met at the turbinates).
2) Rotate the swab 5-10 times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril. –Fig. A1, A2
3) Withdraw the sterile swab; avoid excess volume and high-viscous nasal discharge



NASOPHARYNGEAL SWAB SPECIMEN COLLECTION



1) Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx. –Fig. B1
2) Swab over the surface of the posterior nasopharynx 5-10 times. –Fig. B2
3) Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge. –Fig. B3

Caution: *If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.*

*[1]NOTE: Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 24 hours at 2-8 °C.

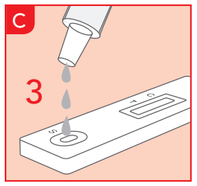
SPECIMEN EXTRACTION AND TEST PROCEDURE

Only the extraction buffer and tubes provided in the kit is to be used for swab specimen preparation.

4) Place the swab specimen in the Extraction tube with Extraction buffer. Rotate the swab for **10-15 seconds** while pressing the head against the inside of the tube to release the antigen in the swab.
5) Remove the swab while squeezing the swab head against the inside of the Extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

*[2]NOTE: The storage of the specimen after extraction is stable for 2 hours at room temperature and 24 hours at 2-8 °C. **Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.**

6) Remove the test cassette from the sealed aluminium pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the aluminium pouch.
7) Invert the specimen extraction tube and add 3 drops of extracted specimen (approx.75-100µl) to the sample well(S) and then start the timer. –Fig. C
8) Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



RESULTS INTERPRETATION

READ THE RESULTS AT 15 MINUTES. DO NOT READ THE RESULTS AFTER 20 MINUTES

POSITIVE:*[3]

Two colored lines appear. A colored line should always appear in the Control (C) region and another line should be in the Test (T) region. Positive result in the Test region indicates detection of SARS–CoV–2 antigens in the sample.

*[3]NOTE: *The color intensity in the test line region may vary depending on the concentration of SARS–CoV–2 antigens present in the sample. Therefore, any shade of color in the test line region should be considered positive.*

NEGATIVE

One colored line appears in the Control region (C).
No apparent colored line appears in the Test line region (T).

INVALID

Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The performance of the COVID-19 ANTIGEN RAPID TEST was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
2. The test Procedure and the Interpretation of test Result must be followed closely when testing for the presence of SARS-CoV-2 Nucleocapsid protein antigens in the human nasopharynx from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
3. The COVID-19 ANTIGEN RAPID TEST is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 Nucleocapsid protein Antigens in swab specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
4. The COVID-19 ANTIGEN RAPID TEST will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
5. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results under the following conditions:
   a) The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
   b) The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting samples at different times for the same patient may avoid false negatives.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
10. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

PERFORMANCE CHARACTERISTICS

SENSITIVITY, SPECIFICITY AND ACCURACY

The COVID-19 ANTIGEN RAPID TEST has been evaluated with swab specimens obtained from the patients. RT-PCR (Nasopharyngeal Swab) is used as the reference method for the COVID-19 ANTIGEN RAPID TEST. Specimens were considered positive if RT-PCR (Nasopharyngeal Swab) indicated a positive result. Specimens were considered negative if RT-PCR (Nasopharyngeal Swab) indicated a negative result.

Nasopharyngeal Swab Specimen

COVID-19 Antigen Rapid Test		RT-PCR		TOTAL
		POSITIVE	NEGATIVE	
COVID-19 Antigen	POSITIVE	99	2	101
	NEGATIVE	7	2016	2023
Total		106	2018	2124
Relative Sensitivity		93.4% (95%CI*: 86.9%~97.3%)		
Relative Specificity		99.9% (95%CI*: 99.6%~>99.9%)		
Accuracy		99.6% (95%CI*: 99.2%~99.8%)		

*Confidence Intervals

Nasal Swab Specimen

COVID-19 Antigen Rapid Test		RT-PCR		TOTAL
		POSITIVE	NEGATIVE	
COVID-19 Antigen	POSITIVE	115	2	117
	NEGATIVE	8	298	306
Total		123	300	423
Relative Sensitivity		93.5% (95%CI*: 87.6%~97.2%)		
Relative Specificity		99.3% (95%CI*: 97.6%~99.9%)		
Accuracy		97.6% (95%CI*: 95.7%~98.9%)		

*Confidence Intervals

LIMIT OF DETECTION

The COVID-19 ANTIGEN RAPID TEST can detect out SARS-CoV-2 heat-inactivated virus strain as low as $1X10^2$ $TCID_{50}$/ml.

SPECIFICITY TESTING WITH VARIOUS VIRAL STRAINS

The COVID-19 ANTIGEN RAPID TEST was tested with the following viral strains. No discernible line regions was observed at these concentrations:

Description	Test Level
Human coronavirus 229E	5x 10^5 $TCID_{50}$/ml
Human coronavirus NL63	1x 10^6 $TCID_{50}$/ml
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/ml
MERS coronavirus Florida	1.17x10^4 $TCID_{50}$/ml
Human coronavirus HKU1	1x 10^6 $TCID_{50}$/ml
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/ml
Influenza A H3N2	1 x 10^5 $TCID_{50}$/ml
Influenza B	3.16 x 10^6 $TCID_{50}$/ml
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/ml
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/ml
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/ml
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/ml
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/ml
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/ml
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/ml
Measles	1.58 x 10^4 $TCID_{50}$/ml
Mumps	1.58 x 10^4 $TCID_{50}$/ml

$TCID_{50}$ = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

SPECIFICITY TESTING WITH VARIOUS ORGANISMA

The following organisms were tested at $1.0x10^8$ org/ml and all found to be negative when tested with the COVID-19 ANTIGEN RAPID TEST:

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Neisseria subflava	*Streptococcus sp group F*

INTERFERING SUBSTANCES

The interfering substances below were spiked with negative, SARS-CoV-2 Antigen weak positive. No substances showed any interference with the COVID-19 ANTIGEN RAPID TEST.

Substance	Concentration
Whole Blood	20µl/ml
Mucin	50µg/ml
Budesonide Nasal Spray	200µl/ml
Dexamethasone	0.8mg/ml
Flunisolide	6.8ng/ml
Mupirocin	12mg/ml
Oxymetazoline	0.6mg/ml
Phenylephrine	12mg/ml
Rebetol	4.5µg/ml
Relenza	282ng/ml
Tamiflu	1.1µg/ml
Tobramycin	2.43mg/ml

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3. 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)
4. 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)
5. 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 July 2020.
6. https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19

MEDICAL DEVICES INSIDE THE KIT:

STERILE EO
Sterile swab
CE 0123
Copan Italia S.p.A
Via F. Perotti,10
25125 Brescia - Italy
www.copangroup. com

STERILE EO
Sterile swab
CE 0123
Zhejiang Gongdong Medical Technology Co., Ltd.
No. 10 Beiyuan Ave. - Huangyan
318020 Taizhou, Zhejiang - China
EC REP *Shanghai International Holding Corp. GmbH (Europe)*
Eiffestrasse 80 – 20537 Hamburg - Germany

STERILE R
Sterile swab
CE 0197
Shenzhen KangDaAn Biological Technology co., LTD
East-1, 3rd floor, Building 2,
Shunheda factory, Liuxiandong
Industrial zone, Xili street,
Nanshan district, Shenzhen - China
EC REP *Share Info Consultant Service LLC*
Repräsentanzbüro
Heerdter Lohweg 83
40549 Düssendorf - Germany

STERILE EO
Sterile swab
CE 0197
Jiangsu Changfeng Medical Industry Co., Ltd
Tougiao Town, Guangling District
225109, Yangzhou, Jiangsu - China
EC REP *Llins Service & Consulting GmbH*
Obere Seegasse 34/2,
69124, Heidelberg - Germany
info@Llins-service.com

STERILE EO
Sterile swab
CE 0197
Jiangsu Hanheng Medical Technology Co., Ltd.
16-B4, #1 North Qingyang Road
Tianning District
213017, Changzhou, Jiangsu - China
EC REP *Luxus Lebenswelt GmbH*
Kochstr. 1 - 47877 Willich - Germany

STERILE EO
Sterile swab
CE 0413
Medico Technology Co., Ltd.
Room 201 of Building 14th and Building 17th Hengyi Lane,
Yuanhu Road, Zhangbei Industrial Park, Longcheng Street,
Longgang district, Shenzen, Guangdong - China
www.medicoswab.com
EC REP *Wellkang Ltd (www.CE-marking.eu)*
Enterprise Hub, NW Business Complex,1,
BeraghmoreRd.Derry, BT488SE, N. Ireland, UK

SYMBOLS

IVD	*In vitro diagnostic device*	LOT	*Lot number*
	Read the instructions before use	+2°C +30°C	*Temperature limits*
STERILE R	*Sterilised using irradiation*		*Do not reuse*
STERILE EO	*Sterilized using ethylene oxide*	n	*Sufficient for <n> tests*
	Do not use if package is damaged	REF	*List number*
	Expiry date (last day of the month)	CE	*CE marking*
EC REP	*Authorised Representative in the European Community*		*Legal manufacturer*