REDCELL

COVID-19 Self Test

REF No: RCCOVST CE 2934 IVD

INTENDED USE

REDCELL COVID-19 Self Test is designed for personal use without a prescription.

This test is intended for use in individuals to suspect a COVID-19 infection.
The REDCELL COVID-19 Self Test is a rapid, lateral flow immunoassay intended for the qualitative detection of SARS-CoV-2 antigens from nasal or mid-turbinate nasal swabs that are self-collected by an individual aged 16 years or older or are collected by an adult from an individual 2 years of age and older.

INTRODUCTION
Covid-19 is an acute respiratory infectious disease. People are generally susceptible. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestation include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases. Some individuals do not show symptoms despite being infected and transmitting the disease.
Antigen is generally detectable in upper respiratory specimens during the acute phase of infection.
A nasal/mid turbinate swab is generally the appropriate sample when testing children aged over 24 months in the community for SARS-CoV-2, the virus associated with COVID-19. The sample collection is generally much less uncomfortable for children and performs well compared with nasopharyngeal sampling in comparative studies and in the experience of a number of pediatric hospitals using this approach. If circumstances arise in which testing of children in the community for SARS CoV-2 only, a nasal/mid turbinate swab is appropriate.

PRINCIPLE
REDCELL COVID-19 Antigen test is a lateral flow immunochromatographic assay for the detection of SARS-CoV-2 N-protein antigens in nasal or mid-turbinate nasal swabs specimens from individuals.
Nasal swabs require a sample preparation step in which the sample is eluted into the extraction buffer solution. Extracted swab sample is added to the sample well of the test device to initiate the test. When the swab sample migrates in the test strip, SARS-CoV-2 viral antigens bind to anti-SARS-CoV-2 antibodies conjugated to indicator and capture particles in the test strip forming an immune complex. The immune complex is then captured by the test line on the nitrocellulose membrane as it migrates through the strip.

DIAGNOSTIC RELEVANCE

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with medical history and other diagnostic information is necessary to determine infection status.
Positive results in an asymptomatic individual are presumptive and may need to be confirmed with a molecular assay tests (NAAT methods, including RT-PCR). Positive results do not rule out a bacterial infection or co-infection with other viruses.
Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or management decisions for the individual, including infection control decisions. Negative results should be considered in the context of an individual's recent exposures, **history** and the presence of clinical signs and symptoms consistent with COVID-19.
It is recommended to seek the opinion of an expert for clinical evaluation of the results obtained and treatment .

MATERIALS SUPPLIED
Each box contains 20 pouches.
One Pouch of Covid 19 Self Test consists of the following components.

1) Covid 19 Antigen Test cassette
2) Nasal Swab (STERILE)
3) Sample Tube
4) Waste bag
5) Package Insert

STORAGE AND STABILITY
The kit can be stored at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

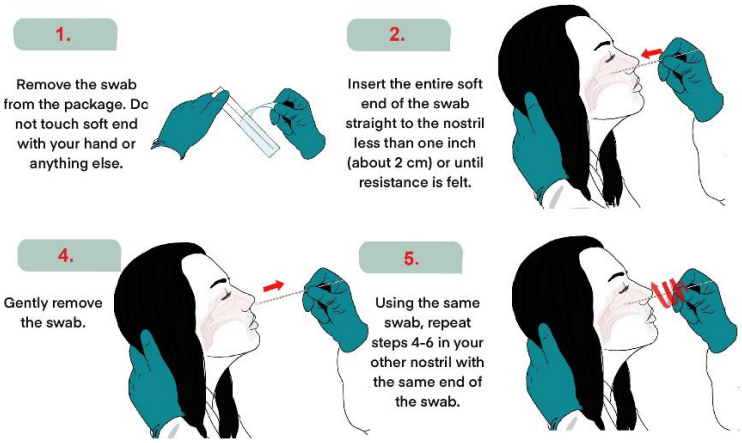
WARNINGS AND PRECAUTIONS

1) This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2) Understand before testing what purpose the test can serve (for early detection of undetectable infections)
3) Be aware that other high quality tests are available. (Consult the expert)
4) Make sure to take the sampling process correctly.
5) Safely evaluate the test result and
6) Act consciously and responsibly according to the test result.
7) Wear protective clothing such as disposable gloves, mask and eye protection during sampling and testing.
8) After use, put the swab , test cassette and test tube in the waste bag, close the lid tightly and dispose of it.
9)Do not use swabs that have a broken tip and stem and do not have a dacron (cotton) zone.
10) Do not use after expiration date.
11) Do not use it if the tube/pouch is damaged or broken.
12) Test is for single use only. Do not re-use under any circumstances.
13) Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
14) Humidity and temperature can adversely affect results.
15) Do not perform the test in a room with strong air flow, i.e.. electric fan or strong air-conditioning.
16) It is recommended to seek the opinion of an expert for clinical evaluation of the results obtained and treatment .

LIMITATIONS
1) The contents of this kit are for the qualitative detection of SARS antigens from nasal swabs.
2) A negative test result may occur if the antigen level in a sample is below the test's detection limit or if the sample has not been correctly collected or stored.
3)Mistakes in the test procedure may affect the test performance and/or invalidate the test result.
4)Test results must be evaluated in conjunction with other clinical data available to the physician.
5) Positive test results do not exclude co-infections with other pathogens.
6) Negative test results do not rule out other viral or bacterial infections.
7) Negative results should be considered a possibility and should be confirmed with a clinical molecular assay, including infection control, as appropriate.
8) A positive result with a suitable antigen test initially indicates a suspicion of a SARS-CoV-2 infection. However, it is not yet a diagnosis of a SARS-CoV-2 infection. The diagnosis is only made by the subsequent RT-PCR test and the medical assessment.
9) It is necessary for the person who tested positive to go into isolation (i.e. consistently reduce contacts) and to contact the family doctor or a suitable test center by telephone.
10) In any case, it is necessary to continue to adhere to infection prevention rules despite a negative antigen test result.
11) These antigen tests are not suitable for use by contact persons in order to avoid or shorten a quarantine on their own responsibility.
12) This IVD has been evaluated for use with human specimen material only.

SPECIMEN COLLECTION
Use the nasal swab supplied in the kit.

Infection prevention and control precautions required by the person taking the sample are as for taking a nasal sample.
Key elements are: to minimize direct physical contact; to maintain distance when possible; to perform hand hygiene (before and after); and to use the following personal protective equipment



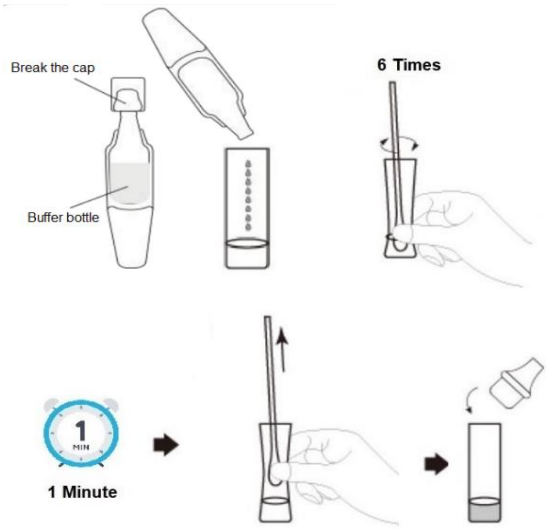
Nasal secretions collection

Hold the swab and insert horizontally (with patient in sitting position) into one nostril parallel to the palate. Insert to the following depth or until resistance is met:
- 1.5 cm if 2-6 years.
- 2 cm if 6-12 years.
- 2-3 cm if more than 12 years.

Rotate swab 5 times against the nasal wall. Follow same method for other nostril. Remove swab and insert into transport medium or vial. Label vial with appropriate patient information.

Specimen extraction

1) Break the cap of the buffer bottle and pour the liquid into the test tube.
2) Insert the swab into the extraction tube which contains extraction buffer. Roll the swab at least 6 times while pressing the head against the bottom and side of the extraction tube.
3) Leave the swab in the extraction tube for 1 minute.
4) Squeeze the tube several times with the fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.
5) Fit the dropper tip with filter on the extraction tube tightly.

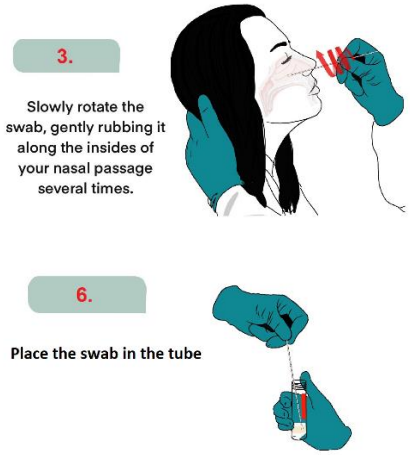


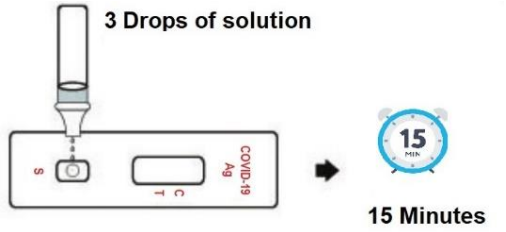
The samples should be treated with the virus sampling solution or the sample extraction solution provided with the kit as soon as possible after collection. And complete the test in 5 minutes.

Waste disposal :

- After use carefully put the swab, test cassette and sample tube into the waste bag and throw it away by closing the mouth tightly.

-Disposable gloves (remove and discard after each person), surgical mask, and plastic apron.



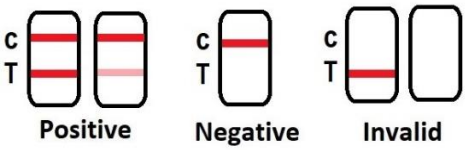


Detection operations

1) Open a pouch containing a test cassette. Place the test cassette on a horizontal work surface.
2) Add 3 drops (about 100 µl) of sample solution extract to the sample well of the cassette.
3) Observe the results showed within 15 minutes.

INTERPRETATION OF RESULTS

Negative: Only red line appears in the control area (**C**), and no line appears in the test area (**T**).
Positive: Two red lines appear. One is in the test area (**T**) an d the other is in the control area (**C**).
Invalid: No red line display in the control area (**C**). This indicates that the incorrect operation or the test cassette has deteriorated or damaged. Repeat the test with a new kit.



QUALITY CONTROL

A procedural control is included in the test. A red line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique.
Control standards are not supplied with this kit; however it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

PERFORMANCE CHARACTERISTICS

1.Analytical sensitivity :

Analytical sensitivity study was carried out with commercially available recombinant antigens of SARS Cov 2 virus with known values.
Analytical sensitivity obtained as a result of testing with the specified antigens is given below.
Nucleoprotein : 50 piccogram

2. Inactivated virus sensitivity:

3. Clinical Performance for RC COVID-19 Self Test
Sensitivity: 96.6 %
Specificity: 99 %
Total agreement rate (%): 99.2 %
Clinical study details: Total 412 Samples .

Clinical performance studies of the antigen tests are performed to compare PCR positive and PCR negative samples. Negative samples are taken from asymptomatic individuals with no apparent risk of COVID-19 infection. The REDCELL Direct SARS-CoV-2 RT-qPCR Kit is included in this study.

154 out of 412 samples were found positive by qPCR test. Of the samples that gave positive results with the PCR test, 149 were detected as positive with the COVID-19 Self Test.
For PCR test, the average Ct at which the antigen tests was positive is 24.8 and the Ct threshold is 33.6.

Although 258 samples were detected as negative by the PCR test, 263 samples were detected as negative with the RC COVID 19 Antigen Rapid Test. Two samples that gave a negative result with the PCR test was detected as positive by the RC COVID 19 Antigen Rapid Test.

COVID-19 Self Test	Direct SARS-CoV-2 RT-qPCR Test		Total
	Positive	Negative	
Positive	149	2	151
Negative	5	256	261
Total	154	258	412

4 .Cross Reactivity
The cross reactivity of REDCELL COVID-19 Self Test was evaluated with a total of 6 bacteria, 10 viruses. Bacteria were evaluated at a concentration over 106 CFU/ml. Viruses were evaluated at a concentration of over 104 TCID50 /ml. None of the microorganisms tested in the following table gave a positive result.

Bacteria panel	**Cross Reactivity (Y/N)**
Escherichia coli	N
Staphylococcus aureus	N
Staphylococcus epidermidis	N
Streptococcus pneumoniae	N
Haemophilus influenzae	N
Pseudomonas aeruginosa	N
Viral panel	
Corona virus (HCoV-OC43)	N
Corona virus (HCoV-NL63)	N
Corona virus (HCoV-229E)	N
MERS	N
Adeno virus type 7	N
Respiratory syncytial virus (18537)	N
Rhinovirus	N
Human parainfluenza virus Type 1-4	N
Influenza A virus (A/TW/344/19 (H1N1))	N
Enterovirus Type 71	N
Influenza B virus (B/TW/2129/19)	N

In the dilution study with 10^9 pfu / ml inactivated SARS Cov 2 virus, it was determined that it reacted at 1 / 30.000 dilution and the sensitivity of inactive virus was 33.000 pfu /ml**.**

5. Interference substances :
Exogenous and endogenous substances were evaluated and did not interfere with REDCELL COVID-19 Self Test at the levels tested below.

Interfering Substances	**Concentration**
Aspirin	20 mg/ml
Oxymetazoline HCl	10 mg/ml
Saline nasal sprays	10%
Whole blood	5%
Hemoglobin	20 mg/ml
Mucin	4.00%
Phenylephrine HCl	100 mg/ml
Dextromethorphan	10 mg/ml
Diphenhydramine HCl	5 mg/ml
Ibuprofen	20 mg/ml

6. Hook Effect:
Even in samples with high virus doses (3.6 x 105 TCID50/mL) no hook effect was detectable.

Label symbols

LOT	Batch code
	Expiry date
30°C 2°C	Storage temperature
	Consult instructions for use
IVD	In vitro diagnostic medical device
REF	Product code
	Manufacturer

REFERRENCE

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2.Masters PS, Perlman S. Coronaviridae. In: Knipe DM, Howley PM, eds. Fields virology. 6th ed. Lippincott Williams & Wilkins, 2013: 825-58.
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8. Antigen-detection in the diagnosis of SARS-CoV-2 infection using rapid immunoassays. WHO Interim guidance 11 September 2020

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REF: RCCOVST

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