core hygienics

**Instructions for Use**
**SARS-CoV-2 Antigen Rapid Test Cassette**

REF COVG-602ST

**Version: Z**
**For self-testing**
Code: 4.15.03.0141-0
**Specimen:** Nasal swab
Effective date: 11-2021

IVD

CE 1434

**Scan this for the instrucional video or**

**to find the instructions for use in other languages.**

## FREQUENTLY ASKED QUESTIONS

- How should I prepare for doing a test?
Regardless of whether or not you have symptoms, please adhere to the basic measures for preventing the spread of coronavirus. Wear a face mask or cover your mouth and nose with a tissue when coughing, and keep at a distance from other people.
- When can I test myself?
You can always test yourself, whether you have symptoms or not. Please note that the test result is a snapshot that is only valid for a short time. Tests should be repeated in accordance with the regulations of the responsible authorities.
- What do I need to do in order to obtain the most accurate test result possible?
Always follow the instructions for use exactly as described. Perform the test immediately after collecting the specimen. Dispense the droplets from the extraction tube only into the designated well of the test cassette. Only dispense two droplets of fluid from the extraction tube. Using too many or too few droplets can lead to an incorrect or invalid test result.
- The test strip in the cassette is discoloured. What is the reason, and what am I doing wrong?
Visible discolouration of the test strip is caused by dispensing too many droplets of fluid from the extraction tube into the test cassette well. The indicator strip can only hold a limited amount of fluid. If the control line does not appear or the test strip is very discoloured, please repeat the test with a new test kit, following the instructions for use.
- What should I do if I took the test but the control line didn't appear?
In this case, the test result should be considered invalid. Please repeat the test with a new test kit, following the instructions for use.
- I am unsure how to interpret the results. What should I do?
If you cannot clearly determine the test result, please contact the municipal health authority.
- My test result is positive. What should I do?
If a horizontal coloured line appears in both the control area (C) and the test area (T), your result is positive, and you should immediately take measures to prevent the spread of the coronavirus and contact the municipal health authority. The municipal health authority will test you again, and if the result is positive, you will receive instructions on what to do next.
- My test result is negative. What should I do?
If a horizontal coloured line appears only in the control area (C), this may mean either that your result is negative or that the viral load is too low to be detected by the test. If you experience symptoms such as headaches, migraines, fever, or loss of sense of smell and taste, please contact the municipal health authority. In addition, you can repeat the test with a new test kit.
- Can this test cassette be reused or used by multiple people?
This test cassette can be used only once, and cannot be reused or used by multiple people.
- Why do I need to swab both nostrils when taking a specimen?
Swabbing both nostrils gives you the best chance of collecting a large enough specimen to generate an accurate result. Some cases have demonstrated the presence of detectable virus in one nostril only, so it is important to collect the specimen from both nostrils. Using the correct swabbing method is important for obtaining an accurate result.

## PACKAGE SPECIFICATIONS

1 test/package, 3 tests/package, 5 tests/package, 7 tests/package, 25 tests/package

## WHAT IS THIS TEST KIT USED FOR?

The kit can be used for rapid testing of suspected COVID-19 cases as well as for PCR tests as confirmation for discharged cases. A positive test result indicates that the specimen contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection. This kit is for use by people without a medical background in a non-laboratory setting (such as at home, or at an office, sports venue, airport, school, etc.). The test results obtained by using this kit are for clinical reference purposes only. It is advisable to carry out a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests. Antigen testing is typically used in the acute phase of infection, when specimens are tested within seven days of the onset of symptoms in a suspected population.

## PRECAUTIONS

Please read all the information in this package insert before performing the test.
- The kit is intended for in vitro diagnostic use only. See the code on the foil packaging for the expiry date.
- The test should remain in the sealed pouch until you are ready to use it.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test should be discarded according to local regulations.
- Avoid the use of bloody specimens.
- Avoid touching the reagent membrane and the specimen well.
- A child or youth wishing to test themselves should be supervised by an adult.

## TEST KIT COMPONENTS

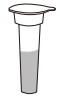
Materials required and provided


Test cassette


Qualification certificate


Instructions for Use


Tube holder (in a box-style packaging, the holder is part of the box)


Extraction tube containing extraction reagent fluid


Extraction tube cap

Extraction tube and cap kit


Sterile swabs

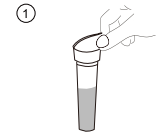
Biohazard waste bag

**Please note:** The components from different batches should not be mixed. Required materials not provided: a timer and disinfection products, such as hand sanitiser, rubbing alcohol, soap, etc.

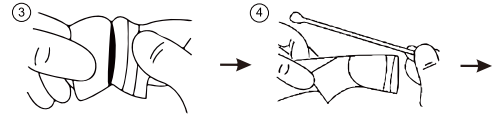
## INSTRUCTIONS FOR USE

**1. Preparation**
- Choose a location to do this test in which the test strip can lie undisturbed for 15-30 minutes. Bring the test cassette, specimen extraction reagent and test components to room temperature for 15-30 minutes, and make sure that they stay at room temperature {15~30°C (59°F-86°F)}.
- Wash your hands with soap and water for at least 20 seconds before carrying out the test. If soap and water are not available, use hand sanitiser containing at least 60% alcohol.
- Do not clean the nasal cavity before the test, in order to ensure that there is sufficient virus material present for the test. If you do clean the nasal cavity, wait at least 30 minutes before collecting the specimen.
- Open the test kit.

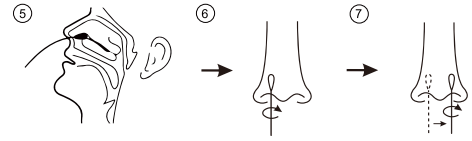
**2 Specimen collection**




- Take out the extraction tube containing reagent and the extraction tube cap and carefully peel off the aluminium foil on the extraction reagent tube.
- Place the tube in the tube holder.




- Remove the swab from the packaging, being careful NOT to touch the soft, absorbent tip.

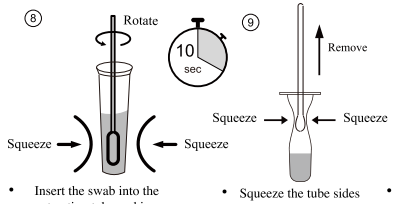



- Gently insert the swab 2-4 cm (1-2 cm for children) into one nostril until you feel a bit of resistance.
- Using medium pressure, rub the swab slowly in a rotating motion around the inside wall of your nostril five times for a period of 7-10 seconds.
- Repeat the same process with the same swab in the other nostril.

**CAUTION: If the swab stick breaks during specimen collection, repeat specimen collection using a new swab. Make sure to use the swab safely while collecting the specimen. Avoid inserting the swab too deeply into the nasal cavity, as this may cause pain and bleeding.**

**Treating the specimen**

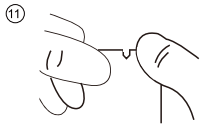
**3.**



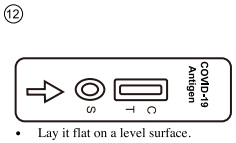

- Insert the swab into the extraction tube and immerse the entire tip of the swab in the extraction reagent.
- Rotate the tip of the cotton swab back and forth in the fluid for 10 seconds and press it against the side of the tube three to five times.
- Squeeze the tube sides together while removing the swab in order to expel any fluid from the swab tip.
- Remove the swab from the extraction tube and close it securely using the extraction tube cap.

**4. Storing the specimen:** The specimen can be stored at room temperature {15~30°C (59°F-86°F)} for one hour.

## TEST PROCEDURE

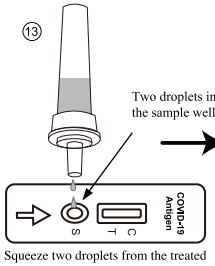



- Open the aluminium foil pouch containing the test cassette and remove the test cassette.



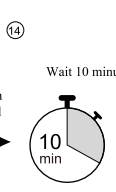

- Lay it flat on a level surface.

**Perform the test**

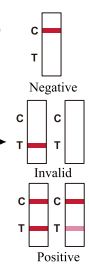



- Squeeze two droplets from the treated specimen into the sample well of the test cassette.

Two droplets in the sample well




- Wait for 10 minutes and then read the test result. The test result will no longer be valid if you wait longer than 30 minutes to read it.




## DISPOSING OF THE SPECIMEN AND CLEAN-UP

- The test cassette, fluid and swab must be placed in the enclosed biohazard waste bag, and can then be disposed of along with the household waste.
- Reapply hand sanitiser.

## INTERPRETATION OF RESULTS

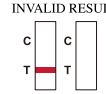
NEGATIVE RESULT:


A single coloured line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that SARS-CoV-2 antigens are either not present in the specimen, or are present in amounts too low to be detected by the test.

POSITIVE RESULT:


Two lines appear. One coloured line appears in the control line region (C) and another appears in the test line region (T). A positive result indicates that SARS-CoV-2 antigens were detected in the specimen.

INVALID RESULT:




Control line fails to appear. The most likely causes of this are insufficient specimen volume or incorrect use of the test. Review the procedure carefully and repeat the test with a new test kit. If the problem persists, stop using the test kit and contact your local distributor.

**PLEASE NOTE:**
The intensity of the test line colour in the test line region (T) will vary depending on the concentration of SARS-CoV-2 antigens present in the specimen. Therefore, any colour in the test line region (T), no matter how pale, should be considered a positive result.

## PRINCIPLE OF THE ASSAY

The SARS-CoV-2 Antigen Rapid Test Cassette is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in human nasal swab specimens. In this test, antibodies specific to the N protein of SARS-CoV-2 are separately applied to the test line region of the test cassette. During the test, the extracted specimen reacts with these antibodies to the N protein of SARS-CoV-2. The mixture migrates through the membrane and reacts with the antibodies to the N protein of SARS-CoV-2 on the membrane, causing a coloured line to appear in the test line region. The presence of this coloured line in the test line region indicates a positive result. A coloured line will always appear in the control line region of the test to show that it has been carried out correctly.

**STORAGE AND STABILITY**
Store the test kit in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable until the expiry date printed on the sealed pouch. The test must remain in the sealed pouch until it is used.

**DO NOT FREEZE**
The date of manufacture and the expiry date are specified on the sealed pouch. Do not use beyond the expiry date.

## LIMITATIONS OF THE TEST

1. The result of this test does not provide absolute certainty. The result should be confirmed by a healthcare professional by means of a new test, clinical symptoms, an epidemiological investigation, and other clinical details.
2. The reliability of the test result is directly correlated with correctly carrying out the test in terms of collecting the specimen, processing, transportation and storage. Any errors made in following the instructions for use may lead to inaccurate results. A false positive result may occur if cross-contamination takes place during the specimen processing.
3. During the early stages of infection, antigen levels in the specimen may be too low for the test to detect, leading to a negative result.
4. A negative result obtained from this test kit should be confirmed by a PCR test. A negative result may occur if the concentration of the SARS-CoV-2 antigens in the specimen is too low to be detected by the test.
5. A negative result is not intended to exclude other non-2019-nCov virus infections.
6. A negative test result does not exclude the possibility of a coronavirus infection and does not exempt you from following the rules for preventing the spread of the virus (such as keeping at a distance from others, and protective measures).
7. Excess blood or mucus on the swab specimen may interfere with the test's performance and yield a false positive result.

## PERFORMANCE CHARACTERISTICS

**Limit of Detection (LoD)**
It has been confirmed that the SARS-CoV-2 Antigen Rapid Test Cassette can detect SARS-CoV-2 at 400 TCID50/ml.

**Investigation into interfering substances**
Test results will not be influenced by the following substances at the specified concentrations:

| Interfering substance | Conc. | Interfering substance | Conc. |
|---|---|---|---|
| Whole blood | 4% | Compound Benzoin Gel | 1. 5mg/ml |
| Ibuprofen | 1mg/ ml | Cromolyn glycate | 1 5% |
| tetracycline | 3ug/ml | chloramphenicol | 3ug/ml |
| Mucin | 0.5% | Mupirocine | 10mg/ml |
| Erythromycin | 3ug/ml | Oseltamivir | 5mg/ml |
| Tobramycin | 5% | Naphazoline Hydrochlo-ride Nasal Drops | 15% |
| menthol | 15% | Fluticasonpropionaat spray | 15% |
| Afrin | 15% | Deoxyepinefrinehydrochloride | 15% |

**Cross-reactivity**
Test results will not be affected by other respiratory viruses and commonly encountered bacterial flora and low pathogenic coronaviruses listed in the table below.

| Name | Concentration |
|---|---|
| HCOV-HKU1 | $10^5$TCID$_{50}$ /ml |
| Staphylococcus aureus | $10^6$TCID$_{50}$ /ml |
| Measles virus | $10^5$TCID$_{50}$ /ml |
| Mumps virus | $10^5$TCID$_{50}$ /ml |
| Mycoplasmal pneumonia | $10^6$TCID$_{50}$ /ml |
| Parainfluenza virus, type 2 | $10^5$TCID$_{50}$ /ml |
| Human coronavirus OC43 | $10^5$TCID$_{50}$ /ml |
| Human coronavirus 229E | $10^5$TCID$_{50}$ /ml |
| Influenza B Victoria LINEAGE | $10^5$TCID$_{50}$ /ml |
| Influenza B Y LINEAGE | $10^5$TCID$_{50}$ /ml |
| Influenza A H1N1 2009 | $10^5$TCID$_{50}$ /ml |
| Influenza A H3N2 | $10^5$TCID$_{50}$ /ml |
| H7N9 | $10^5$TCID$_{50}$ /ml |
| H5N1 | $10^5$TCID$_{50}$ /ml |
| Epstein-Barr-virus | $10^5$TCID$_{50}$ /ml |
| Enterovirus CA16 | $10^5$TCID$_{50}$ /ml |
| Human coronavirus NL63 | $10^5$TCID$_{50}$ /ml |
| MERS coronavirus | $10^5$TCID$_{50}$ /ml |
| MERS CoV Florida/ USA-2 Saudi Arabia 2014 | 1,17 x $10^4$TCID$_{50}$ /ml |
| Respiratory syncytial virus | $10^5$TCID$_{50}$ /ml |
| RSV-A 2006 isolate | 5,01 x $10^4$TCID$_{50}$ /ml |
| RSV-B CH93-18(19) | 1,55 x $10^5$TCID$_{50}$ /ml |

**Clinical performance**
The clinical performance of the SARS-CoV-2 Antigen Rapid Test Cassette has been established by testing 109 positive and 300 negative specimens for the SARS-CoV-2 antigen. Analytical results with correlation to Ct values of the positive samples:

| Ct value | PCR confirmed | Correct number of specimens | Percentage found |
|---|---|---|---|
| ≤30 | 82 | 82 | 100% (sensitivity) |
| ≤32 | 94 | 92 | 97,9% (sensitivity) |
| ≤34 | 102 | 98 | 96,1% (sensitivity) |
| ≤36 | 109 | 103 | 94,5 % (sensitivity) |
| Negative | 300 | 300 | 99,9% (specificity) |
| total | 409 | 403 | 98,5% (total accuracy) |

The correlation between the Ct values of the analysed samples and the sensitivity reveals a sensitivity of 100% (95%CI* 95.5%-100.0%) for samples with a Ct value of up to 30. This sensitivity is 97.9% (95%CI* 92.6%-99. 4%) for specimens with a Ct value of up to 32. This sensitivity is 96.1% (95%CI* 90.4%-98.5%) for specimens with a Ct value of up to 34. The sensitivity is still very good at 94.5% (95%CI* 88.5%-97.5%) up to a Ct value of 36. This is in line with expectations regarding viral detection by antigen rapid testing compared to PCR analysis.
99.9% (95%CI* 98.7%-100%) Specificity: In total 300 negative results confirmed by PCR testing: 300 specimens confirmed negative by PCR testing were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette. There were no cases of false positive results.
98.5% (95%CI* 96.8%-100%) Accuracy: In total, 409 specimens were confirmed by PCR testing: 403 PCR-confirmed specimens were correctly detected by the SARS-CoV-2 Antigen Rapid Test Cassette. The observed accuracy may vary depending on the prevalence of the virus in the population.

## BIBLIOGRAPHY

1.Weiss SR, Leibowitz JZ. Coronavirus pathogenesis. Adv Virus Res 2011; 81:85-164.
2.Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019; 17:181-192.
3.Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016; 24:490-502.

**Index of symbols**

| | | | | | |
|---|---|---|---|---|---|
| | Consult the instructions for use | Σ | Tests per kit | EC REP | Authorised Representative |
| IVD | For in vitro diagnostic use only | | Use by date | | Do not reuse |
| | Temperature limitation | LOT | Lot Number | REF | Catalogue number |
| CE 1434 | For self-testing | | Manufacturer | | Date of manufacture |

**Importer and Distributor:** Core Hygienics
Oud Camp 22, 3155 DL Maasland, Nederland
info@core-hygienics.com
www.core-hygienics.nl

EC REP **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestrasse 80, 20537 Hamburg, Germany

**Hangzhou Sejoy Electronics & Instruments Co.,Ltd.**
Area C, Building 2, No. 365, Wuzhou Road,
Yuhang Economic Development Zone 311100
Hangzhou City, Zhejiang, China
Website: www.sejoy.com