TESTSEALABS®
Rapid Test Kit

Package insert

COVID-19 Antigen Test Cassette-self test

CE 1434 IVD

A Rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal swabs. The test is designed for home test by lay users.

Background

The Common signs of SARS-CoV-2 infection include respiratory Symptoms, fever, cough, shortness of breath and dyspnea. In more severe cases,infection can lead to pneumonia,severe acute respiratory syndrome,renal failure,and even death.There is no specific treatment for diseases caused by SARS-CoV-2.But many symptoms can be treated,if SARS-CoV-2 can be detected or diagnostic early

Intended use

The COVID-19 Antigen Test Cassette is a rapid test for the qualitative detection of SARS-CoV-2 nucleocapsid antigen in anterior nasal swabs. It is used to aid in the diagnosis of SARS-CoV-2 infection that may lead to COVID-19 disease.

The test can be carried out at any time and is suitable for symptomatic persons. Minors must be assisted in the test by Adults

It is recommended to use this test only as a supplement to other diagnostic procedures. The test is designed for self-administration by lay users and can be performed outside the laboratory.

Materials

Materials required - but not supplied:

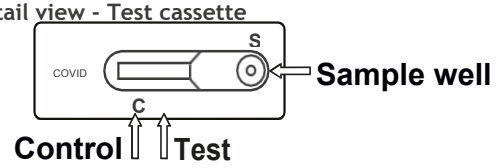
Stopwatch Waste garbage

Materials provided:

Spec	1T	5T	20T
Test cassette	1	5	20
Nasal swab	1	5	20
Prepackaged extraction buffer	1	5	20
Package insert	1	1	1
Tube stand Workbench	/	/	1

Workbench for 1 Pcs and 5 pcs on the back of the box

Detail view - Test cassette



Attention! *Hands should be cleaned carefully before and after testing , the operation area should be located far away from foods and Crowd, After the test,disinfectant should be used to disinfect the operation area;and used test components should be disposed in accordance with local regulations.*

Test procedure

1. Open the packaging. You should have the test cassette 、 Prepackaged extraction buffer、 the nasal swab and package insert in front of you.

Attention! Put the illustrated quick start guide with it.

The test should be used at room temperature 15-30°C . Wash or disinfect your hands and make sure they are dry.

Open the foil pouch with the test cassette and place it in front of you. Place the tube in the tube stand workbench. Depending on which variant you have, a separate tube stand is included in the test cassette. please use the tube stand workbench in the packaging. To do so, press the perforation on the back.

2. Peel the foil seal from the top of the extraction tube containing the extraction buffer.

3. Open the swab on the side of the swab tip. Carefully remove the swab without touching the tip.

Insert the entire tip of the swab 2 to 3 cm into the right nostril. You can feel this with your fingers when inserting the nasal swab or check it in the mirror. Rub the inside of the nostril in circular movements 5 times for at least 15 seconds.when minors are tested the swab insertion depth should be smaller than for adults.

4. Now take the same nasal swab and insert it into the other nostril. Swab the inside of the nostril in a circular motion 5 times for at least 15 seconds. Please perform the test directly with the sample and do not leave it standing!

Attention! For an accurate result, you must carefully rub both nostrils with the nasal swab for 15 seconds each.

5. Place the nasal swab into the tube filled with extraction buffer . Rotate the swab for at least 30 seconds while pressing the swab tip against the inside of the tube,to release the antigen in the swab.

Attention! For an accurate result, the swab must remain in the extraction tube for the full 30 seconds.

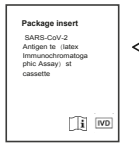
6. Press the swab tip against the inside of the tube. Try to release as much liquid as possible from the swab.

7. Put the cap tightly back on the tube to avoid any leaks

8. Place 3 drops of sample from the top into the sample well of the test Cassette. The sample well is the round recess at the bottom of the the test Cassette and is marked with an "S". Start the stopwatch and wait 15 minutes before reading, even if the control line becomes visible before. Before that, the result may not be correct.

Attention! *For an accurate result, wait 15 minutes before reading, regardless of whether the control line appears beforehand.*

results read after 20 minutes are invalid.



You will find the instructions for evaluation and interpretation on the reverse side.

9. Used components should be disposed of in accordance to local regulations.

Frequently asked questions

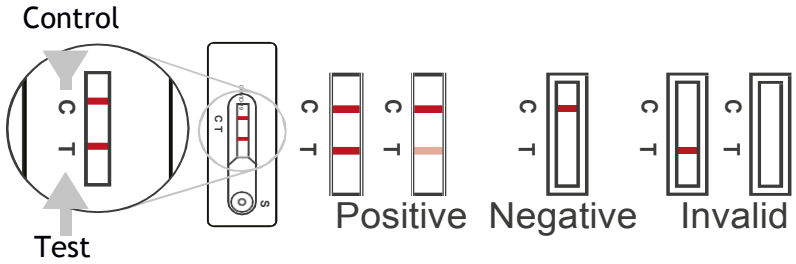
When can I test myself?

The test can be done at any time and is suitable forsymptomatic persons from the age of 15 years. Minors must be accompanied by a Adult during the test. Please follow the instructions of your physician or local health department if you are testing after a diagnosed SARS-CoV-2 disease. Please note that the test result is basically a snapshot and this means that you are unlikely to be infectious in the next 6 hours. Please follow instructions from authorities on how often a test should be repeated.

The test shows a colored line in the test region (T) after some times that the test has been performed. Is the test now positive?

The test result should only be read within 15-20 minutes after application of the sample. If there are any changes after this time, they are not relevant for the test. You can repeat the test at any time with a new test Cassette.

Test-Evaluation



Negatives Test result

one colored line appear in the control region (C). No apparent colored line appear in the test region (T). Make sure that you have waited the full 15 minutes. The negative result indicates that no SARS-CoV-2 antigens could be detected in your sample

SARS-CoV-2 antigens were no founded in the sample or the amount is below the detection limit.

Please note that the test result is basically only a reference and this means that you are highly unlikely to be infectious for the next 6 hours.

If you still experience symptoms related to COVID-19 disease, such as loss of sense of taste and smell, fever, cough, or headache, please contact a medical facility in accordance with applicable regulations

If it is a negative result , but with typical symptoms of SARS-CoV-2 infection , it is still nessary to go to a professional medical institution as soon as possible

Positives Test result

Two colored line appear.One colored line appears in the control region (C) and one colored line appears in the test region (T). The test is considered positive as soon as even a faint line appears. A positive result means that SARS-CoV-2 antigens were detected in your sample.

Attention! Parts of the SARS-CoV-2 virus were detected in your sample.

Attention! Please go into self-isolation immediately.

If the results are positive, It is best to contact the nearest medical facility and follow local regulations.

Invalid Test result

No colored line appears in the control region (C). The test is invalid even if there is one line in the test region (T). Insufficient sample volume or incorrect handling are the most likely reasons for this.

Check the test procedure and repeat the test with a new test cassette.
If the problem persists, stop using the test immediately and contact the distributor.

What should I do if I am unsure about the evaluation?

If you cannot interpret the result clearly, please contact a medical facility.

What do I have to pay attention to in order to obtain the most accurate result possible?

Read the Package insert carefully before carrying out the procedure and follow the Package insert exactly. Carry out all steps carefully in the order given, making sure to apply exactly three drops from the extraction tube into the sample well.

Can I use or reuse the test with more than one person?

The test and the included test cassette are designed for single use. Please do not use any components more than once and only use the components included in this test kit.

Can the rapid antigen test detect viral mutations?

Emerging viral mutations mainly alter the spike protein of the virus. However, this test detects the nucleocapsid protein, which is unaffected by most mutations. According to the current state of knowledge, the detection of an infection is just as possible with this test

Safety precautions

- For in vitro diagnostic use only. Do not use after the expiry date. Read the Package insert carefully before use and use only the ingredients included in this test cassette .
- Make sure that the foil pouch containing the test cassette is not damaged before opening it for use. The test cassette should be used within 30 minutes after opening the foil pouch.
- Wear gloves and personal protective equipment when applying foreign samples. Do not touch the reagent membrane and the sample well.
- Do not eat, drink or smoke in the area where the samples and kits are handled.
- the user should not take any decision of medical relevance without first consulting his or her medical practitioner
- Handle all samples as if they contained infectious agents
- Carry out the test at a room temperature of 15 - 30 °C.
  Humidity not more than 90%, Humidity and temperature can influence the results.
- Do not return the nasal swab used to collect the sample to its original paper packaging.

Restrictions

- The test result of the COVID-19 Antigen Test Cassette should not be used as the only method for the diagnosis of SARS-CoV-2 infection. Further molecular diagnostics and clinical parameters should be used for a diagnosis
- Incorrect sampling may result in a false negative result
- the test should not be used if the packaging is damaged
- the test should not be used if stored in abnormal conditions

- This test detects both replicable and nonreplicable SARS-CoV-2 viruses. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral load.
- Positive test results do not rule out co-infection with other pathogens. Please contact your local medical facility or GP for repeat tests or further molecular diagnostics.
- Positive test results do not differentiate between SARS-CoV and SARS-CoV-2.
- False results may occur if samples are not tested immediately after collection. Samples should be tested immediately after collection.
- sampling for too short a time may produce a negative result.
- A negative test result may occur if the antigen concentration in a sample is below the detection limit of the test. This can occur especially in the first asymptomatic days after infection.
- False negative results may occur if a sample is collected, transported or handled improperly.
- Negative results from patients with symptom onset after more than seven days should be treated as presumptive and confirmation with another molecular assay should be done.

Storage and stability

Store at room temperature or in a cool dry place(4-30°C). Do not freeze. The shelf-life of the test kit is 24 months. printed on the sealed test cassette. Do not use after the expiry date. The test must remain in the sealed pouch until use.

Principle of the rapid test

The COVID-19 Antigen Test Cassette is a qualitative immunoassay based on a membrane for the detection of SARS-CoV-2 Nucleocapsid (N) antigen in nasal swabs. In this assay, an anti-SARS-CoV-2-N antibody is immobilised in the test zone of the membrane. After a sample is placed in the sample well, it reacts with anti-SARS-CoV-2-N antibody coated particles that are on the sample pad. This mixture migrates chromatographically along the length of the test membrane and interacts with the immobilised anti-SARS-CoV-2-N antibody

If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line region, indicating a positive result. If the sample does not contain SARS-CoV-2 antigen, no coloured line appears in this area, indicating a negative result. As a procedural control, a coloured line always appears in the control line region, indicating that the correct sample volume has been added and the membrane has been wetted through.

Reagents

The test contains an anti-SARS-CoV-2-N antibody as capture reagent and another anti-SARS-CoV-2-N antibody as detection reagent. A goat anti-mouse antibody is used in the control line system.

Performance features

Detection limit: The detection limit of the test was determined with infectious SARS-CoV-2 virus and is 100pg/ml.

Clinical parameters

To determine sensitivity and specificity, the COVID-19 Antigen Test Cassette was performed as a nasal swab, as described in the package insert, and compared to a commercial PCR assay.

Sensitivity describes the percentage of cases in which the test cassette correctly detects a positive sample.

Specificity describes the percentage of cases in which the test cassette correctly detected a negative sample.

Sensitivity	95.1%
specificity	>99.9%

		Vitassay Healthcare S.L.U. kit (PCR)		Total
		positive	negative	
COVID-19 Antigen Test Cassette	positive	214	0	214
	negative	11	459	470
Total		225	459	684
agreement		95.1%	>99.9%	98.54%

Project	Value	Percentage (95% confidence interval)
Relative Sensitivity	214/225	95.1% (91.36%～97.34%)
Relative Specificity	459/459	>99.9%(99.00%～100.00%)

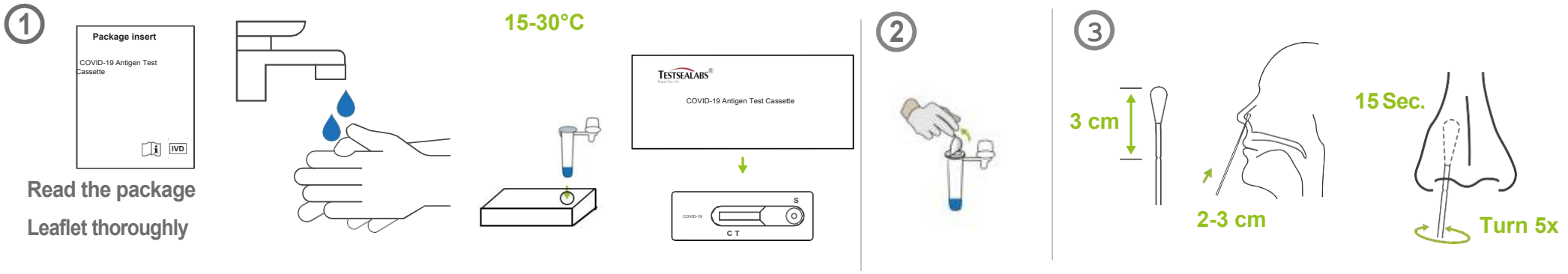
The sensitivity of COVID-19 Antigen Test Cassette is 95.1%, that is to say, 95 out of 100 patients can be detected as positive patients, and the other 5 are false negative, that is to say, there is a 5% probability of false negative.

The specificity of COVID-19 Antigen Test Cassette is >99.9%

Cross-reaction: The COVID-19 Antigen Test Cassette has been tested for specificity and cross-reactivity with other pathogens that may cause similar symptoms. No cross-reaction with other strains and Virus

Pathogen	Concentration
Pseudomonas aeruginosa	$1x10^8$ org/mL
Streptococcus sp group F	$1x10^8$ org/mL
Streptococcus salivarius	$1x10^8$ org/mL
Streptococcus pygenes	$1x10^8$ org/mL
Streptococcus pneumoniae	$1x10^8$ org/mL
Staphylococcus epidermidis	$1x10^8$ org/mL
Staphylococcus aur. subspaureus	$1x10^8$ org/mL
Neisseria subflava	$1x10^8$ org/mL
Neisseria lactamica	$1x10^8$ org/mL
Moraxella catarrhalis	$1x10^8$ org/mL
Escherichia coli	$1x10^8$ org/mL
Corynebacterium	$1x10^8$ org/mL
Candida albicans	$1x10^8$ org/mL
Arcanobacterium	$1x10^8$ org/mL
Human Coronavirus OC43	2.45×10^6 LD_{50} /ml
Human Coronavirus NL63	1.17×10^5 U/ml
Influenza A H1N1	3.16×10^5 $TCID_{50}$/ml
Influenza A H3N2	1×10^6 $TCID_{50}$/ml
Influenza B	3.16×10^6 $TCID_{50}$/ml
Human Rhinovirus 2	2.81×10^4 $TCID_{50}$/ml
Human Rhinovirus 14	1.58×10^6 $TCID_{50}$/ml
Human Rhinovirus 16	8.89×10^6 $TCID_{50}$/ml
Masern	1.58×10^4 $TCID_{50}$/ml
Mumps	1.58×10^4 $TCID_{50}$/ml
Parainfluenza Virus 2	1.58×10^7 $TCID_{50}$/ml
Parainfluenza Virus 3	1.58×10^8 $TCID_{50}$/ml
Respiratorisches Syncytial-Virus	8.89×10^4 $TCID_{50}$/ml
Human coronavirus 229E	1×10^6 $TCID_{50}$/ml
MERS	1.5×10^6 $TCID_{50}$/ml

Quick guide



Symbol	Meaning	Symbol	Meaning
IVD	Medical in vitro diagnosis		Storage temperature Limits (4-30°C)
	Manufacturer	Σ	Tests per set
LOT	Batch code		Do not reuse
	Follow the Package insert	EC REP	Authorised Representative in the European Community
	Expiry date	REF	Catalogue number
	Date of manufacture		Do NOT USE IF PACKAGE IS DAMAGED
CE 1434	Standard of 98/79/EC	CE 0197	CE mark of Swab
STERILE EO	Swabs are sterilized	CE 0123	CE mark of Swab

Interfering substances: The following compounds were tested with COVID-19 Antigen Test Cassette. No interference was obsereved

Substance	Substance
Whole Blood	Mupirocin
Mucin	Oxymetazoline
Budesonid Nasenspray	Phenylephrine
Dexamethasone	Rebetol
Flunisolide	Relenza

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www.testsealabs.com

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