English

Instruction manual

SARS-CoV-2 Antigen Rapid Test

Read the instructions for use completely before performing the test.

For in vitro diagnostic and for self-testing use.

Product

SARS-CoV-2 Antigen Rapid Test

Purpose

HIGHTOP Antigen Rapid Test for self-application is used for the detection of SARS-CoV-2 antigens in samples from the human anterior nasal cavity area. It is used to detect SARS-CoV-2 nucleoprotein antigens within 7 days of the onset of symptomssuspected of coronavirus infection. Positive test results can be used for early isolation and rapid treatment of suspected cases, but they cannot serveas a basis for a definitive diagnosis of coronavirus infection.

Important for self-application:

In case of a positive test result, please isolate yourself and contact your doctor or call the Corona hotline. A positive test result must be confirmed by a PCR test.

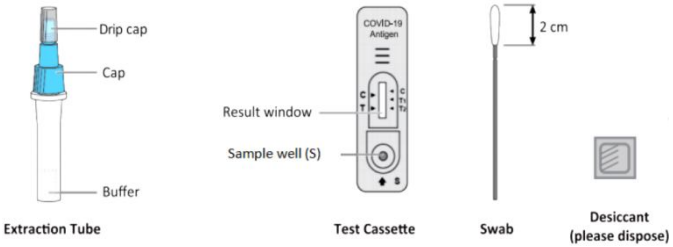
Note that even if the result is negative, infection is not guaranteed to be excluded, as a low virus load or a possible sampling error can result in a wrong result.

Delivery

Test cassette & desiccant

Extraction tubes with buffer, cap and drip cap

Swab



Note: The diagram is for reference only. See the real object for details.

The appearance of extraction tube and color of it's cap may be different from the actual product, which has no effect on normal use.

An error of 0.3cm in the length of the sampling swab head will not affect results, it can be used normally.

MATERIALS REQUIRED BUT NOT PROVIDED

Watch/Timer

Garbage bag

Safety

1. The test kits should be stored at temperatures of 4-30°C and should not be exposed to direct sunlight or moisture. Before use, tests stored at low temperature should be brought to room temperature.
2. Do not use expired and damaged products. The expiry date is printed on the outer packaging.
3. Suitable for people aged 16 and over. Keep the test kits away from young children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
4. The test cassette should be used as soon as possible after removal from the foil bag to avoid prolonged exposure to moisture, as these could affect the test result.
5. Under room temperature (15-30°C) and humidity of less than 60%, the test kits must be used within half an hour after opening the packaging. If the humidity exceeds 60%, use immediately after opening the packaging.
6. Do not freeze the test kits.
7. The test set should be disposed after use in a lockable garbage bag in the household waste.
8. Incorrect operation may affect the accuracy of the results, such as e. g. too little effective time in the buffer solution, too little or too much buffer in the solution, insufficient sample addition, inaccurate detection time, etc.
9. False-negative results can occur when the swab is placed in a bag between sampling and evaluation.
10. Do not suck the sample with your mouth.
11. During the test, do not smoke, eat, drink alcohol, apply make-up or put in contact lenses, or take them out.
12. Disinfect spilled samples or reagents with disinfectant.
13. If the extraction reagent come into contact with the skin or eyes, wash / rinse the affected area with plenty of water. If irritation is found, contact your doctor.
14. After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.
15. Wash hands thoroughly after test completion.

Test flow

Bring all components of the test kit 30 minutes before use to room temperature (15-max. 30°C) and wash your hands.

1. Preparation:

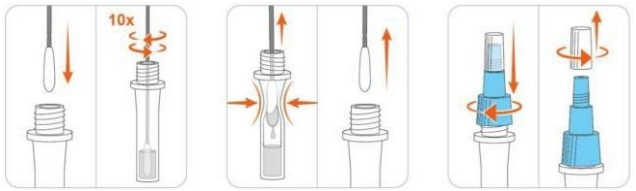
- Have a watch ready or use a timer.
- Open the extraction tube with buffer by unscrewing the cap. Do not spill the liquid.
- Open the foil bag with the test cassette at the marked location and discard the desiccant.
- Remove the test cassette and place it on a flat and clean surface. The test cassette becomes unusable half an hour after opening. Therefore, perform the test immediately.
- Unpack the swab on the stem.

2. Sample in the anterior nose:

- Insert the swab about 2-2.5cm into the first nostril. The swab tip should be completely immersed in the nasal cavity. If you feel resistance, no longer penetrate deeper into the anterior nose.
- Rub 5 times in circular movements on the inner nasal wall (approx. 15 sec.).
- Then insert the same swab into the second nostril and repeat the above operation.

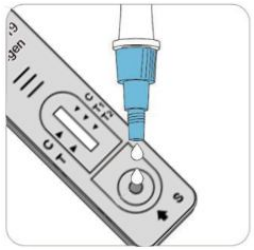
3. Preparation of the sample

- After sampling, immerse the swab in the solution of the extraction tube and rotate the swab 10 times. Let it work for 1 minute.
- Squeeze out the swab using the extraction tube. Collect the liquid in the tube.
- Remove the swab and put it in the garbage bag.
- Close the extraction tube with the sample with the cap. Unscrew the drip cap at the top. The sample is ready for testing.



4. Evaluation of the sample

- Add 2, max. 3 drops of mixed liquid from the extraction tube to the sample well (S) to the test cassette.



- Read the result after 15 minutes. Results after 20 minutes have no

meaning.

- Note: Do not reuse the test cassette. It is for single use only.

Interpretation of the test result

POSITIVE: A red line appears on both the control line (C) and the test line (T)

NEGATIVE: The red line appears only on the control line (C), no red line on the test line (T).

INVALID: If no line appears on the control line (C), indicating insufficient sample volume, incorrect operation, or expired tests.

The lines shown can vary in intensity!

Restrictions of the test procedure

1. The results of this product should not be considered a definitive diagnosis and are for clinical reference only. The judgment should be based on the RT-PCR results, clinical symptoms, prevalence of infectious diseases, and other clinical data.
2. If the virus antigen content in the sample is below the detection limit, the test result may be negative.
3. As the disease lasts, the number of antigens in the sample may decrease and the results may be negative 7 days after symptoms appeared compared to the RT-PCR test.
4. Due to the limitations of testing procedures, negative results cannot rule out the possibility of infection. A positive result should not be viewed as a definitive diagnosis, but should be assessed in the context of clinical symptoms and other diagnostic methods.

Quality

The test cassette has a test line (T) and a control line (C) on the surface of the membrane. Neither the test nor control line is visible in the results window before a sample is applied. The control line is used for procedural control and should be displayed whenever the test procedure is properly carried out and the control line reagents work.

The occurrence of the control line (C) confirms sufficient sample volume, sufficient membrane discharge and correct process technology.

Test principle

The rapid test is based on the GICA principle, whereby the nitrocellulose membrane is coated with monoclonal coronavirus (SARS-CoV-2) antibody 2 and goat-anti-mouse IgG antibody, the monoclonal coronavirus (SARS-CoV-2) antibody 1 fixed on a gold conjugate pad solid phase. When the antigen is contained in the sample, it combines with the appropriate gold-labelled monoclonal antibodies to form a complex and moving forward under the chromatography on the membrane, then combines with the coated antibody on the test line to form Au-novel coronavirus (SARS-CoV-2) monoclonal antibody 1-antigen-novel coronavirus (SARS-CoV-2) monoclonal antibody 2 complex to condenses into a red band (Test line, T).

Excess particles are intercepted at the control line (C). If a red line appears in the test line area (T), this should be considered a positive result.

If no antigen is included in the sample, no complex can form on the test line, and no red line appears, which is a negative result. The gold-labelled monoclonal antibody binds to the coated goat-anti-mouse IgG antibody on the control line to form a complex of "Au-coronavirus (SARS-CoV-2) monoclonal antibody 1-goat-anti-mouse-IgG antibody", regardless of whether the sample contains antigen, and the color is developed as a cohesion (Control line, C). If the control line is not visible, the test must be repeated with a new cassette.

Performance specification of the rapid test

1. Limit of Detection

The LOD of SARS-CoV-2 Antigen Rapid Test is 8 $TCID_{50}$/mL.

2. Clinical performance

The performance of the SARS-CoV-2 antigen rapid test was evaluated in Germany with European subjects. A total of 402 frozen swab samples including 102 positive samples and 300 negative samples from the anterior nose were tested. All the swab specimens were confirmed as positive or negative and validated with Ct value by the RT-PCR (throat swab) as a comparator method.

SARS-CoV-2 Antigen Rapid Test	RT-PCR		Total
	Positive	Negative	
Positive	100	0	100
Negative	2	300	302
Total	102	300	402

Sensitivity (Ct≤36): 98.04% (95%CI:93.13%-99.44%)
Specificity: 100% (95%CI:98.74%-100%)
Reliability: 99.5% (95%CI:98.20%-99.86%)

Explanation of terms:

Sensitivity: right positive / all positives*100
Specificity: right negative / all negatives * 100
Reliability: (right positive + right negative) / total * 100

3. Analytical specificity

1) Interfering substances

The test showed no interference with following substances:

Name	Concentration	Results
Mucin	0.50%	Negative
Blood (human)	5%	Negative
Guaiacol glyceryl ether	1ug/mL	Negative
Arbidol hydrochloride hydrate	1mg/mL	Negative
Zanamivir	2mg/mL	Negative
Meropenem	1mg/mL	Negative
Oseltamivir	3mg/mL	Negative
Ritonavir	1mg/mL	Negative
Peramivir trihydrate	3mg/mL	Negative
Ribavirin	1mg/mL	Negative
Histamine hydrochloride	2mg/mL	Negative
Levofloxacin	1mg/mL	Negative
Oxymetazoline hydrochlorid	1mg/mL	Negative
Ceftriaxone sodium	1mg/mL	Negative
Cefradine	100mg/mL	Negative
Cefalexin	100mg/mL	Negative
Benzocaine	5mg/mL	Negative
Tobramycin	2mg/mL	Negative
Lopinavir	1mg/mL	Negative
Azithromycin	3mg/mL	Negative
Watermelon frost buccal tablets	100mg/mL	Negative
Dexamethasone	0.5mg/mL	Negative
Flunisolid	2mg/mL	Negative
Beclomethasone	10mg/mL	Negative
Sodium chloride	0.90%	Negative
Alpha interferon	1mg/mL	Negative
Phenylephrine hydrochloride	5mg/mL	Negative
Acetaminophen	10mg/mL	Negative
Ibuprofen	1mg/mL	Negative
Aspirin	5mg/mL	Negative
Acetylsalicylic acid	5mg/mL	Negative
Hydrocortisone	1mg/mL	Negative
Albuterol	1mg/mL	Negative
Chlorpheniramine	5mg/mL	Negative
Diphenhydramine	5mg/mL	Negative
Budesonide	10mg/mL	Negative
Mometasone	1mg/mL	Negative
Fluticasone	1mg/mL	Negative
NeilMed	5mg/mL	Negative
Menthol	0.15mg/mL	Negative
Quinine (malaria)	150uM	Negative
Lamivudine (retroviral drug)	1mg/mL	Negative
Biotin	100ug/mL	Negative
HAMA	600ng/mL	Negative

2) Cross-reactivity

By testing 26 viruses and 14 other microorganisms, except for the Human SARS-coronavirus Nucleoprotein, other viruses and microorganisms have no effect on the test results.

Virus	Concentration	Results
HCoV-NL63	1 x 10^5 $TCID_{50}$/mL	Negative
HCoV-OC43	8 x 10^5 $TCID_{50}$/mL	Negative
HCoV-229E	1 x 10^5 $TCID_{50}$/mL	Negative
HCoV-HKU1	10ug/mL	Negative
MERS	4 x 10^4 $TCID_{50}$/mL	Negative
Human SARS-coronavirus Nucleoprotein	25ng/mL	Positive
Adenovirus Type3	1.0 x 10^6 $TCID_{50}$/mL	Negative
Adenovirus Type7	1.0 x 10^6 $TCID_{50}$/mL	Negative
Adenovirus Type1	2 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus Type5	3 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus Type8	2.5 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus Type11	3 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus Type21	3 x 10^5 $TCID_{50}$/mL	Negative
Adenovirus Type55	3 x 10^5 $TCID_{50}$/mL	Negative
Echovirus	4.0 x 10^5 PFU/mL	Negative
Influenza virus A (H1N1)	2.5 x 10^5 PFU/mL	Negative
Influenza virus A(H3N2)	8.0 x 10^4 PFU/mL	Negative
Influenza virus B Strain	3 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza Type 1	1 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza Type 2	1 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza Type 3	1 x 10^5 $TCID_{50}$/mL	Negative
Parainfluenza Type 4	1 x 10^5 $TCID_{50}$/mL	Negative
Respiratory syncytial virus (RSV) type A	4 x 10^5 $TCID_{50}$/mL	Negative
Respiratory syncytial virus (RSV) type B	4 x 10^5 $TCID_{50}$/mL	Negative
Rhinovirus A16	1 x 10^5 $TCID_{50}$/mL	Negative
Human Metapneumovirus (hMPV) 16 Type A1	1 x 10^5 $TCID_{50}$/mL	Negative
Candida albicans	1.8 x 10^6 CFU/mL	Negative
Legionella pneumophila	1 x 10^6 CFU/mL	Negative
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL	Negative
Pseudomonas aeruginosa	1 x 10^6 CFU/mL	Negative
Staphylococcus epidermidis	1 x 10^6 CFU/mL	Negative
Staphylococcus salivarius	1 x 10^6 CFU/mL	Negative
Mycoplaa Pneumoniae	1 x 10^6 CFU/mL	Negative
Chlamydia Pneumoniae	1 x 10^6 CFU/mL	Negative
Streptococcus pyogenes	1 x 10^6 CFU/mL	Negative
Mycobacterum tuberculosis	1 x 10^6 CFU/mL	Negative
Hemophilus influenzae	1 x 10^6 CFU/mL	Negative
Bordetella pertussis	5 x 10^6 CFU/mL	Negative
Pneumocystis	1 x 10^6 CFU/mL	Negative
Pooled human nasal wash	NA	Negative

3)Microbial Interference Studies

By testing 10 other microorganisms, it was found that other microorganisms have no effect on the test results.

Other microorganism	Concentration	Results
Staphylococcus aureus	1 x 10^6 CFU/mL	Negative
Escherichia coli	1 x 10^6 CFU/mL	Negative
Streptococcus salivarius	1 x 10^6 CFU/mL	Negative
Proteus mirabilis	1 x 10^6 CFU/mL	Negative
Klebsiella pneumoniae	1 x 10^6 CFU/mL	Negative
Staphylococcus haemolyticus	1 x 10^6 CFU/mL	Negative
Mumps Virus Ag	2 x 10^3 $TCID_{50}$/mL	Negative
Avian Influenza Virus（H7N9）	8.0 x 10^4 PFU/mL	Negative
Measles virus	2 X 10^3 $TCID_{50}$/mL	Negative
Norovirus	1 X 10^5 $TCID_{50}$/mL	Negative

4. Hook Effect

No high dose hook effect was observed up to 1.6 x 10^5 $TCID_{50}$/mL of SARS-CoV-2 with SARS-CoV-2 Antigen Rapid Test.

What your results mean and what to do with your results

Positive result

A positive result means it is very likely you have SARS-CoV-2 infection. Please isolate yourself, stay at home, avoid contact with your roommates as much as possible and don't receive visitors. Contact your doctor or call the Corona hotline. A positive test result must be confirmed by a PCR test.

Negative result

This means you probably don't have SARS-CoV-2 infection. Pay attention! A negative result of a self-test is not 100% reliable. So stay careful. You still need to take precautions. Keep your distance, wear a mouth mask and wash your hands often.

Invalid result

An invalid result means this test was unable to determine whether you have SARS-CoV-2 or not. A new test is needed to get a valid result.

Explanation of the symbols

	Consult instructions for use		Keep dry
30℃ 4℃	Temperature limit	LOT	Batch code
	Do not re-use	IVD	*In vitro* diagnostics medical device
	Manufacturer		Date of Manufacture
	Use-by date	Σ	contains sufficient for <n> tests
EC REP	Authorized representative in the European Community		Keep away from sunlight
CE 1434	CE Marking, certified by Polish Centre For Testing And Certification		

Information of swabs

The information about swab manufacturer, CE number and European representative are placed on swab package and outer packing box.

Manufacturer information

MANUFACTURER / POST-SALE SERVICE UNIT

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