Coretests® COVID-19 Ag Test

Instructions for use for article numbers (REF) 1002 and 1003
In-vitro diagnostics. For professional use only.
Please read the instructions for use carefully before use.

General

USAGE

The Coretests® COVID-19 Ag test is a chromatographic test and is used for the qualitative detection of the COVID-19 antigen in humans by means of a nasopharynx, nasal cavity swab (front nose) or throat swab. The target antigen that is detected with the test is an N-protein (nucleocapsid) with a high degree of preservation, even in the case of virus mutations. It is designed to detect SARS-CoV2 disease in the early phase of the disease, especially immediately after the onset of typical disease symptoms. This test should never be used as the sole basis for diagnosing or excluding a possible SARS-CoV2 disease. SARS-CoV-2 is mainly transmitted through direct contact with secretions or through aerosols and droplets. The clinical symptoms are fever,weakness and systemic symptoms with dry cough, difficulty breathing etc. and can lead to severe pneumonia, respiratory failure, acute,respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolic disorders, etc. and even quickly life-threatening to develop.

SCOPE OF DELIVERY OF THE PACKAGING UNIT

Scope of delivery	5 Testkits (REF 1002)	25 Testkits (REF 1003)
Coretests® COVID-19 Ag test cassette, partially welded	5	25
Swab swabs, sterile packed	5	25
Sample tube with Reagent liquid	5	25
Instructions for use (this document)	1	1
Sample holder	1	1

GENERAL NOTES AND PRECAUTIONS

- Read the instructions for use carefully before performing this test.Improper use or an incorrect test procedure can lead to incorrect test results.
- The test cassette can be used for a single test.It cannot be reused.
- The test device should remain in the sealed pouch until use.Do not use the test cassette if the pouch is damaged or the seal is broken.
- The test cassette must not be used after the expiry date.
- Store the test between + 2 ° C and + 30 ° C in the closed original packaging.
- The test should be carried out at room temperature (between + 15 ° C and + 30 ° C). If the test was stored in a cooler environment, wait to start the test until the components have warmed up to room temperature
- The test has been validated with the attached nasal swab. You can use a different swab or a commercially available cotton swab possibly lead to an incorrect test result.

LIMITATION OF THE TEST

- The test results in a negative test result,if the viral load in the sample is below the specified minimum detection limit
- If a COVID-19 infection is still suspected, a negative test result should not be used as the only validation method.
- A positive test result can also be caused by an infection with pathogens (other pathogens)

DISPOSAL

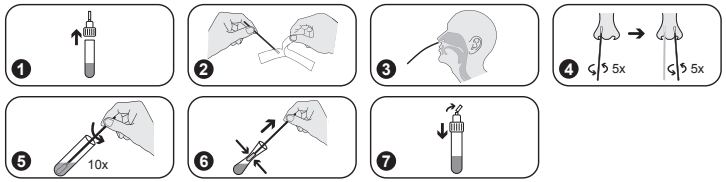
The test samples should be considered as infectious agents and the use should be in accordance with the hygiene regulations for infectious material respectively. After performing the test, all potentially infectious materials should be disposed of in a sanitary waste container.
Although the reagent solution deactivates the virus inside the sample tube, the test samples should still be regarded as infectious agents and use should be made in accordance with the hygiene regulations for infectious material. After performing the test, all potentially infectious materials should be disposed of in a sanitary waste container. The handling and disposal of potentially infectious materials should be in accordance with local, national or regional regulations.

Test procedure in three phases

1.TEST PREPARATION

Notes:
- Wash your hands thoroughly before collecting a sample.
- Avoid touching the tip of the swab before, during or after the swab.
- It is recommended to process the sample immediately after taking it, within one hour at the most.
- Have a stopwatch or clock ready.

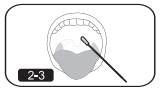
Passage through the nasal cavity



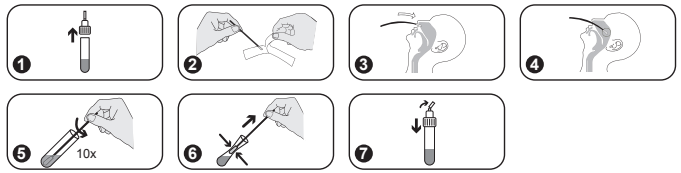
1. Unscrew the lid of the sample tube.
2. Take the nasal swab into out of the packaging.
3. Gently insert the swab 2-3 cm into the nostril.
4. Roll the swab 5 times along the nasal mucosa in the nostril so that both secretion and cells are absorbed. Repeat the process with the same swab in the other nostril to collect a sample from both nostrils.
5. Insert the swab into the tube all the way to the bottom. Turn the swab 10 times and squeeze it out at the bottom.
6. Squeeze the tube a few times with two fingers so that the swab is wrung out before removing it.
7. Screw the cap onto the sample tube, break off the tip of the cap, and then begin the test procedure.

Alternative or additional throat swab (oropharyngeal)

Follow steps 1 and 4-7 analogous to the procedure for the nasopharyngeal swab. Instead, steps 2 and 3 should be carried out as follows:
2. Insert the swab into the back of the throat, into the tonsil area.
3. Carefully stroke the swab over the tonsil columns and the base of the throat. Avoid using teeth, gums and tongue touch.



Execution of the nasopharyngeal swab:

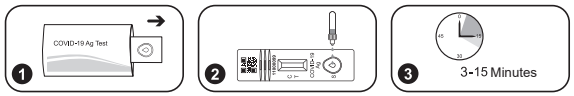


1. Unscrew the lid of the sample tube.
2. Take the nasopharyngeal swab out of the packaging
3. Carefully insert the swab into the patient's nostril until the base of the nasopharynx can be felt.
4. Gently move the swab over the surface of the base of the nasopharynx a few times and then carefully remove the swab from the nostril.
5. Insert the swab into the tube all the way to the bottom. Turn the swab 10 times and squeeze it out at the bottom.
6. Squeeze the tube a few times with two fingers so that the swab is wrung out before removing it.
7. Screw the cap onto the sample tube, break off the tip of the cap, and then begin the test procedure.

2.TEST PROCEDURE

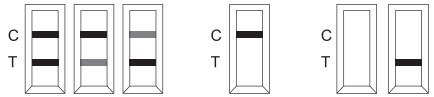
Notes:
- Make sure, that the test cassette is at room temperature (between +15 C and +30 C)
- Do not open the packaging of the test cassette immediately until performing the test.
- If the test result is not visible after 20 minutes, the test is invalid.

Implementation:



1. Take the test cassette out of the sealed pouch. Place this on a flat, clean and dry surface.
2. Add 2-3 drops of the solution from the test tube to the test cassette by squeezing the center of the test tube.
3. The result of the test appears after 3 minutes, but not later than 15 minutes. After 20 minutes the result is no longer valid.

3.TEST RESULT



Positive: After a maximum of 20 minutes, the control line (C) and test line (T) are visible in the display window. The test was carried out successfully and is positive. It can happen that the discoloration of one of the lines is weaker than the other, the result is also to be classified as positive in this case.
If the test result is positive, there is currently a suspicion of a COVID-19 infection:
- Contact your doctor / general practitioner or the local health department immediately.
- Comply with local guidelines for self-isolation.
- Have a PCR confirmation test performed.

Negative: After a maximum of 20 minutes, only the control line (C), but no test line (T), is visible in the display window. The test was carried out successfully and is negative.
Please also consider the following points if the test result is negative:
- Furthermore, all applicable rules regarding contact with other people and all protective measures must be observed.
- Even if the test is negative, there may be an infection.
- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be precisely detected in all phases of an infection.

Invalid: If no line appears in the control area (C) after a maximum of 20 minutes, the test result is invalid, regardless of whether there is a line in the test area (T). The instructions may not have been followed correctly or the test may be incorrect. It is recommended to repeat the test with a new test kit. If the test results are still invalid, contact a doctor or a COVID-19 test center. Stop using the product and contact the distributor.

Performance characteristics

1.DETECTION LIMIT (LOD)

The detection limit of the Coretests® COVID-19 Ag test was confirmed to be 22.5 $TCID_{50}$/ml.

2.CROSS REACTIVITIES

The tests carried out show that the Coretests® COVID-19 Ag test does not show any significant cross-reactivity with the organisms listed below:

Potential cross-reactivity		Test concentration
Yeasts	Candida albicans	1.0 x 10^6 cells/ml
Bacteria	Bordetella pertussis	1.0 x 10^6 cells/ml

	Chlamydia pneumoniae	1.0 x 10^6 IFU/ml
	Haemophilus influenzae	1.0 x 10^6 cells/ml
	Legionella pneumophila	1.0 x 10^6 cells/ml
	Mycoplasma pneumoniae	1.0 x 10^6 U/ml
	Streptococcus pneumoniae	1.0 x 10^6 cells/ml
	Streptococcus pyogenes (Group A)	1.0 x 10^6 cells/ml
	Mycobacterium tuberculosis	1.0 x 10^6 cells/ml
	Staphylococcus aureus	1.0 x 10^6 org/ml
	Staphylococcus epidermidis	1.0 x 10^6 org/ml
	Pooled human nasal lavage	N/A
Viruses	Adenovirus	1.0 x 10^5TCID 50/ml
	Humanes Metapneumovirus (hMPV)	1.0 x 10^5TCID 50/ml
	Rhinovirus	1.0 x 10^5 PFU /ml
	Enterovirus/Coxsackievirus B4	1.0 x 10^5TCID 50/ml
	Human Coronavirus OC43	1.0 x 10^5TCID 50/ml
	Human Coronavirus 229E	1.0 x 10^5TCID 50/ml
	Humanes Coronavirus NL63	1.0 x 10^5 TCID 50/ml
	Humanes Parainfluenza virus 1	1.0 x 10^5TCID 50/ml
	Humanes Parainfluenza virus 2	1.0 x 10^5 TCID 50/ml
	Humanes Parainfluenza virus 3	1.0 x 10^5 TCID 50/ml
	Humanes Parainfluenza virus 4	1.0 x 10^5 TCID 50/ml
	Influenza A	1.0x 10^5 TCID 50/ml
	Influenza B	1.0 x 10^5 TCID 50/ml
	Respiratonsches Syncylial Virus A	1.0 x 10^5 PFU /ml
	MERS-Coronavirus	1.0 x 10^5 TCID 50/ml

3.POSSIBLE INTERFERENCES

It was found that the following substances and conditions did not affect the test.
The following potentially interfering substances were tested:

Substance	Effective	Concentration
Body genes	Mucin	2% v/v
	Whole blood	1% v/v
OTC Nasentropfen	Phenylephnne 15% v/v	15% v/v
OTC Nasengel	Sodium Chloride (z.B. NeilMed)	5% v/v
OTC nasal spray 1	Cromolyn	15% v/v
OTC nasal spray 2	Oxymetazohne	15% v/v
OTC nasal spray 3	Fluconazole	5% v/v
Sore throat dragees	Benzocain, Menthol	0.15% v/v
OTC homeopathic nasal spray 1	Galphimia glauca, Sabadilla,	20% v/v
OTC homeopathic nasal spray 2	Zincum gluconium (i.e., Zicam)	5% v/v
OTC homeopathic nasal spray 3	Alkalol 10% v/v	10% v/v
OTC homeopathic nasal spray 4	Fluticasone Propionate	5% v/v
Phenol spray for sore throats	Phenol 15% v/v	15% v/v
Antiviral drug	Tamiflu (Oseltamivir Phosphate)	0.5% v/v
Antibiotics nasal ointment	Mupirocin	0.25% v/v
System great antibiotic	Tobramycin	0.0004% v/v

4.DIAGNOSTIC SENSITIVITY AND SPECIFICITY

Nasopharynx smear

A clinical study was performed with a total of 655 swab specimens from the nasopharynx. The results of the Coretests® COVID-19 Ag test were compared with a nucleic acid detection test (PCR). The diagnostic sensitivity and specificity of the test results are given below:

Coretests® COVID-19 Ag test (nasopharynx smear)

Reference		Nucleic Acid Detection Test Results		Overall result
		positive	negative	
Results of the Coretests® COVID-19 Ag test	positive	152	2	154
	negative	3	498	501
Overall results		155	500	655

Sensitivity: 98.1% (152/155) (95%-cl* 94.45% to 99.06%)
Specifilat: 99.6% (498/500) (95%-cl* 98.6% to 100%)
Combined percentage agreement: 99.2% (650/655) (95%-cl*98.2% to 99.8%)

***** Confidence intervals

Nasal cavity smear

A clinical study was performed with a total of 415 swab specimens from nasal cavities. The results of the Coretests® COVID-19 Ag test were compared with a nucleic acid detection test (PCR). The diagnostic sensitivity and specificity of the test results are given below:

Coretests® COVID-19 Ag test (nasal cavity swab)

Reference		Nucleic Acid Detection Test Results		Overall result
		positive	negative	
Results of the Coretests® COVID-19 Ag test	positive	152	2	154
	negative	3	258	261
Overall results		155	260	415

Sensitivity: 98.1% (152/155) (95% -cl*94.45% to 99.06%)
Specificity: 99.2% (258/260) (95% -cl*97.25% to 99.91%)
Combined percentage agreement: 98.8% (410/415) (95% -cl*97.21% to 99.61%)

***** Confidence intervals

ADDITIONAL INFORMATION

INDEX OF SYMBOLS

	Do not re-use	LOT	Batch code
IVD	In vitro diagnostic medical device		Use-by date
2°C 30°C	Store at 2-30˚C		Consult instructions for use
EC REP	Authorized representative in the European Community		Manufacturer
REF	Catalogue number		Caution
	Keep dry		Keep away from sunlight
	Importer		

MANUFACTURER CONTACT INFORMATION

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Catalogue number:

REF **5 Testkits REF 1002**
25 Testkits REF 1003

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