CORA CHECK-19 comfort

Antigen rapid test (SARS-CoV-2)

Test cassette (saliva test) Instructions for use

A rapid test for the qualitative detection of the novel Corona Virus antigens in human saliva. Suitable for professional in-vitro diagnostics and private use.

Intended use

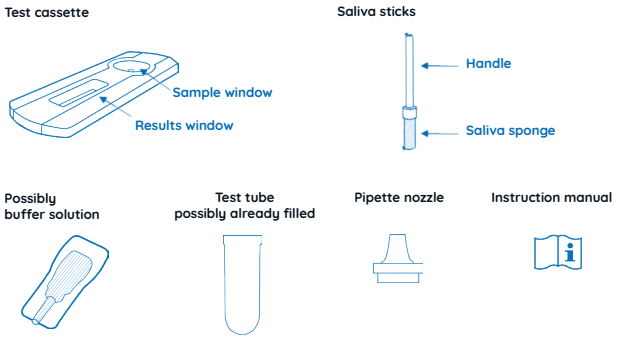
The CORA CHECK-19 comfort is an in vitro diagnostic device for the qualitative detection of novel coronavirus antigens in human saliva using the rapid immunochromatographic method. The detection of the antigens is based on the monoclonal antibodies specific for the coronavirus antigen. COVID-19 is an acute infectious respiratory disease to which humans are susceptible. Currently, individuals infected with the virus are the primary source of infection, although individuals with an asymptomatic course may also be infectious. Based on current epidemiologic research, the incubation period ranges from 1 to 14, but most commonly 3 to 7 days. The most common symptoms are fever, fatigue, and dry cough. In some cases, a stuffy and/or runny nose, sore throat, muscle aches, and diarrhea also occur.

Storage and minimum shelf life

Store the SARS-CoV-2 Saliva Rapid Test at temperatures between 4°C and 30°C. Do not freeze the test. All test components are stable until the best-before date indicated on the outer packaging and the buffer solution.

Materials

The CORA CHECK-19 comfort test kit contains: A test cassette for evaluating the sample, a saliva stick with sponge for taking the sample, the buffer solution, for mixing with the saliva sample, a sample tube, a pipette nozzle for closing the sample tube and dripping onto the test cassette and these operating instructions.
Depending on the product version, the buffer solution is already in the test tube, in which case there is no extra bottle of buffer solution in this test kit.



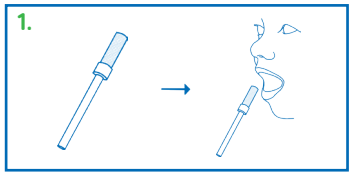
You also need a way to stop the time during the evaluation. This can be done, for example, using a timer integrated in the smartphone or an alarm clock. Gloves, breathing mask and disinfectant are recommended.

Safety instructions

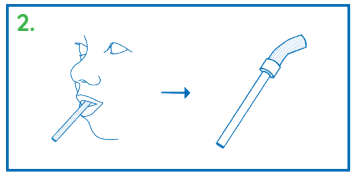
- The test should only be used for the in vitro diagnostic purpose for which it is advertised.
- Make sure that the expiration date of the test has not yet passed. Do not use the test after the expiration date. Check that the foil packaging of the test components is not damaged before opening and using it.
- Perform the test at room temperature between 15°C and 30°C.
- Use of the self-test from 10 years of age. Test subjects under 10 years of age must be assisted in its use.
- If you perform the test on someone other than yourself, be sure to follow universal hygiene measures, such as hand disinfection and protective clothing (respirator and gloves).
- This test kit is intended for single use and cannot be used or reused by more than one person.
- Avoid touching the evaluation window and the specimen window.
- Avoid using bloody specimens.
- If the buffer solution comes into contact with hands or eyes, wash hands or rinse eyes.
- The oral saliva sample should be collected using the saliva stick provided in this kit. For this, follow the more detailed instructions under „Procedure“. When using this test kit, no other saliva stick should be used to collect the saliva.
- You can perform the test at any time of the day.
- Collect components of the kit and swab samples in a plastic bag and dispose of them in the residual waste. Disinfect your hands afterwards.
- Avoid contact with contaminated material.

Implementation

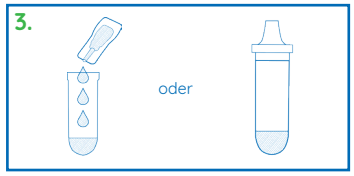
Allow the test cassette, specimen, and buffer solution to reach room temperature (15°C-30°C) before testing. Make sure that the person to be tested has not had anything in their mouth, be it food, a drink, chewing gum or a mouthwash, for at least 10 minutes before testing. Also, the person to be tested should not smoke during the time period previously indicated. Please read the following instructions completely before performing the test.



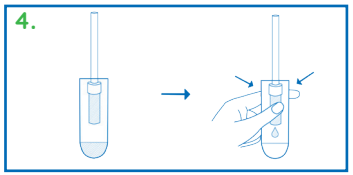
Open the sealed package of the saliva stick and take it out.
There is a sponge at one end of the stick. Place the side with the sponge in the mouth of the person to be tested.



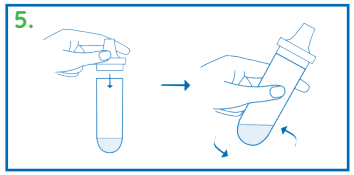
Now the test person should actively press the sponge against the cheek with the tongue for approx. 10 seconds until it feels soft in the mouth and is completely saturated with saliva. You will know the sponge is completely soaked when it feels soft in the mouth. Be careful never to touch the sponge with your hands.



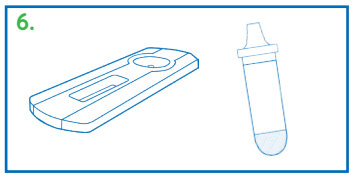
Take a test tube and a bottle full of buffer solution to hand while keeping the sponge in your mouth. Twist off the cap of the buffer bottle and fill the entire buffer solution of this bottle into the test tube.
Depending on the product version, the buffer solution may already be in the test tube. In this case, this step is not necessary.



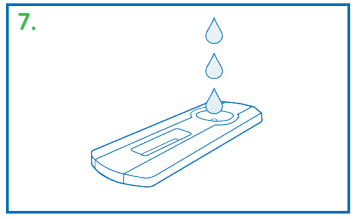
Remove the saliva sponge from the mouth of the test person and place it in the test tube.
Squeeze the sample tube from the outside to wring out the sponge inside the tube. Squeeze until some saliva has flowed out of the sponge into the tube.



Close the test tube with the pipette nozzle. Then swivel and rotate the test tube around its own axis for approx. 5 seconds so that the saliva and the buffer solution mix.



Remove the test cassette from the sealed packaging and place it on a clean and flat surface.
The mixture of buffer solution and saliva, which is now in the test tube, should be added to the sample window as soon as possible. The best results are obtained if the sample is run immediately after opening the packaging.



Place 3 drops of sample from the test tube vertically onto the sample window in the test cassette. The sample window is the round depression at the bottom of the test cassette.
Then start the timer. You can read the results after 10-20 minutes.
Do not interpret the results after more than 20 minutes, as an invalid result cannot then be ruled out.

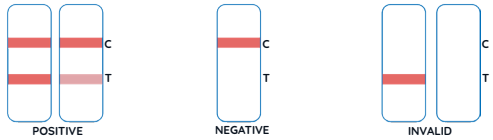
Reading the results

(Please refer to the picture below)

POSITIVE: Two red lines appear. One red line appears in the control region (C) and another in the test region (T). The hue may vary, but the result should be interpreted as positive even if the line appears pale.

NEGATIVE: Only one red line appears in the control region (C), none in the test region (T). The negative result indicates that there were no coronavirus antigens in the sample or that the number of coronavirus antigens is below the detectable limit.

INVALID: No red line appears in the control region (C). The test is invalid even if a red line appears in the test region (T). Insufficient sample volume or incorrect test procedure are the most common causes of an invalid result. In this case, refer again to the instructions for performing the test and repeat the test with a new test kit. If the result remains invalid, stop using the test kit and contact us.



In the event of a positive result

Go into quarantine at home and contact your family doctor or your local public health department by telephone. They will provide you with information on how to proceed.

A positive test result should be confirmed by PCR.
If the test result of your rapid test is negative, but you have specific symptoms, the result should also be verified by PCR, as the possibility of a false negative test result cannot be 100% excluded.

Application limits

- The Antigen Saliva Rapid Test is an acute phase screening test for the qualitative detection of coronavirus antigens. It is possible that the saliva sample collected may be below the sensitivity limit of the test, so a negative result may not completely rule out infection with coronavirus.
- The test is sensitive to viable and non-viable coronavirus antigens. The performance of the test depends on the antigen load in the sample and may not correlate with the cell culture performed on the same sample. To clarify this, the results of the test should be compared with other available clinical and laboratory information to give an accurate diagnosis.
- A negative test result may occur if the amount of collected antigens in the specimen is below the sensitivity of the test or if a specimen of insufficient quality was collected or transported. Therefore, a negative result does not exclude the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or PCR.
- Performance of the antiviral treatment monitoring test was not demonstrated.
- Positive results do not rule out co-infection with other pathogens.
- Negative test results are not designed to rule out other corona viruses except SARS-CoV-2 virus.
- Children tend to shed virus over a longer period of time than adults, which may result in differences in test sensitivity between adults and children.

Principle

This test is based on immunochromatographic technology with colloidal gold. It uses the double antibody sandwich method. The sandwich method measures the amount of antigen between two layers of antibodies and is used to detect the N-protein of SARS-CoV-2 antigen in human saliva. The detection line (T-line) of the Novel test cassette was coated with novel coronavirus antibody and the quality control line (C-line) was coated with sheep anti-mouse. During the test, SARS-CoV-2 antigen in the sample interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles, forming an antibody antigen-gold particle complex. Due to the capillary effect, this complex migrates upward to the C-line. The SARS-CoV-2 antigen in the sample binds first to the colloidal gold-labeled SARS-CoV-2 antibody, forming a solid-phase antibody antigen-gold particle complex at the T-line position and a sheep anti-mouse-labeled SARS-CoV-2 antibody-gold particle complex at the C-line position. After completion of the assay, observe the colloidal gold color reaction of the T-line and C-line to determine the results of SARS-CoV-2 antigen in human saliva.

Specific SARS-CoV-2 proteins and mutation forms

The Novel Coronavirus 2019-nCoV antigen assay (colloidal gold) detects the N protein.
The current mutation positions of the Novel Coronavirus mutant strain (B.1.1.7 strain) are D3L and S235F. Of the two antibodies used, one has a recognition site of 75-119aa; the other has a recognition site of 45-181aa. The epitope recognized by our antibody does not contain any mutated epitopes. The mutation of the UK variant is mainly on the S protein. Thus, the rapid test is still effective in detecting the antigen of novel coronavirus. The mutation does not affect the detection result of the product. The rapid test can reliably detect both the UK variant and the South African variant.

Clinical assessment

A clinical evaluation was performed to compare results obtained using the CORA CHECK-19 comfort for novel coronavirus (SARS-CoV-2) and by PCR. The results are summarized below:
Table: CORA CHECK-19 comfort compared to PCR:

Method		PCR test results		Total result
CORA CHECK-19 comfort	Result	Positive	Negative	
	Positive	104	1	105
	Negative	4	114	118
Total result		108	115	223

Sensitivity: 104/108=96,3% (90,86%;98,55%)
Specificity: 114/115=99,13% (95,24%;99,85%)
Accuracy: (104+114)/(104+1+4+114)*100%=97,76% (94,86%;99,04%)

Cross-reactions

No cross-reaction was detected with the Antigen Saliva Rapid Test kits and the following pathogens:

Viruses/Bacteria/Parasites	Strain	Concentration
Human coronavirus	HKU1	2 x 10^5TCID$_{50}$/mL
	229E	2 x 10^5TCID$_{50}$/mL
	OC43	2 x 10^5TCID$_{50}$/mL
	NL63	2 x 10^5TCID$_{50}$/mL
	SARS	2 x 10^5TCID$_{50}$/mL
	MERS	2 x 10^5TCID$_{50}$/mL
Adenovirus	Type 1	2 x 10^5TCID$_{50}$/mL
	Type 2	2 x 10^5TCID$_{50}$/mL
	Type 3	2 x 10^5TCID$_{50}$/mL
	Type 4	2 x 10^5TCID$_{50}$/mL
	Type 5	2 x 10^5TCID$_{50}$/mL
	Type 7	2 x 10^5TCID$_{50}$/mL
	Type 55	2 x 10^5TCID$_{50}$/mL
Human metapneumovirus (hMPV)	hMPV 3 Typ B1 / Peru2-2002	2 x 10^5TCID$_{50}$/mL
	hMPV 16 Typ A1 / IA10-2003	2 x 10^5TCID$_{50}$/mL
Parainfluenza virus	Type 1	2 x 10^5TCID$_{50}$/mL
	Type 2	2 x 10^5TCID$_{50}$/mL
	Type 3	2 x 10^5TCID$_{50}$/mL
	Type 4A	2 x 10^5TCID$_{50}$/mL
Influenza A	H1N1	2 x 10^5TCID$_{50}$/mL
	H3N2	2 x 10^5TCID$_{50}$/mL
	H7N1	2 x 10^5TCID$_{50}$/mL
	H7N9	2 x 10^5TCID$_{50}$/mL
Influenza B	Yamagata	2 x 10^5TCID$_{50}$/mL
	Victoria	2 x 10^5TCID$_{50}$/mL
Enterovirus	Typ 68	2 x 10 TCID$_{50}$/mL
	09/2014 Isolat 4	2 x 10^5TCID$_{50}$/mL
Respiratory syncytial virus	Typ A	2 x 10^5TCID$_{50}$/mL
	Typ B	2 x 10^5TCID$_{50}$/mL
Rhinovirus	Typ 16	2 x 10^5TCID$_{50}$/mL
	Typ B42	2 x 10^5TCID$_{50}$/mL
Chlamydia pneumoniae	TWAR Stamm TW-183	5 x 10^6CFU /mL
Haemophilus influenzae	NCTC 4560	5 x 10^6CFU /mL
Legionella pneumophila	Bloomington-2	5 x 10^6CFU /mL
	Los Angeles-1	5 x 10^6CFU /mL
	82A3105	5 x 10^6CFU /mL
Mycobacterium tuberculosis	K	5 x 10^6CFU /mL
	Erdman	5 x 10^6CFU /mL
	HN878	5 x 10^6CFU /mL
	CDC1551	5 x 10^6CFU /mL
	H37Rv	5 x 10^6CFU /mL
Streptococcus pneumonia	4752-98 (Maryland (D1)6B-17	5 x 10^6CFU /mL
	178 (Poland 23F-16)	5 x 10^6CFU /mL
	262 (CIP 104340)	5 x 10^6CFU /mL
	Slovakia 14-10(29055)	5 x 10^6CFU /mL

Cross-reactions

Streptococcus pyrogens	Typstamm T1 [NCIB 11841, SF130]	5 x 10^6CFU /mL
Bordetela Pertussis	NCCP 13671	5 x 10^6CFU /mL
Mycoplasma pneumoniae	Mutant 22	5 x 10^6CFU /mL
	FH Stamm von EatonAgent [NCTC 10119]	5 x 10^6CFU /mL
	M129-B7	5 x 10^6CFU /mL
Pneumocystis jirovecii (PJP)	N/A	N/A
Padded human Nose wash	N/A	N/A
Candida albicans	3147	5 x 10^6CFU /mL
Pseudomonas aeruginosa	R. Hugh 813	5 x 10^6CFU /mL
Staphylococcus epidermidis	FDA Stamm PCI 1200	5 x 10^6CFU /mL
Staphylococcus salivarius	S21B [IFO 13956]	5 x 10^6CFU /mL

Detection limit

CORA CHECK-19 comfort was confirmed to detect 2.5x102.2 TCID50/mL SARS-CoV-2.

Interfering substances

There is no interference for the potential interfering substances listed below.

Exogenous factor	Interfering substances	Test concentration
Nasal sprays or drops	Phenylephrine	128µg/mL
	Oxymetazoline	128µg/mL
	Saline nasal spray 10%	10%(v/v)
Nasal corticosteroids	Dexamethasone	2µg/mL
	Flunisolid	0,2µg/mL
	Triamcinolone acetonide	0,2µg/mL
	Mometasone	0,5µg/mL
Throat lozenges	Strepsils (Flurbiprofen 8.75mg)	5% (w/v, 50mg/mL)
	Throat Candy	5% (w/v, 50mg/mL)
Oral anesthetic	Anbesol (Benzocain 20%)	5% (v/v)
Antiviral medications	α-Interferon-2b	0.01µg/mL
	Zanamivir (Influenza)	2µg/mL
	Ribavirin (HCV)	0.2µg/mL
	Oseltamivir (Influenza)	2µg/mL
	Peramivir (Influenza)	60µg/mL
	Lopinavir (HIV)	80µg/mL
	Ritonavir (HIV)	20µg/mL
	Arbidol ((Influenza)	40µg/mL
Antibiotic	Levofloxacin tablets	40µg/mL
	Azithromycin	200µg/mL
	Ceftriaxon	800µg/mL
	Meropenem	100µg/mL
Antibacterial, systemic	Tobramycin	128µg/mL
Other	Muzin: Submaxillardrüse vom Rind	100 µg/mL
	Biotin	100 µg/mL

Exogenous factor	Interfering substances	Test concentration
Autoimmune disease	Human antimouse Antibody, HAMA	800 ng/mL
Serum protein	Whole blood (human), EDTA anticoagulated	10% (w/w)

Legend

Symbol	Meaning	Symbol	Meaning
IVD	in vitro diagnostic		Temperature limit
	Do not reuse	LOT	Charge
	Manufacturer		Expiration date
	Date of manufacture		Instruction manual
	for self application intended		

Contact

Service and sales in Germany:

fameditec GmbH
Großenbaumer Weg 6 - 40472 Düsseldorf

Order hotline:
Tel: 0211-86842 100 - Fax: 0211-977 12 105
order@fameditec.de

Technical hotline:
Tel: 0211-86842121 - Fax: 0211-977 12 105

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