Test for self-application - Temporary special approval for self-application according to §11 MPG in Germany (BfArM GZ: 5640-S-058/21)

Rapid COVID-19 Antigen Test (Colloidal Gold)
Rapid test (spitting test) for personal use

For use by people between 18 and 75 years of age.
For children and adolescents under 18 years of age, as well as for people over 75 years of age, only under the supervision of a person authorized to use it.

INTENDED USE

The "HYGISUN® COVID-19 antigen rapid test (colloidal gold) rapid test (spit test) for personal use" is an immunological lateral flow test for the qualitative determination of SARS-CoV-2 nucleocapsid antigens in human saliva samples and for personal use suitable. The test provides a quick result about the possible presence of a COVID-19 infection in the person examined. No invasive sampling is necessary to perform the test.
If the instructions for use are followed, the antigen test can make an important contribution to fighting pandemics, as the antigen test already reacts in the acute phase of the infection, when the viral load is high but the patient is often still symptom-free. If the test is carried out correctly and positive test results are subsequently confirmed by a PCR test, taking measures quickly and independently can improve protection against infection and slow down the spread of SARS-CoV-2.

Testing does not release you from complying with the AHA + L rule (distance, hygiene, everyday masks, ventilation).

Positive test result: A positive result indicates a SARS-CoV-2 infection. Please quarantine, follow local guidelines for self-isolation and contact a doctor or local health department immediately. A PCR confirmation test is necessary!
Negative test result: A negative result does not rule out an infection with SARS-CoV-2. A negative test result is just a snapshot. If it is suspected, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection. A negative result is not a release of compliance with the AHA + L rule.
Invalid test result: An invalid result may be caused by incorrect test execution. So please repeat the test. If the test results are still invalid, contact a doctor or a COVID-19 test center.

SUMMARY

SARS-CoV-2 (severe acute respiratory syndrome coronavirus type 2) is a new beta-coronavirus that was identified at the beginning of 2020 as the cause of COVID-19 disease. Coronaviruses are widespread among mammals and birds. They mainly cause mild colds in humans, but can sometimes cause severe respiratory diseases. The most common symptoms include cough, fever, runny nose, and impairment of the sense of smell and / or taste. The main route of transmission for SARS-CoV-2 is the respiratory uptake of virus-containing particles that arise when breathing, coughing, speaking, singing and sneezing. The transmission takes place from already infected persons with symptoms but also from symptom-free infected persons. Based on current epidemiological studies, the mean incubation period is 5-6 days, but it can also last up to 14 days.

PACKAGING UNITS

Single pack (1 test / pack).

TEST PRINCIPLE

The test is used to detect the SARS-CoV-2 nucleocapsid antigen. This antigen is usually detectable in saliva during the acute phase of the infection. The COVID-19 Antigen Rapid Test Cassette (Saliva) is an immunological lateral flow test based on the principle of the double antibody sandwich technique. The monoclonal SARS-CoV-2 nucleocapsid protein antibody conjugated with colored microparticles is used as a detector and sprayed onto the conjugation pad. During the test, the SARS-CoV-2 antigen in the sample interacts with the SARS-CoV-2 antibody, which is conjugated with colored microparticles, creating an antigen-antibody-labeled complex. Due to the capillary action on the membrane, this complex migrates to the test line, where it is captured by the pre-coated monoclonal SARS-CoV-2 nucleocapsid protein antibody. A colored test line (T) will be
visible in the result window if SARS-CoV-2 antigens are present in the sample. The absence of the T-line indicates a negative result. The control line (C) is used as a procedural control and should always be displayed if the test procedure has been carried out properly.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostics only.
- Only suitable for single use.
- Negative results do not rule out SARS-CoV-2 infection. A negative test result is just a snapshot. People who test negative and continue to have symptoms similar to COVID should contact their doctor / general practitioner.

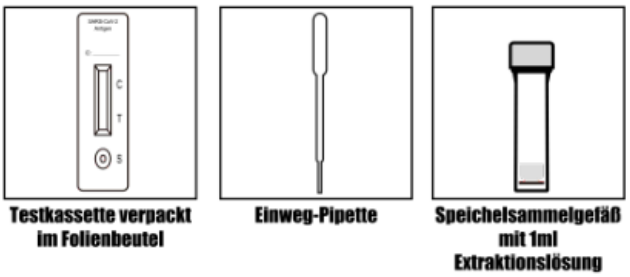
DISPOSAL

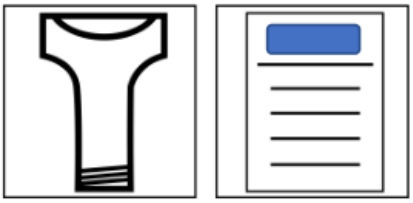
The test kit can be disposed of with normal household waste in compliance with the applicable local regulations.

- Do not use this product after the expiry date, which you can find on the outer packaging.
- Please read all of the information in this leaflet before performing the test.
- The test cassette should be kept in the sealed pouch until use.

Single pack

- 1 test cassette packed in a foil pouch
- 1 disposable pipette
- 1 saliva collection vessel with 1ml extraction solution
- 1 funnel (to collect the saliva)
- 1 instruction manual





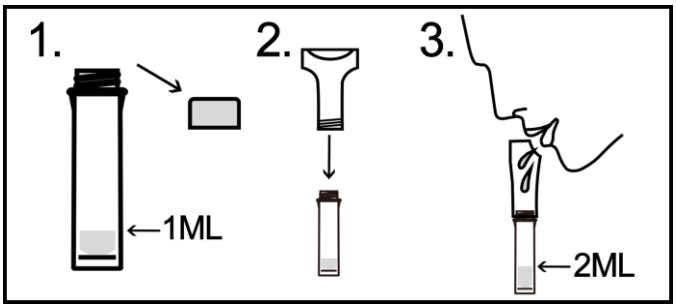
SAMPLING AND PREPARATION

1. The COVID-19 rapid antigen test is performed with a saliva sample.
2. Attention: Please do not consume any food or drinks 30 minutes before taking the sample and avoid consuming chewing gum and tobacco during this time, as this can affect the test result.
3. Familiarize yourself with the contents of the test kit beforehand. All materials should be at room temperature (15-30 ° C). Please read the instructions for use carefully before starting the test. If you have any questions, please contact the manufacturer.
4. Provide a clock.
5. Please wash your hands before taking samples. Avoid unnecessary skin contact with the inside and the edge of the funnel and other materials to prevent contamination.
6. Open the test package and collect all of the test components.

Saliva sampling:

- Please do not consume any food or drinks for 30 minutes before taking the sample and avoid consuming chewing gum and tobacco during this time, as this can affect the test result.
- You need the funnel and the collection tube for taking the sample.

1. Place the funnel in the collection tube (see illustration.)
2. Clear your throat and loosen the saliva from the throat.
3. Then hold the funnel close to your lips and let the saliva flow through the funnel into the collection tube.
   The graduation mark on the collection tube tells you how much saliva is required for the sample (corresponds to approx. 1 ML).

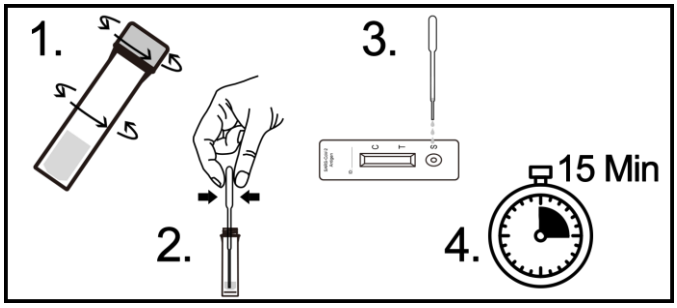


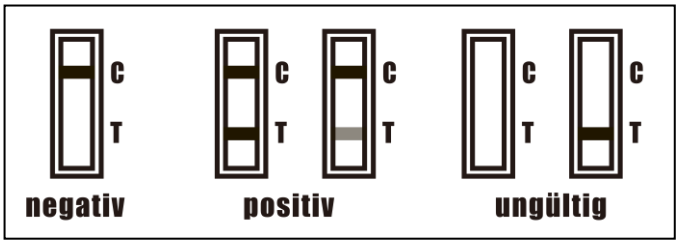
Storage of the samples

Freshly taken samples should be processed as soon as possible, but no later than one hour after sampling.

Test procedure

1. Please dispose of the funnel. Close the collection tube with the attached cap. Then shake the collection tube vigorously at least 10 times to mix the saliva and the extraction reagent.
2. Carefully remove the lid and take the saliva sample with the disposable pipette.
3. Take the test cassette out of the packaging, place it on the flat surface that has been cleaned beforehand. Use the disposable pipette to add three drops of your saliva sample to the well (S) of the cassette.
4. Start the stopwatch or timer and read the test result after **15 minutes**.





INTERPRETATION OF THE RESULTS

Positive: Two lines appear. A colored line appears in the control area (C) and another colored line appears in the test area (T); this can vary in terms of intensity and visibility depending on the amount of SARS-CoV-2 in the sample.

Negative: A colored line appears in the control area (C), but no line in the Test area (T).

Invalid: Either no line or only one line appears in the test area (T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat all steps with a new test.

QUALITY CONTROL

A procedural control is included in the test. A colored line in the control area (C) is considered to be internal procedural control. It confirms a sufficient sample volume, the complete Penetration of the membrane with the sample as well as and a correct procedural technique.

RESTRICTIONS

- The COVID-19 rapid antigen test can only be used for saliva samples. Use of other specimens such as blood, serum, plasma, or nasal swabs has not been tested and should not be used with this test.
- The product is limited to a qualitative proof. The intensity of the test line does not necessarily correspond to the concentration of the antigen in the sample. It is not possible to specify the concentration.
- If your sample tested positive, please contact a health care institution. A confirmation test is necessary! To reduce the risk of transmission, rapid isolation after a positive test result is necessary, as well as the identification and early quarantine of close contact persons. By contacting the doctor / health institution, the entry into the reporting system takes place, if the test result is confirmed. No medically important decisions can be made without first consulting a doctor.
- A negative test result is only a snapshot and does not rule out the possibility of a SARS-CoV-2 infection at any time. Negative results can e.g. B. exist when the viral load is low, such as in the early incubation phase or from the second week after the onset of symptoms. A false negative test result can also occur if the sample was taken incorrectly, the amount of virus is below the detection limit of the test or the virus has undergone one or more minor amino acid mutation (s) in the target epitope region caused by the monoclonal antibodies used in the test be recognized.
- Please continue to observe the hygiene rules and repeat the test if necessary.
- In the event of repeated negative test results and the presence of clinical symptoms
- or contact with the virus or infected persons, an additional follow-up examination using other clinical methods must be carried out in order to rule out an infection.
- The test result cannot be used as the sole basis for patient management decisions. A doctor must evaluate the results in combination with the patient's medical history, physical findings, and other diagnostic procedures.

Note: Insufficient sample size, incorrect test procedure, or an expired test are the most common causes of invalid results

PERFORMANCE CHARACTERISTICS

Clinical performance

The clinical performance of the COVID-19 rapid antigen test (colloidal gold) was determined in prospective studies with samples collected from 609 individual symptomatic patients (within 7 days of onset of illness) and asymptomatic patients with suspected COVID-19 . The summarized data of the COVID-19 Antigen Rapid Test (Colloidal Gold) Rapid Test (Spit Test) for personal use are as follows:

The RT-PCR cycle threshold (Ct) is the relevant signal value. A lower Ct value indicates a higher viral load. The sensitivity was calculated for the different Ct value ranges (Ct value ≤ 35 and Ct value ≤ 40).

COVID-19 Antigen		RT-PCR (Ct-value ≤35)		Total
		Positive	Negative	
HYGISUN®	Positive	279	0	279
	Negative	3	123	126
Total		282	125	405

PPA (Ct ≤ 35): 98,94% (279/282), (95% CI: 96,92%~99,78%) NPA: 100,00% (123/123), (95%CI: 97,05%~100,00%)

COVID-19 Antigen		RT-PCR (Ct-value ≤40)		Total
		Positive	Negative	
HYGISUN®	Positive	465	0	465
	Negative	21	123	144
Total		486	123	609

PPA (Ct ≤ 40): 95,68% (465/486), (95% CI: 93,47%~97,31%) NPA: 100,00% (123/123), (95%CI: 97,05%~100,00%)

Limit of Detection (LoD)

The LOD for Rapid COVID-19 Antigen Test(Colloidal Gold) was 4.25 x10^2 $TCID_{50}$/mL. The LOD was established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Cross-Reactivity

Rapid COVID-19 Antigen Test(Colloidal Gold) does not cross with the following common respiratory pathogens.

S.N.	Potential Cross-Reactant	Species	Concentration
1	H1N1(2009)	A-H1N1-2009	10^6pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10^6pfu/mL
3	H3N2 influenza virus	A-H3N2	10^6pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10^6pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL
6	Influenza B Yamagata	B-Yamagata	10^6pfu/mL
7	Influenza B Victoria	B-Victoria	10^6pfu/mL
8	Respiratory syncytial virus type	RSV-A2	10^6pfu/mL
9	Respiratory syncytial virus type	RSV-B	10^6pfu/mL
10	Enterovirus A	CV-A10	10^6pfu/mL
11	Enterovirus B	Echovirus 6	10^6pfu/mL
12	Enterovirus C	CV-A21	10^6pfu/mL
13	Enterovirus D	EV-D68	10^6pfu/mL
14	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10^6pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10^6pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10^6pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10^6pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10^6pfu/mL
20	Adenovirus type 1	HAdV-1 VR-1	10^6pfu/mL
21	Adenovirus type 2	HAdV-2 VR-846	10^6pfu/mL
22	Adenovirus type 3	HAdV-3	10^6pfu/mL
23	Adenovirus type 4	HAdV-4 VR-1572	10^6pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10^6pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10^6pfu/mL
26	Adenovirus type 55	HAdV-55	10^6pfu/mL
27	Human metapneumovirus	HMPV	10^6pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10^6pfu/mL
29	Measles virus	MV VR-24	10^6pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10^6pfu/mL
31	Rotavirus	RV VR-2018	10^6pfu/mL
32	Norovirus	NOR	10^6pfu/mL
33	Mumps virus	MuV VR-106	10^6pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10^6pfu/mL
35	Legionella	33152	10^7cfu/mL

36	Bordetella pertussis	BAA-589	10^7cfu/mL
37	Haemophilus influenzae	Hib	10^7cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10^7cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10^7cfu/mL
42	Mycobacterium tuberculosis	25177	10^7cfu/mL
43	Mycoplasma pneumoniae	39505	10^7cfu/mL
44	Chlamydia pneumoniae	VR-2282	10^7cfu/mL
45	Aspergillus fumigatus	AF293	10^7cfu/mL
46	Candida albicans	SC5314	10^7cfu/mL
47	Candida glabrata	ATCC 2001	10^7cfu/mL
48	Cryptococcus neoformans	H99	10^7cfu/mL
49	Cryptococcus gutii	R265	10^7cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10^7cfu/mL
51	Coronavirus229E	VR-740	10^6pfu/mL
52	CoronavirusOC43	VR-1558	10^6pfu/mL
53	CoronavirusNL63	COV-NL63	10^6pfu/mL
54	Coronavirus HKU1	COV-HKU1	10^6pfu/mL
55	Coronavirus MERS	MERS	10^8TU/mL
56	Coronavirus SARS	SARS	10^8TU/mL
57	Pooled human nasal wash	/	10^7cfu/mL

Interfering Substances

The following potentially interfering substances have no impact on Rapid COVID-19 Antigen Test(Colloidal Gold). The final test concentrations of the interfering substances are documented in the Table below.

S.N.	Substance Name	Concentration
1	Whole Blood	4%(v/v)
2	Mucin	0.5%(v/v)
3	Ricola (Menthol)	1.5mg/mL
4	Sucrets (Dyclonin)	1.5mg/mL
5	Sucrets (Menthol)	1.5mg/mL
6	Chloraseptic (Menthol)	1.5mg/mL
7	Chloraseptic (Benzocaine)	1.5mg/mL
8	Naso GEL (NeilMed)	5%(v/v)
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)
10	Afrin (Oxymetazoline)	15%(v/v)
11	CVS Nasal Spray (Cromolyn)	15%(v/v)
12	Nasal Gel (Oxymetazoline)	10%(v/v)
13	Zicam	5%(v/v)
14	Homeopathic (Alkalol)	1:10
15	Fisherman's Friend	1.5mg/mL
16	Sore Throat Phenol Spray	15%(v/v)
17	Tobramycin	4μg/mL
18	Mupirocin	10mg/mL
19	Fluticasone Propionate	5%(v/v)
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL

Hook Effect

The concentration is $3.40x10^5$ $TCID_{50}$/mL, the test results are all positive, and there is no HOOK effect.

PACKAGING USED SYMBOLS

IVD	In-vitro-Diagnostikum, nicht schlucken		Nur einmal verwenden
	Verwendbar bis		Vor dem Verwenden Gebrauchsanleitung beachten
	Achtung, bitte Anweisungen im Anhang beachten		Hersteller
	Temperaturgrenze	LOT	Chargennummer
EC REP	Zugelassener Vertreter der Europäischen Union		Produkt trocken lagern
	Vor Sonneneinstrahlung schützen		Nicht verwenden, wenn die Verpackung beschädigt ist
	Herstellungsdatum		Biologische Risiken

Instructions version

Document: A6061213-IFU
Version: Rev V5.0
Date of approval: 02/05/2021
Issuing date: 2021.02.05
REF: A6061213

Manufacturer

Anbio (Xiamen) Biotechnology Co., Ltd.
No.2016, Wengjiao West Road, Xinyang Street, Haicang District, Xiamen,Fujian,China
Tel.: +49 (0) 2241 266 04 20

EC REP **Lotus NL B.V.**
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands