SARS-CoV-2 Ag Self-test Kit (Colloidal Gold)
Instructions for Use (IFU)

REF **LFA0401-1N**

For Lay Use
For invitro Diagnostic Use Only
For Use with Saliva Specimens

Befristet zugelassen zur Eigenanwendung nach §11 MPG in Deutschland (BfArM GZ: 5640-S-032/21) ohne abgeschlossenes Konformitätsbewertungsverfahren.

This instruction for use (IFU) must be read carefully prior to use. Instruction for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions for use.

INTENDED USE
This kit is used for in vitro qualitative detection of Nucleocapsid(N) Protein antigen from SARS-CoV-2in human saliva samples.
This kit is authorized for lay use with self-collected observed direct saliva samples from adults.
Results are for the identification of SARS-CoV-2 Nucleocapsid Protein antigen. Antigen is generally detectable in saliva during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive and confirmation with a molecular assay. Negative results cannot exclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY AND EXPLANATION OF THE TEST
Coronaviruses are a large family of viruses which may cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the β genus. The virus can cause mild to severe respiratory illness and has spread globally.
The SARS-CoV-2Ag Test Kit is a rapid lateral flow immunoassay for the qualitative detection of SARS-CoV-2 directly from saliva, without viral transport media. The Kit contains all components required to carry out an assay for SARS-CoV-2.

PRINCIPLE OF THE PROCEDURE
TheSARS-CoV-2 Ag Test Kit is a lateral flow immunoassay for the qualitative determination of Nucleocapsid Protein of SARS-CoV-2 virus in human saliva samples.
SARS-CoV-2antibody is immobilized in the test region on nitrocellulose membrane. If the specimen contains SARS-CoV-2 antigen, during the assay specimen is allowed to react with the colored conjugate (SARS-CoV-2 antibody-colloidal gold conjugate); the mixture then migrates chromatographically on the membrane by the capillary action. An SARS-CoV-2 positive specimen produces a distinct color band in the test region, formed by the specific antibody antigen colored conjugate complex "(Au-SARS-CoV-2-Ab)-(SARS-CoV-2-Ag)-(SARS-CoV-2-Ab)". Absence of this colored band in the test region suggests a negative result. A colored band always appears in the control region serving as procedural control regardless of the specimen contains SARS-CoV-2 or not.

REAGENTS AND MATERIALS
Materials provided

Specification / Ingredients	components
Test card with desiccant in a sealed foil pouch	1
Tube with sample extraction solution	1
Disposable sterile swab	1
Instruction for use	1
Quick guide	1

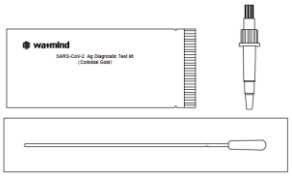
Materials required but not provided
• Clock, timer or stopwatch

PRECAUTIONS
1. For in vitro diagnostic use.
2. This product has been authorized only for the detection of nucleocapsid protein from SARS-CoV-2, not for any other viruses or pathogens.
3. Proper sample collection and handling are essential for correct results.
4. Do not touch swab tip when handling the swab sample.
5. Leave test card sealed in foil pouch until just before use. Do not use if pouch is damaged or open.
6. Do not use kit past its expiration date.
7. Do not mix test card and sample extraction solution from different kit lots.
8. All kit components are single use items. Do not use with multiple specimens. Do not reuse the used test card.

STORAGE AND STABILITY
Kits should be stored in 2°C~30°C in a cool, dark, dry place preservation, valid for 18 months, forbidden to store under 2°C and avoid using expired products.
Manufacture date (MFD) and Expiry date (EXP): marked on the label.

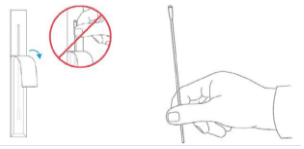
TEST PROCEDURE
Do not open the pouch until you are ready to perform a test, and the single-use test is suggested to be used under low environment humidity (RH≤70%) within 1 hour.
Before performing the test, you must read the instruction manual of the product completely, and please balance the test cards and sample extraction solution to room temperature (18℃~26℃) before the test. Do not perform the test only when the reagent was equilibrated to room temperature (18℃~26℃) to avoid affecting the accuracy of the experimental results.

1. Open your test kit and you should have:
1Test Card in a sealed foil pouch, 1Tubewith sample extraction solution and 1 Swab.

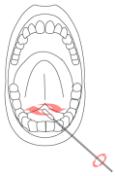


2. Open Pouch and place the card on a clean, dry, flat surface
NOTE: Do not touch any parts on inside of the card.

3. Open Swab
Open swab package and take the swab out.
NOTE: Keep fingers away from swab end.

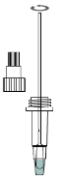


4. Sample Collection Process
Do not eat food or beverages, including gum or tobacco, for 30 minutes before sampling.
Press the tip of tongue against the root of jaw to concentrate saliva. Apply the swab under the tongue for at least 40 seconds rotate 5 times or more and soak it completely.
NOTE: False negative results may occur if the saliva is not properly collected.

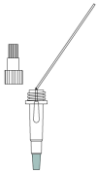


5. Open the lower cover of the tube that has been pre-filled with sample extraction solution

6. Elution of samples from swab
Place the swab into the sample tube and then completely immerse the swab head in the sample. Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 10 times (while submerged) and squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction buffer.



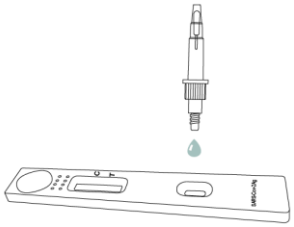
7. Snap the swab head and keep it in the tube



8. Close the lower cover of the tube and waggle tube for 5-6 times

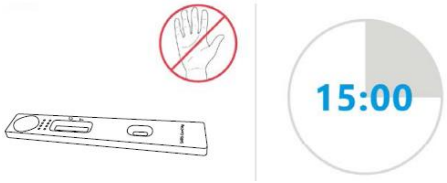
9. Open the upper cover of the tube

10. Dispense 100μL (3drop) of the specimen into the circular well on the card. Close the upper cover of the tube.



11. Wait 15 minutes

NOTE: Do not disturb card during this time. False results can occur if the card is disturbed/moved or test results are read before 15 minutes.



12. Interpret the test results at 15~20 minutes.

Do not interpret the results after 20 minutes.

DISPOSE IN TRASH

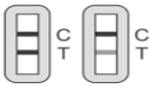
The kit components and patient samples should be handled as infectious waste. The kit components must be disposed of in accordance with local disposal regulations.

INTERPRETATION OF TEST RESULTS

There are three types of results possible.

1. Positive

Both red/purplish test band (T) and red/purplish control band (C) appear in window.



Positive

Note: The red/purplish band in the test area (T) can show the color depth. However, within the specified observation time, regardless of the color of the ribbon, even a very weak ribbon should be judged as a positive result.

In case of a positive test result:

- COVID-19 infection is currently suspected.

Immediately contact physician/family physician or local health department.

Follow local guidelines for self-isolation.

Have a PCR confirmatory test performed.

2. Negative

Only the red/purplish control band (C) appears in window. The absence of a test band (T) indicates a negative result.

Negative

In case of a negative test result:

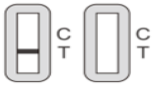
- Continue to follow all applicable rules regarding contact with others and protective measures.

- Even if the test is negative, an infection may be present

- In case of suspicion, repeat the test after 1 - 2 days, as the coronavirus cannot be accurately detected at all stages of an infection

3. Invalid

There should always be a red/purplish control band (C) in the control region regardless of test result. If control band (C) is not seen, it indicates that the incorrect operation process or the kit has deteriorated or damaged..



Invalid

In case of an invalid test result

- Possibly caused by incorrect test performance

- Repeat the test

- If test results remain invalid, contact a physician or COVID-19 testing center.

Handling instructions/Actions after the test result

1. The following reasons may cause false negative results:
   1) Inappropriate sample collection, using other non-matching solution, sample transfer time is too long (more than half an hour), the volume of solution added when eluted the swab are too much, non- standardized elution operation, low virus titer in the sample, these may all lead to false negative results.
   2) Mutations in viral genes may lead to changes in antigen epitope, leading to false negative results.
2. Analysis the possibility of false positive results:
   1) Inappropriate sample collection, using other non-matching solutions, non- standardized elution operation, these may all lead to false positive results.
   2) Cross-contamination of samples may lead to false positive results.
   3) False negative result from nucleic acid.
3. Analysis the possibility of invalid result:
   1) If the sample volume is not enough, the chromatography cannot be carried out successfully.
   2) The test card would invalid if the package was broken. The packaging status must be carefully checked before use.

LIMITATIONS

1. The result of the product should not be taken as a confirmed diagnosis, for clinical reference only. Judgement should be made along with RT-PCR results, clinical symptoms, epidemic condition and further clinical data.
2. Due to the limitation of the detection method, the negative result cannot exclude the possibility of infection. The positive result should not be taken as a confirmed diagnosis. Judgement should be made along with clinical symptoms and further diagnosis methods.
3. Positive test results do not rule out co-infections with other pathogens.
4. False negative results are more likely after 8 days or more of symptoms.
5. Negative results, from patients with symptom onset beyond 7 days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
6. This reagent can only qualitatively detect SARS-CoV-2 antigens in human saliva samples. It cannot determine the certain antigen content in the samples.
7. The accuracy of the test depends on the sample collection process. Improper sample collection will affect the test results.
8. False negative results may occur if swabs are stored in their paper sheath after specimen collection.
9. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.
10. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
11. Cross reactions maybe exist due to the N protein in SARS has a high homology with the new coronavirus (SARS-CoV-2). However, the interpretation of the results is not affected during seasons without SARS infection.

PERFORMANCE CHARACTERISTIC

1. Analytical Performance

1.1. Limit of detection

This kit was confirmed to detect 1.5×10^2 $TCID_{50}$/mL of SARS-CoV-2 which was isolated from USA-WA1/2020, Gamma-Irradiated.

1.2. Cross reactivity

The following viruses and other Microorganism have no effect on the test results.

Potential Cross-Reactant		Test Concentration	Test Result
Virus	Respiratory Syncytial Virus A	1.0 x 10^5 PFU/mL	No cross reaction
	Respiratory Syncytial Virus B	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Measles Virus	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Adenovirus Type 3	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Adenovirus Type 7	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Human cytomegalovirus	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Varicella-zoster virus	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Rotavirus	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Influenza B	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Influenza A	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Mycoplasma pneumonia	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Epstein Barr Virus	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	MERS-CoV	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	HCoV-HKU1	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
	Coronavirus NL63	1.0 x 10^5 $TCID_{50}$/mL	No cross reaction
Other Microorganism	Staphylococcus aureus	1.0 x 10^6CFU/mL	No cross reaction
	Streptococcus pneumoniae	1.0 x 10^6CFU/mL	No cross reaction

1.3. Interfering Substances

The following interfering substances have no effect on the test results.

Substance	Active Ingredient	Concentration	Test Result
Endogenous	Mucin	2.0 % w/v	No interference
Nasal Spray	Oxymetazoline	12 % v/v	No interference
Sore Throat Phenol Spray	Phenol	15 % v/v	No interference
Throat Lozenge	Benzocaine, Menthol	0.15% w/v	No interference
Anti-viral Drug	Ribavirin	12.9 mg/mL	No interference
Antibacterial, Systemic	Tobramycin	4.0 ug/mL	No interference

1.4. High Dose Hook Effect

No high dose hook effect was observed when tested with up to a concentration of 1.6 x 10^5 TCID50/mL of heat inactivated SARS-CoV-2 virus.

2. Clinical study

Performance of SARS-CoV-2 Ag Test Kit, with the test performed and results interpreted by the home user is similar to performance obtained by test operators with no laboratory experience.

The clinical evaluation was performed to compare the results obtained with the SARS-CoV-2 Ag Test Kit and a comparative reverse transcriptase polymerase chain reaction test (Novel Coronavirus(2019-nCoV) Nucleic Acid Diagnostic Kit(PCR-Fluorescence Probing) manufactured by Sansure Biotech Inc). Among patients, there are 157 positive and 182 negative saliva samples by RT-PCR confirmed. The presentation of the results of the SARS-CoV-2 Ag Test Kit is as follows:

CT	Number of	2019	SARS-CoV-2 antigen test result as compared

value	samples	nCoVRT-PCR Results	to RT-PCR
≤30	46	positive	44/46=95.65%（95%CI:85.47%-98.80%）
≤36	157	positive	142/157=90.45%（95%CI:84.84%-94.12%）
＞40	182	negative	181/182=99.45%（95%CI:96.95%-99.90%）

days	Number of samples	2019 nCoV RT-PCR Results	SARS-CoV-2 antigen test result as compared to RT-PCR
≤7	89	positive	85/89=95.51%（95%CI:89.01%-98.24%）
≤14	116	positive	107/116=92.24%（95%CI:85.91%-95.86%）
＞14	41	positive	35/41=85.37%（95%CI:71.56%-93.12%）

Sensitivity: 90.45%（95%CI:84.84%-94.12%）for CT values ≤36
Sensitivity: 95.51%（95%CI:89.01%-98.24%）for onset of symptoms within 7 days
Specificity: 99.45%（95%CI:96.95%-99.90%）

3. Human Factors Study

Watmind conducted a human factor's study to evaluate whether home user patients or caregivers (lay user) could perform the test and accurately interpret test results from the SARS-COV-2 Ag Card.

In this study, a total of 50 lay users, age 15 and older with either good or corrected vision (far/near-sighted or wear bifocals) participated in a 30-minute session including an introduction, a product overview, and simulated use cases of SARS-COV-2 Ag Test Kit result interpretation. Participants were asked to read and interpret a panel of 7 different SARS-COV-2 Ag Card test results, including high positive, low positive, negative and invalid.

46/50 participants described the process of reading and interpreting the test card results as being easy. However, 4/50 of the participants commented that it was difficult to see some of the fainter line conditions.

A total of 350 trials were recorded in this study. Participants were able to perceive and interpret the results correctly for 327 trials, or 93.4% of the time. Positive results with stronger intensity lines were easier to read than the positive lines with less intensity.

After the human factors evaluation, participants were asked for their overall impressions of the instructional materials they were provided. Nearly all participants (49/50) thought the instructions were straightforward and easy to understand and follow.

4. Usability Study

Watmind conducted a study to evaluate whether a home user can read the instructions and successfully perform the test steps for the SARS-COV-2 Ag Card test, including swab collection at home, and correctly interpreting the results.

120 home users, including individuals (n=60) and caregivers (n=60), participated in the study. Each individual or caregiver pair participated in a 30-minute session with an instruction. The usability evaluation session included one simulated use of the SARS-CoV-2 Ag Test Kit.

97.5% (117 out of 120) home users produced a valid result (all negative) and 3 participants produced an invalid result. (The causes of the invalid tests were insufficient amount of reagent added, and damage to the test strip). 117 out of 120 participants interpreted their test result correctly and 3 participants interpreted their result incorrectly (where they perceived a faint line in the sample window (as positive) when there was none (all results were verified by the study moderator).

The individual home use group completed 98.4% (1358/1380) of the total tasks/steps correctly. The caregiver home user group completed 98.3% (1356/1380) of the total tasks/steps correctly. The most common use errors observed during critical tasks included incorrectly swabs collection and contacting the test strip with the hands or with the surface.

97.5% (117 out of 120) of the home (individual and caregiver) participants had positive impressions of the SARS-CoV-2 Ag Test Kit. The test was perceived as being easy to use.

SYMBOLS

IVD	For In Vitro Diagnostic Use		This symbol indicates that you should consult the instructions for use
REF	This symbol indicates the product's catalog number	LOT	This symbol indicates the product's Batch Number
	This symbol indicates the product's Expiry Date		This symbol indicates the product's Manufacturing Date
	This symbol indicates that the product is for single use only. It is not to be re-used.		This symbol indicates that the product should be Stored between 2～30℃
	This symbol indicates that the product should be kept away from sunlight		This symbol indicates that the product should be kept dry
	This symbol indicates the product's Manufacturer	EC REP	EU Authorized Representative

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