ARDİ RESEARCH COVARD SARS-COV/COV2
COVID-19 SALIVA ANTIGEN TEST KIT (Colloidal Gold)

CoVard COVID-19 SALIVA ANTIGEN RAPID TEST KIT

CE

INSTRUCTION

CoVard Covid-19 Rapid Antigen (Ag) Test, is a lateral flow sandwich test designed for the qualitative detection of nucleocapsid protein antigen directly from SARS-CoV-2 in saliva sputum specimens. The antigen test is quick and easy to apply, can be stored at room temperature and provides reliable test results in just 15 minutes.

SUMMARY AND EXPLANATION

SARS-CoV-2 virus causes acute respiratory infectious disease. Patients currently infected by the novel coronavirus are the main source of infection; people with asymptomatic infections can also be a source of contagion. According to current epidemiological research, the incubation period is between 1 and 14 days, mostly 3 to 7 days. The main symptoms are fever, tiredness, and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea are seen.

PURPOSE OF USAGE

This kit is used for in vitro qualitative detection of the SARS-CoV-2 antigen and is used only for clinical laboratory use or emergency review by medical personnel. This test cannot be used for the diagnosis and exclusion of pneumonia caused by the new coronavirus infection and is not suitable for screening by the general population. A positive test result needs further confirmation. A negative test result cannot exclude the possibility of infection. Kit and test results are for clinical reference only. It is recommended to combine the patient's clinical signs and other laboratory tests for a comprehensive analysis of the situation. This kit does not distinguish between SARS-CoV and SARS-CoV-2.

WORKING PRINCIPLE OF THE KIT

This COVID-19 antigen kit uses a double antibody sandwich method to detect the antigen of the novel coronavirus (SARS-CoV-2) in saliva sputum samples. During detection, the gold-labeled anti-SARS-CoV-2 monoclonal antibody on the labeling pad binds to the SARS-CoV-2 antigen in the sample and forms a complex. The reaction complex then moves forward across the nitrocellulose membrane under the influence of chromatography and captured by the anti-SARS-CoV-2 monoclonal antibody pre-coated by the detection zone (T) on the nitrocellulose membrane. Thereupon, a red colored reaction line is formed in the T-zone. If the sample does not contain the SARS-CoV-2 antigen, a red colored reaction line cannot form in the T region. Regardless of whether the sample to be tested contains the SARS-CoV-2 antigen, a red colored reaction line will always appear in the quality control area (C).

CONTENTS OF THE KIT

Materials provided with test kits:
- Test Cassettes
- Sample Collection and Lysis Tubes
- Saliva Collector
- Dropper Cap
- Silica Gel
- User Guide

Note: Components from different batches of the kit cannot be mixed.

SAMPLE REQUIREMENTS

- Saliva samples must be collected using collector cap.
- The samples should be processed as soon as possible after collection (within half an hour).
- Samples should not be deactivated.

STORAGE AND STABILITY

- Store in the sealed bag at 2-30 °C until the expiry date printed on the package, it is prohibited to store below 2 °C and avoid using expired products.
- The test card is used within 15 minutes after being removed from the foil envelope.
- MFG date and EXP date: marked on the label. The expiry date of the product is 12 months.

PROCEDURE

The test consists of two stages. The saliva goes through a rapid process so that samples can be collected with the collector cap taken primarily. Then the processed sample is added to the test cassette. The detailed procedure is as follows.

Sample processing:

1. The tube contains 500 µl Extraction Buffer.
2. Open the cap of the extraction tube and attach saliva collector.
3. Spit in to the collection tube 2-3 times.
4. Remove and discard the saliva collector.
5. Attach dropper cap, then attach the tip to the dropper cap and mix the liquid by inverting 8-10 times.
6. Samples should be used immediately after collection; at the same time, the samples should not be inactivated, stored, or frozen and thawed.

Test operation:

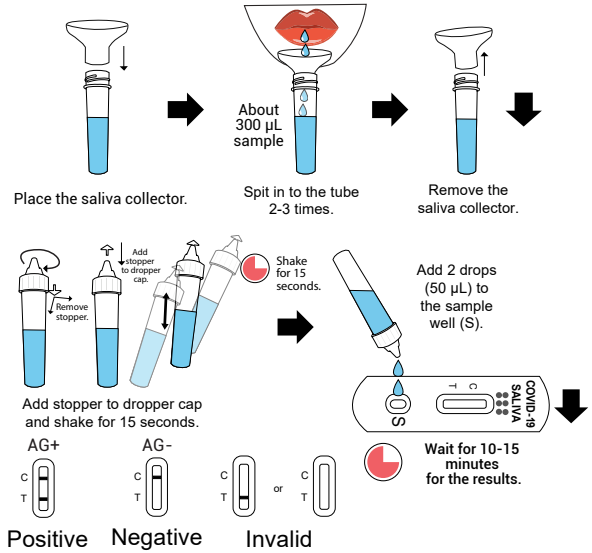
- Please read the user guide before usage.

1. Equilibrate the required reagents and test cards to room temperature
2. Open the aluminum foil package and remove the test casette, place it horizontally on the table and mark it with the sample code / name.
3. Add 50µL (2 drops) of the processed sample to the sample (S) well and wait for 15 min. The use of lysis solution and a dropper cap from the test kit for sampling is recommended to reduce bias.

INTERPRETING TEST RESULTS

This product can only perform qualitative analysis on the detected object.

Positive Result (+): If both (C) and (T) lines appear within 15 minutes, the test result is positive and valid.
Negative Result (-): If the test area (T) line has no color and the control area shows a colored line, the result is negative and valid.
Invalid Result: If a colored line does not appear in the control region (C), the test result is invalid. The sample must be retested using a new test cassette.



PERFORMANCE CHARACTERISTICS

Clinical Validation

Samples from 150 RT-PCR-identified positive patient samples were processed with this test kit and 147 samples were identified as positive; On the other hand, 247 samples were detected as negative in samples taken from 250 RT-PCR-identified negative patients. Test was validated using RT-PCR with nasopharyngeal samples from the same patients.

Method		PCR		Total Results
Ardi RESEARCH	Results	Positive	Negative	
	Positive	147	5	152
	Negative	3	245	248
Total Result		150	250	400

Sensitivity: 98% (147/150) **(95%CI** 94.27% - 99.59%)
Specificity: 98% (245/250) **(95%CI** 95.39% - 99.35%)

Detection Limit

A positive rate of 95% or higher was detected when the virus culture concentration was 400 $TCID_{50}$/mL or more. At virus culture concentration of 200 $TCID_{50}$/mL and below, the positive rate is not higher than 95%, so the minimum detection limit of the SARS-CoV-2 Rapid Antigen Assay is 400 $TCID_{50}$/mL.

Precision

- 10 negative and positive repeat tests were performed using reference materials. Negative results and positive results are 100% confirmed.
- Three different sets of lots containing positive and negative reference materials were tested. Negative results and positive results are 100% confirmed .

Hook Effects

No Hook effect was detected when the concentration of the inactivated virus stock solution increased to 4.0×10^5 $TCID_{50}$/mL.

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CAUTIONS

- For in vitro diagnostic use.
- Do not use the contents of the kit after the expiry date printed on the outside of the box.
- Take appropriate precautions during collection, use, storage and disposal of patient samples and used kit contents. When working with patient samples, nitrile, latex gloves are recommended..
- Do not reuse used Test Card, Lysis Tubes or Saliva Collectors.
- The user should not open the foil pouch of the Test Card and expose it to the surrounding environment until the Test Card is ready for use. Discard and do not use the damaged or dropped Test Card or material.
- Lysis Solution contains a salt solution. If the solution comes in contact with the skin or eyes, rinse with copious amounts of water.
- Inadequate or improper specimen collection, storage and transport may cause false test results.
- Specimen collection and handling procedures require special training and guidance.
- Use the appropriate Saliva Collector Device according to the test procedures.
- Do not use visually bloody or highly viscous samples to obtain accurate results.
- To obtain accurate results, an opened and exposed Test Card should not be used inside a laminar flow cabinet or in a highly ventilated area.
- The test should be done in an area with adequate ventilation.
- When using the contents of this kit, use suitable protective wear clothing, gloves and eye/face protection.
- Wash your hands thoroughly after use.

LIMITATIONS

- The result of the product should be taken as a clinical reference only, not as a confirmed diagnosis. The decision should be made in conjunction with RT-PCR results, clinical symptoms, epidemiological information and other clinical data.
- The contents of this kit will be used for the qualitative detection of SARS-CoV-2 antigens from saliva sputum8.
- This test detects both living and non-living, SARS-CoV and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not be associated with viral culture results performed on the same sample.
- Sample lysis tubes and test card should be equilibrated to room temperature (18-26 °C) before use, otherwise results may be incorrect.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was improperly collected or transported.
- Failure to follow the test procedure may adversely affect test performance and / or invalidate the test result.
- Reaction time of less than 15 minutes may lead to a false negative result; Reaction time of more than 15 minutes may cause a false positive result.
- Positive test results do not exclude the possibility of co-infection with other pathogens. Positive test results do not distinguish between SARSCoV and SARS-CoV-2.
- Negative test results are not intended to be valid for other non-SARS viral or bacterial infections.
- Clinical performance was evaluated with frozen samples, performance of fresh samples can differ.
- Users must perform the test right after sample collection procedure.

CROSS-REACTIVITY

The cross-reactivity of the kit was evaluated. The results showed no cross-reactivity with the following samples;

HCoV-HKU1	(10^5 $TCID_{50}$/mL)
Staphylococcus aureus	(10^6 CFU/mL)
Streptococcus pyogenes	(10^6 CFU/mL)
Measles virus	(10^5 $TCID_{50}$/mL)
Paramyxovirus parotitis	(10^5 $TCID_{50}$/mL)
Adenovirus 3	(10^5 $TCID_{50}$/mL)
Mycoplasma pneumoniae	(10^6 CFU/mL)
Parainfluenza virus 2	(10^5 $TCID_{50}$/mL)
Human Metapneumovirus (hMPV)	(10^5 $TCID_{50}$/mL)
Human coronavirus OC43	(10^5 $TCID_{50}$/mL)
Human coronavirus NL63	(10^5 $TCID_{50}$/mL)
Human coronavirus 229E	(10^5 $TCID_{50}$/mL)
MERS Coronavirus	(10^5 $TCID_{50}$/mL)
Bordetella parapertussia	(10^6 CFU/mL)
Influenza B (Victoria strain)	(10^5 $TCID_{50}$/mL)
Influenza B (Ystrain)	(10^5 $TCID_{50}$/mL)
Influenza A (H1N1 2009)	(10^5 $TCID_{50}$/mL)
Influenza A (H3N2)	(10^5 $TCID_{50}$/mL)
Avian influenza virus (H7N9)	(10^5 $TCID_{50}$/mL)
Avian influenza virus (H5N1)	(10^5 $TCID_{50}$/mL)
Epstein-Barr virus	(10^5 $TCID_{50}$/mL)
Enterovirus CA16	(10^5 $TCID_{50}$/mL)
Rhinovirus	(10^5 $TCID_{50}$/mL)
Respiratory syncytial virus (RSV)	(10^5 $TCID_{50}$/mL)
Streptococcus pneumoniae	(10^6 CFU/mL)
Candida albicans	(10^6 CFU/mL)
Chlamydia pneumoniae	(10^6 CFU/mL)
Bordetella pertussis	(10^6 CFU/mL)
Pneumocystis jirovecii	(10^6 CFU/mL)
Mycobacterium tuberculosis	(10^6 CFU/mL)
Legionella pneumophila	(10^6 CFU/mL)

INTERFERENCE

No interference for whole blood, mouthwash, phenylephrine, acetylsalicylic acid, beclomethasone, benzocaine, flunisolide, guaiacolglyceryl ether, menthol, oxymetazoline, tobramycin, zanamivir, oseltamivir phosphate, mucus.

REFERENCE

On the True Number of COVID-19 Infections: Effect of Sensitivity, Specificity and Number of Tests on Prevalence Ratio Estimation.
Altman E, Mounir I, Najid FZ, Perlaza SM.
Int J Environ Res Public Health. 2020 Jul 24;17(15):5328. doi: 10.3390/ijerph17155328.
PMID: 32722110 Free PMC article.

Detecting the Coronavirus (COVID-19).
Pokhrel P, Hu C, Mao H.
ACS Sens. 2020 Aug 28;5(8):2283-2296. doi: 10.1021/acssensors.0c01153. Epub 2020 Jul 17.
PMID: 32627534 Free PMC article.

ISO 15223 Symbols

CE	This product fulfils the requirements of the Directive 98/79/EC on in vitro diagnostic medical device
	Read instructions for use
	Use by
	Do not re- use
	Do not use if package is damaged
2℃ 30℃	Temperature limit
	Keep away from sunlight
Σ	Tests per kit
LOT	Batch code
IVD	In vitro diagnostic medical
	Manufacturer
	Date of manufacture
	For Use by Qualified Personnel Only
	Protect from moisture
	Biohazard

Merdivenköy Dis. Nur St. No: 1/1
Business Istanbul Plaza
A Block 12th Floor No: 119-120
Kadıköy / ISTANBUL / TURKEY
T: +90 (216) 443 05 44
info@ardimed.com
www.ardimed.com

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