COVID-19 Antigen Detection Kit (Colloidal Gold)

Instructions for use

For self-testing

IVD CE 1434

【NAME OF PRODUCT】

COVID-19 Antigen Detection Kit (Colloidal Gold)

【BRAND NAME OF PRODUCT】

Lituo COVID-19 Antigen Detection Kit (Colloidal Gold)

【PACKING SPECIFICATION】

Composition	Package		
Detection Card	25 Tests	5 Tests	1 Test
Product Code	LCV03	LCV035	LCV03I
Extraction Buffer in tubes	25 Bottles	5 Bottles	1 Bottle
Sampling Swab (Nasal)	25 Pieces	5 Pieces	1 Piece
Instructions for Use	1 Piece	1 Piece	1 Piece

【PRINCIPLE &INTENDED USE】

The COVID-19 Antigen Detection Kit (Colloidal Gold)) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human nasal swab specimen. This is dedicated for medical laypersons (aged 18 and over) as a self-test. This test can be performed in individuals who have experienced typical SARS-CoV-2-like symptoms: fever, cough, headache, sore throat, loss of taste and smell, etc. The test is just for COVID-19 as an auxiliary diagnostic tool.

Positive results indicate the presence of viral antigens, but a clinical correlation with the patient's medical history and other diagnostic information is required to test infection status. Positive results do not rule out bacterial infections or co-infections with other viruses.

Negative results do not rule out the possibility of infection. People who test negative but still have symptoms similar to COVID should contact their doctor/general practitioner for further diagnosis.

【GENERAL REMARKS】

The disease caused by SARS-CoV-2 infection was named COVID-19, an acute infectious disease of the respiratory tract. People are generally susceptibility. Infected individuals are currently the main source of infection. According to the current epidemiological investigation, the incubation period is 1 to 14 days, but mostly 3 to 7 days. The main manifestations are fever, fatigue, and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are found in a few cases.

【SELF-TESTING PRECAUTIONS】

- This self-test is suitable for laypersons of each age (aged 18 and over by themselves / aged below 18 with assistance through an adult). If it is a positive test result, please consult your family doctor or local medical institution.
- If the test procedure of self-test is not followed or the specimen added into the test card is not sufficient, a false result might occur.
- If you have a nosebleed during or immediately after the test, or if you feel pain due to sample collection, please contact your doctor.
- After the test is completed, please put the waste and the used packaging box separately into the empty trash can, and do not mix it with the household trash can.

【ADDTIONALLY REQUIRED MATERIALS】

- Stopwatch
- Container for sample disposal

【STORAGE CONDITION & SHELF LIFE】

The unopened package should be stored at 2-30℃ and protected from direct sunlight. Do not use the product after the expiration date. A test cassette is packed individually in an aluminum bag. After opening the aluminum foil, the test cassette can be used within one hour. Prolonged contact with a humid environment leads to a deterioration of the product.

【TEST PREPARATION】

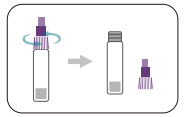
1.Wash or disinfect your hands with soap thoroughly at least 30 seconds before performing the test.

2.Open the test kit and take out all the contents. Please make sure that all components are intact.

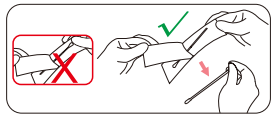
3. Please read the instructions for use carefully before performing the test.
4. The test should be performed at room temperature (18-30 ℃). Make sure all components reach room temperature before testing.

【SAMPLING PREPARATION】

1. Open the extraction tube with buffer solution by unscrewing the cap as shown in the figure.

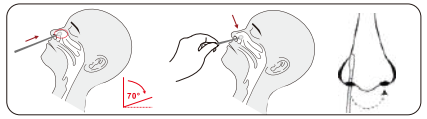


2. Take the swab out of the packaging. Make sure you only touch the swab by the handle, not the tip with the "cotton ball".



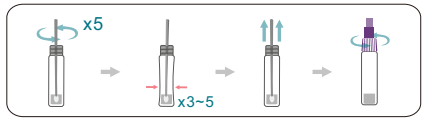
3. Sampling for the nasal swab

Tilt your head back slightly. Insert the swab into a nostril with the "cotton ball" first. Carefully push the swab approx. 2.5 cm until you feel resistance. Press the swab 3x against the nasal wall. Repeat sampling with the same swab in the other nostril to collect as many cells and mucus as possible. Then remove it from your nose and immediately add it to the extraction buffer for sample extraction.



4. Sample extraction:

Stir the swab back and forth 5 times in the extraction buffer. And press the cotton wool head of the swab firmly against the wall of the tube so that the removed sample is dissolved in the liquid. Repeat this carefully 3-5 times. Then remove the swab, making sure that as much of the solution as possible remains in the tube. Then screw the cap back on.

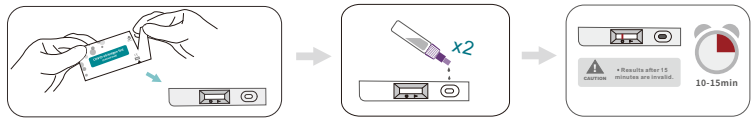


【TEST PROCEDURES】

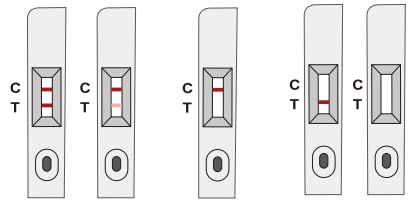
1. Open the aluminum pouch, remove the test cassette, and place it on a flat surface. Do not disturb during testing.
2. Unscrew the top end of the dropper cap and dispense 2 drops (approx. 60μL) of the sample solution (swab sampling and extraction buffer) from the tube into the sample well of the test cassette.

Note: Please make sure you add 2 drops of sample volume. If the sample volume is more or less than 2 drops, invalid test results may occur, e.g., there is no red line in the quality control area (C).

3. Read the displayed results (bands) within 10 to 15 minutes. If the test result is read after more than 15 minutes, the result may be incorrect.



【INTERPRETATION OF TEST RESULTS】



Positive result:

A red reaction line appears in the quality control area (C) and in the test area (T). The test result for SARS-CoV-2 antigen in the sample is positive. There is currently a suspicion of a COVID-19 infection. Please contact your doctor / general practitioner or the local health department immediately and comply with the local guidelines for self-isolation. The presence of a virus does not necessarily mean that you will have a severe form of the disease, but in any case, you must take the necessary precautions according to local government to avoid passing the virus on to others.

Negative result:

A red line appears in the quality control area (C), but no red reaction line appears in the test area (T). A negative result indicates that the sample is negative for the SARS-CoV-2 antigen or the antigen level is below the detection limit. If the sample collection was performed incorrectly, a negative result may be obtained incorrectly.

A negative result does not completely rule out a COVID-19 infection. If you have persistent symptoms or your symptoms become more severe, the test should be repeated after 1-2 days, as the SARS-CoV-2 cannot be accurately detected at all stages of an infection. In case of a negative result, the person must continue to comply with the requirements and recommendations of legal acts, including personal hygiene recommendations, observance of physical distance, wearing personal protective equipment.

Invalid result:

There is no red reaction line in the quality control area (C), the test is invalid. Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. Please note that too much or too little sample volume can lead to invalid test results. If the problem persists, immediately stop using the batch and contact your local distributor.

Please pay attention that the T line might appear prior to C line. Please wait for at least 10 minutes to read the final results.

【QUALITY CONTROL】

A procedural control is included in the test. A red line in the control area (C) is considered an internal procedural control. It confirms sufficient sample volume, complete penetration of the membrane with the sample and correct procedural technique.

【SENSITIVITY & SPECIFICITY】

A total of 595 fresh nasal swab specimens were collected and tested, including 191 positive specimens and 404 negative specimens. The results of the Lituo COVID-19 Antigen Test were compared with the results of the RT-PCR assays. The overall results of the study are shown in below table.

Product manufacturer/ Count Actual frequency	Nasal swab specimen		
	Positive(PCR＜33)	Negative	Total
Positive	189	1	190
Negative	2	403	405
Total	191	404	595
Sensitivity	98.95%		
99% confidence interval	94.82%-99.80%		
Specificity	＞99%		
99% confidence interval	97.93%-99.97%		
Accuracy	99.50%		

【CROSS-REACTIVITY & INTERFERENCE】

Cross-reactivity:

Cross-reactivity with the following organisms was investigated. Samples that tested positive for the following organisms were negative with the Lituo COVID-19 Antigen Detection Kit.

Microorganisms Name	
Human coronavirus 229E	*Candida albicans*
Human coronavirus OC43	*Bordetella pertussis*
Human coronavirus NL63	*Mycoplasma pneumoniae*
MERS pseudovirus	*Chlamydia pneumoniae*
SARS pseudovirus	*Legionella pneumophila*
Adenovirus type 1	*Staphylococcus aureus*
Adenovirus type 2	*Staphylococcus epidermidis*
Adenovirus type 3	*Neisseria meningitidis*
Parainfluenza virus Type 1	*Pseudomonas aeruginosa*
Parainfluenza virus Type 2	*Proteus vulgaris*
Parainfluenza virus Type 3	*Streptococcus hemolytic-β*
Influenza A H5N1	*Streptococcus oralis*
Influenza A H7N9	Coxsackievirus A6
Influenza B (Y Series)	Coxsackievirus B5
Enterovirus EV70	Epstein-Barr virus (humanherpesvirus type 4)
Enterovirus EV71	Measles virus
Respiratory syncytial virus type A	Mumps virus
Respiratory syncytial virus type B	influenza B Yamagata
Rhinovirus A2	influenza B Victoria
Rhinovirus A30	Influenza A virus H1N1
Rhinovirus B52	Influenza A virus HiNi
Haemophilus influenza	influenza A H3N2
Streptococcus pneumonia	Human metapneumovirus (HMPV) type B1
Streptococcus pyogenes	Pooled human nasal washes

Microbial Interference:

The following microorganism that is naturally presented in nasal cavity or would cause similar symptoms was investigated. Samples that tested positive for the following organisms were negative with Lituo COVID-19 Antigen Detection Kit.

Microorganisms Name	
Human coronavirus 229E	Respiratory syncytial virus type A
Human coronavirus OC43	Respiratory syncytial virus type B
Human coronavirus NL63	Rhinovirus A2
MERS pseudovirus	Rhinovirus A30
SARS pseudovirus	Rhinovirus B52
Adenovirus type 1	*Haemophilus influenzae*
Adenovirus type 2	*Streptococcus pneumoniae*
Adenovirus type 3	*Streptococcus pyogenes*
Parainfluenza virus Type 1	*Candida albicans*
Parainfluenza virus Type 2	*Bordetella pertussis*
Parainfluenza virus Type 3	*Mycoplasma pneumoniae*
Influenza A H5N1	*Chlamydia pneumoniae*

Influenza A H7N9	*Legionella pneumophila*
Influenza B (Y Series)	*Staphylococcus aureus*
Adenovirus	*Staphylococcus epidermidis*
Enterovirus EV70	Human metapneumovirus (HMPV) type B1
Enterovirus EV71	Pooled human nasal washes

【LIMITATIONS OF TEST METHOD】

1. The kit is a qualitative test. Therefore, quantitative values of the SARS-CoV-2 antigen concentration cannot be determined.
2. The accuracy of the test depends on the sampling process. Improper specimen collection, improper specimen storage, thawing of the specimen, or repeated freezing and thawing of the specimen can affect the test results. If cross-contamination is not controlled during sample processing, false positive results may occur.
3. The presence of individual drugs in the collected samples, such as high concentrations of prescription and prescription drugs (nasal sprays), can affect the results. If the result is suspicious, repeat the test.
4. The test result of this kit may indicate false positive or false negative. If physical discomfort still occurs or you get positive results of this SARS-CoV-2 antigen test, please go to hospital or professional laboratory for further confirmation.

【WARNINGS】

1. The kit is only intended for in vitro diagnostics.
2. This product is one-time disposable in vitro diagnostic reagent. Please do not reuse.
3. Do not use expired products.
4. If there are no lines in the quality control area (C) and in the test area (T), it means that the result is invalid. Please test again.
5. Only use the sample extraction buffer contained in this kit for sampling.
6. If buffer is drunk or contaminated with your skin and eyes, flush with copious amount of water and seek immediate medical attention.
7. Do not mix different lots of the test cassette and specimen extraction buffer.
8. Improper specimen collection, storage, and outdated specimens will affect results.
9. Do not use swab if the package is broken. If allergic reaction occurs after use with the swab, please stop using immediately.
10. Please do not eat, smoke or drink 30 minutes before sampling to avoid affecting the sampling operation.
11. If you have a nosebleed during or immediately after the test, or if you feel pain due to sample collection, please stop immediately and contact your doctor.
12. Patients who have been treated with antiviral drugs might have a large decrease of virus levels in their bodies, which can lead to false negative results.
13. A negative result does not completely rule out the possibility of infection with the new coronavirus. If the result is negative but clinical symptoms are present, it is recommended that other clinical methods of testing be used.
14. Treat all samples as if they contain infectious agents. Dispose of the used test materials in accordance with local regulations carefully.
15. Wash or disinfect your hands thoroughly before starting the test and when you are finished with the test.

【INDEX OF SYMBOLS】

	Never re-use	IVD	In-vitro-diagnostic medical devices		Keep dry
2°C 30°C	Store at 2-30 ℃		Refer to the instruction of use		Manufacturer
LOT	Lot number	Σ	Contains sufficient for 〈n〉 tests		Date of manufacture
	Use-by date		Keep away from sunlight		Do not use if package is damaged
CE 1434	The device up to the relative EU directives and certified by NB1434			EC REP	Authorized representative in the European Community

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【Date of Issue or Revision】

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