OJABIO

Influenza A&B/SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)

CE IVD

【Product name】

Influenza A&B/SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)

【Packing specification】

20 Tests/Kit (Cat: AHS003)

【Intended use】

The Influenza A&B Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of influenza A and B antigens in throat swab specimens. It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.

The SARS-CoV-2 Antigen Rapid Test (swab) is an in vitro diagnostic test for the qualitative detection of novel coronavirus antigens in Nasal Swab and nasal aspirate samples, using the rapid immunochromatographic method. The identification is based on the monoclonal antibodies specific for the New Coronavirus antigen.

【Test principle】

The Influenza A&B Rapid Test Device is a qualitative, lateral flow immunoassay for the detection of Influenza A and Influenza B nucleoproteins in nasal swab, throat swab or nasal aspirate specimens. In this test, antibody specific to the Influenza A and Influenza B nucleoproteins is separately coated on the test line regions of the test device. During testing, the extracted specimen reacts with the antibody to Influenza A and/or Influenza B that are coated onto particles. The mixture migrates up the membrane to react with the antibody to Influenza A and/or Influenza B on the membrane and generate one or two colored lines in the test regions. The presence of this colored line in either or both of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

The SARS -CoV-2 Antigen Rapid Test (swab) is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to New Coronavirus.

The test device is composed of the following three parts, namely sample pad, reagent pad and reaction membrane. The whole strip is fixed inside a plastic device. The reagent membrane contains the colloidal-gold conjugated with the monoclonal antibodies against New Coronavirus; the reaction membrane contains the secondary antibodies for New Coronavirus and the polyclonal antibodies against the mouse globulin, which are pre-immobilized on the membrane.

When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If New Coronavirus is present in the sample, a complex formed between the anti-New Coronavirus conjugate and the virus will be caught by the specific anti-New Coronavirus monoclonal coated on the T region. Results appear in 10 minutes in the form of a red line that develops on the strip.

Whether the sample contains the virus or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

【Precautions】

Please read all the information in this package insert before performing the test.

1.For professional in vitro diagnostic use only. Do not use after expiration date.
2.The test device should remain in the sealed pouch until use.
3.Do not eat, drink or smoke in the area where the specimens or kits are handled.
4.Do not use test if pouch is damaged.
5.Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
6.Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
7.The used tests, specimens and potentially contaminated materials should be discarded according to the local regulations.
8.Humidity and temperature can adversely affect result.

【Storage conditions & period of validity】

Store at 4℃~30℃, and it is valid for 24 months.

After the aluminum foil bag is unsealed, the test card should be used as soon as possible within one hour.

【Specimen request】

Throat swab:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little hard back and forth at least 3 times; The swab should be inserted into a bottle that contains extraction buffer directly, rotate the swab for about 10 seconds, and press the swab head against the bottle wall to release the antigen in the swab.

Nasal swab:

Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patient's nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the same way; the swab should be inserted into a bottle that contains extraction buffer directly, rotate the swab for about 10 seconds, and press the swab head against the bottle wall to release the swab antigen.

Nasopharyngeal swabs:

Place the nasal swab and throat swab inserted into a bottle that contains extraction buffer directly, so-called nasopharyngeal swab bottle. Rotate the swab for about 10 seconds, and press the swab head against the bottle wall to release the antigen in the swab

【Main components】

No.	Components	Quantity
1	Test Card	20 tests
2	Extraction Buffer	20 bottles
3	Disposable Sampling Swab	20 pcs

【Applicable instrument】

1. Specimen collector
2. Timer

【Test methods】

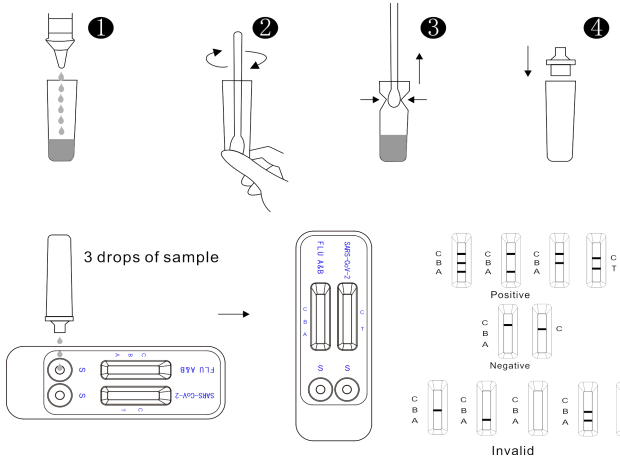
The test method was colloidal gold. Please read the manual and the instrument operation manual carefully before use.

1.Open the package and take out the test card.Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2.The swab should be inserted into a bottle that contains extraction buffer directly, rotate the swab for about 10 seconds, and press the swab head against the bottle wall to release the antigen in the swab. Squeeze the swab over the head to remove the swab so as to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.

3.Add 3 drops into the specimen hole of the test card, and start the timer.

4.Read the result at 10~20 minutes. Do not interpret the result after 20 minutes



【Interpretation of test results】

(Please refer to the illustration above)

POSITIVE Influenza A:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.

POSITIVE Influenza B:* Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.

POSITIVE Influenza A and Influenza B:* Three distinct colored lines appear. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.

*NOTE: The intensity of the color in the test line regions (A or B) will vary based on the amount of Flu A or B antigen present in the sample. So any shade of color in the test regions (A or B) should be considered positive.

POSITIVE SARS -CoV-2 : Two red lines appear. One red line appears in the control region (C), and one red line in the test region (T). The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line regions (A or B) / (T).

INVALID: Control line fails to appear. Insufficient specimen 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 device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【Quality control】

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

【Limitations of inspection methods】

The Influenza A&B Rapid Test Device

1.The Influenza A&B Rapid Test Device is for professional in vitro diagnostic use only. The test should be used for the detection of Influenza A and/or B virus in nasal swab, throat swab or nasal aspirate specimens. Neither the quantitative value nor the rate of increase in Influenza A and/or B virus concentration can be determined by this qualitative test.
2.The Influenza A+B Rapid Test Device will only indicate the presence of Influenza A and/or B virus in the specimen from both viable and non-viable Influenza A and B strains.
3.As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4.A negative result obtained from this kit should be confirmed by culture. A negative result may be obtained if the concentration of the Influenza A and/or B virus present in the nasal swab is not adequate or is below the detectable level of the test.
5.Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6.The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7.The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8.A positive result for influenza A and/or B does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

The SARS -CoV-2 Antigen Rapid Test Device

1 The SARS -CoV-2 Antigen Rapid Test (swab) is an acute-phase screening test for qualitative detection. Sample collected may contain antigen titles below the reagent's sensitivity threshold, so a negative test result does not exclude infection with New Coronavirus.
2 The SARS -CoV-2 Antigen Rapid Test (swab) detects viable and non-viable novel coronavirus antigen. Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present. Therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
3 A negative test result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor-quality specimen is obtained.
4 Performance of the test has not been established for monitoring antiviral treatment of New Coronavirus.
5 Positive test results do not rule out co-infections with other pathogens.
6 Negative test results are not intended to rule in other coronavirus infection except the SARS-Cov-1.
7 Children tend to shed virus for longer periods of time than adults, which may result in differences in sensitivity between adults and children List.
8 A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of COVID-19 infection, and should be confirmed by viral culture or a molecular assay or ELISA.

【Product performance index】

Sensitivity, Specificity and Accuracy

The Influenza A&B Rapid Test Device has been evaluated with specimens obtained from the patients.RT-PCR is used as the reference method for the Influenza A&B Rapid Test Device. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result

Throat Swab Specimen:

		Type A			Type B		
		RT-PCR		Total Results	RT-PCR		Total Results
		Positive	Negative		Positive	Negative	
Flu A+B	Positive	58	1	59	65	1	66
	Negative	3	150	153	4	162	166
Total Results		61	151	212	69	163	232
Relative Sensitivity		95.1%			94.2%		
Relative Specificity		99.3%			99.4%		

Accuracy	98.1%	97.8%

Reactivity with Human Influenza Strain

The Influenza A&B Rapid Test Device was tested with the following human influenza strains and a discernible line at appropriate test-line regions was observed:

Influenza A Virus	Influenza B Virus
A/NWS/33 10(H1N1)	Bright
A/Hong Kong/8/68(H3N2)	B/R5
A/Port Chalmers/1/73(H3N2)	B/Russia/69
A/WS/33(H1N1)	B/Lee/40
A/New Jersey/8/76(HswN1)	B/Hong Kong/5/72
A/Mal/302/54(H1N1)	

Specificity Testing with Various Viral Strains

Description	Test Level
Human adenovirus C	5.62 x 105 TCID50/mL
Human adenovirus B	1.58 x 104 TCID50/mL
Adenovirus type 10	3.16 x 103 TCID50/mL
Adenovirus type 18	1.58 x 104 TCID50/mL
Human coronavirus OC43	2.45 x 106 LD50/mL
Coxsackievirus A9	2.65 x 104 LD50/mL
	1.58 x 105 TCID50/mL
Coxsackievirus B5	1.58 x 107 TCID50/mL
Human herpesvirus 5	1.58 x 104 TCID50/mL
Echovirus 2	3.16 x 105 TCID50/mL
Echovirus 3	1 x 104 TCID50/mL
Echovirus 6	3.16 x 106 TCID50/mL
Herpes simplex virus 1	1.58 x 106 TCID50/mL
Human herpesvirus 2	2.81 x 105 TCID50/mL
Human Rhinovirus 2	2.81 x 104 TCID50/mL
Human Rhinovirus 14	1.58 x 106 TCID50/mL
Human Rhinovirus 16	8.89 x 106 TCID50/mL
Measles	1.58 x 104 TCID50/mL
Mumps	1.58 x 104 TCID50/mL
Sendai virus	8.89 x 107 TCID50/mL
Parainfluenza virus 2	1.58 x 107 TCID50/mL
Parainfluenza virus 3	1.58 x 108 TCID50/mL
Respiratory syncytial virus	8.89 x 104 TCID50/mL
Human respiratory syncytial virus	1.58 x 105 TCID50/mL
Rubella	2.81 x 105 TCID50/mL
Varicella-Zoster	1.58 x 103 TCID50/mL

TCID50 = Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision

Intra-Assay＆Inter-Assay

Within-run and Between-run precision has been determined by using five specimens of Influenza standard control. Three different lots of the Influenza A&B Rapid Test Device have been tested using negative,Influenza A weak,Influenza B Weak, Influenza A Strong and Influenza B Strong.Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-reactivity

The following organisms were tested at $1.0x10^8$ org/mL and all found to be negative when tested with the Influenza A&B Rapid Test Device:

Arcanobacterium	Pseudomonas aeruginosa
Candida albicans	Staphylococcus aureus subspaureus
Corynebacterium	Staphylococcus epidermidis
Enterococcus faecalis	Staphylococcus saprophylicus
Enterococcus faecium	Streptococcus agalactiae
Escherichia coli	Streptococcus bovis
Haemophilus	Streptococcus dysgalatiae / subsp.dysgalatiae
Moraxella catarrhalis	Streptococcus oralis formerly Streptococcus
Neisseria gonorrhoeae	Streptococcus pneumoniae
Neisseria lactamica	Streptococcus pygenes
Nesseria subllava	Streptococcus salivarius
Proleus vulgaris	Streptococcus sp group F.type 2

Clinical evaluation was performed to compare the results obtained by New Coronavirus (COVID-19) Antigen Rapid Test (swab) and PCR. The results were summarized below:

Table: SARS-CoV-2 Antigen Rapid Test Cassette (swab) vs. PCR

Method		**PCR**		**Total Results**
SARS-CoV-2	Results	Positive	Negative	
	Positive	26	2	28
	Negative	5	106	111
Total Results		31	108	139

Relative Sensitivity: 83.9% Relative Specificity:98.1%

Relative Accuracy: 95.0%

Precision

No cross reaction has been confirmed of the SARS-CoV-2 Antigen Rapid Test (swab) with the following pathogens:

①Bacteria

Acinetobacter baumannii, Bordetella pertussis, Branhamella catarrhalis, Candida albicans, Candida glabrata, Cardiobacterium hominis, Eikenella corrodens, Enterococcus faecalis, Enterococcus gallinarum. Escherichia coil, Group C streptococcus, Group G streptococcus, Haemophilus aphrophilus, Haemophilus influenzae, Haemophilus paraphrophilus, Klebsiella pneumoniae, Neisseria gonorrhoeae Peptococcus asaccharolyticus, Peptostreptococcus anaerobius, Proteus mirabilis, Proteus vulgaris, Pseudomonas aeruginosa, Serratia marcescens, Staphylococcus epidermidis, Streptococcus agalactiae (group B), Streptococcus mutans, Streptococcus pneumoniae, Streptococcus pyogenes (group A), Veillonella parvula

②Virus

Influenza A, Influenza B, Adenovirus Type 1～8, 11, 19, 37, Coxsackie virus Type A16, B1～5, Cytomegalovirus, Echovirus Type 3, 6, 9, 11, 14, 18, 30, Enterovirus Type 71, HSV-1, Mumps virus, Tyep I simple herpes virus Parainfluenza virus Type 1～3, Poliovirus Type 1～3, Respiratory syncytial virus, Rhinovirus Type 1A, 13, 14, Type I simple herpes virus.

③Mycoplasma etc.

No cross reaction with Chlamydia pneumoniae, Chlamydia psittaci, Chlamydia trachomatis Mycoplasma pneumoniae.

【References】

1.Williams, KM, Jackson MA, Hamilton M. (2002) Rapid Diagnostic Testing for URIs in Children; Impact on Physician Decision Making and Cost. Infec. Med.19(3): 109-111.

2.Betts, R.F. 1995. Influenza virus, p. 1546-1567.In G.L.Mandell, R.G.Douglas,Jr. and J.E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone,Inc.,New York, N.Y.

3.WHO recommendations on the use of rapid testing for influenza diagnosis,World Health Organisation, July 2005.

【Index of CE Symbols】

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community
	Date of Manufacture		Use by date
	Do not reuse		Consult instruction foe use
LOT	Batch code	CE	Meet the requirements of EC Directive 98/79/EC

Wenzhou OJA Biotechnology Co., Ltd.
No.1, Fumao Road, Wuwei Economic and Development Zone, Wuhu, Anhui, P.R. China
Email: ojaservice@163.com

EC REP **Lotus NL B.V.**
Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.
Email:peter@lotusnl.com