SARS-CoV-2&Respiratory Syncytial Virus&Flu A & Flu B Antigen Rapid Test Cassette(Colloidal Gold)

Cassette

Instruction for Use

An in vitro diagnostic test for the qualitative detection of SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B antigens in nasopharyngeal swab,oropharyngeal swab, and nasal swab specimens.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PROUDCT SPECIFICATION

1T/BOX,10T/BOX,20T/BOX,25T/BOX,40T/BOX，50T/BOX

INTENDED USE

The SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen Rapid Test *Cassette*(Colloidal Gold) is an in vitro diagnostic test for the qualitative detection of SARS-CoV-2&Respiratory Syncytial Virus&Flu A ＆ Flu B antigens in nasopharyngeal swab,oropharyngeal swab, and nasal swab specimens.

PRINCIPLE

The SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen Rapid Test *Cassette*(Colloidal Gold)is based on the principle of Immunochromatography sandwich-like assay for determination of Flu A/Flu B/RSV/SARS-CoV-2 antigens extracted from the swab specimen.
When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample,the specimen is absorbed into the device by capillary action,mixes with the SARS-CoV-2/RSV/Influenza type A and B antibody colloidal conjugate and flows across the pre-coated membrane.
When the antigen level in the specimen is at or above the target cutoff (the detection limit of the test), the antigen bound to the antibody colloidal conjugate are combined by antibody immobilized in the Test Region (T) of the device, and this produces a colored test band that indicates a positive result. When the antigen level in the specimen is zero or below the target cutoff, there is no visible colored band in the Test Region (T) of the device. This indicates a negative result.
To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

MATERIALS PROVIDED

Test devices, each cassette is Individual sealed in a foil pouch with a package of desiccant.
Sterilized Swab
Extraction Tube
Tube Tip
Extraction Buffer
Package Insert

PRECAUTIONS

1. This kit is for in vitro diagnostic use only.
2. All specimens should be treated as capable of transmitting diseases.Use appropriate precautions in the collection, handling,storage and disposal of patient samples and used kit contents.
3. Discard after first use.The sample extraction tube, the dropper and the test device cannot be used more than once.
4. DISPOSAL OF THE DIAGNOSTIC: All specimens and the used-kit has the infectious risk.The process of disposing the diagnostic must follow the local infectious disposal law or laboratory regulation.
5. Do not touch the reaction area of test strip.
6. Do not use test kit beyond the expiration date.
7. Do not use the kit if the pouch is punctured or not well sealed.
8. Wear appropriate personal protective equipment (e.g. gowns, gloves, eye protection) when handing the contents of this kit.
9. Proper specimen collection storage and transport are critical to the performance of this test.
10. The test result should be interpreted by the physician along with clinical findings and other laboratory test results.

STORAGE AND STABILITY

1. Store at 2℃~30℃ in the sealed pouch up to the expiration date printed on the package. **Do not freeze.**The shelf-life of the kit under these storage conditions is 24 months.
2. The test cassette should be used within 30 minutes after taking out from the foil pouch.
3. Keep away from sunlight, moisture and heat.
4. Kit contents are stable until the expiration date printed on the outer box.

SAMPLE COLLECTION

The test can be performed with nasal swab, nasopharyngeal swab or oropharyngeal swab specimen.

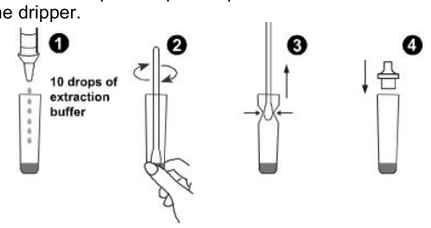
1. According to standard nasal swab, nasopharyngeal swab or oropharyngeal swab specimen collection procedure.
2. Nasal swab:Tilt the head of the patient backwards (about 70 degrees).Gently twist the swab,insert the entire absorbent tip of the nasal swab into a nostril to about 1.5 cm deep.Perform the first sampling by rubbing the nasal wall firmly with the nasal swab, turning it five times against the nasal walls so that the absorbent surface of the nasal swab is wetted all round.

Note: a) Be careful not to hurt the patient.b)This process may take about 15 seconds.Slowly remove the nasal swab from the first nostril.Repeat the collection process with the same nasal swab in the other nostril.

3. Nasopharyngeal swab specimen collection:Tilt patient's head back 70 degrees.Insert swab into nostril.(Swab should reach depth equal to distance from nostrils to outer opening of the ear.)Leave swab in place for several seconds to absorb secretions.Slowly remove swab while rotating it.
4. Oropharyngeal swab specimen collection:Insert swab into the posterior pharynx and tonsillar areas.Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.
5. It should be processed as soon as possible after the specimen is collected,if the specimens are not processed immediately,specimens should be stored in a dry, disinfected tube and tightly sealed(Place tip of swab into a tube and snap/cut off the applicator stick).They may be stored at 2℃~8℃ for up to 8 hours,or they may be stored at -70℃ for long time.

SAMPLE PREPARATION PROCEDURE

1.Transfer 0.5 mL （ about 10 drops) extraction buffer to the sample extration tube vertically.
2.Insert the swab which has collected secretions into the specimen extraction buffer and rotate about 10 times to dissolove the specimen in the solution as much as possible.
3.Squeeze the swab tip to keep the liquid in the tube as much as possible.
4.Cover the dripper.

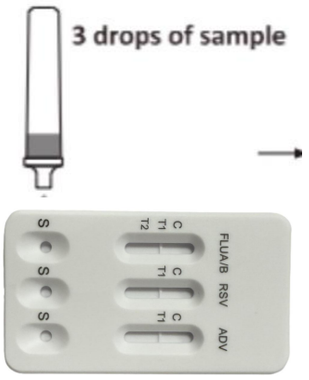


TEST PROCEDURE

Allow the test device, test sample and buffer to equilibrate to room temperature (10-30°C) prior to testing.
Use freshly collected samples of nasopharyngeal(NP) swab, oropharyngeal swab, and nasal swab for optimum performance.

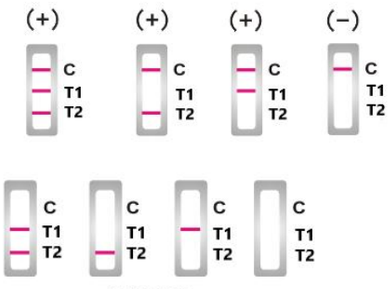
Assay Procedure

1) Remove test device from the sealed pouch just prior to the testing and lay flat on work bench.
2) Insert a tube tip into the sample extraction tube tightly.
3) Reverse the sample extraction tube, and add 3 drops (about 80μl) of test sample by squeezing the extracted solution tube into the sample window.
4) Read the result at 15 minutes.Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULT

POSITIVE: 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: Only one red line appears in the control region(C), and no line in the test region(T). .It indicates that the concentration of the antigens is zero or below the detection limit of the test.
INVALID: No red line appears in the control region(C). The test is invalid even if there is a line on test region(T). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.



POSITIVE:The Control line (C) and a colored T1 line appear；the Control line (C) and a colored T2 line appear；the Control line and both colored T2 test line and T1 test line appear. The color intensities of the lines do not have to match.The test is positive when any of the above occurs.
NEGATIVE:

Only the Control line (C) is visible. No T2 line or T1 line appears. The result is negative.

INVALID：

Result is invalid if Control line (C) is not colored, regardless of any colored line in the T2 line or T1 line . Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the kit immediately and contact your local distributor.

LIMITATIONS OF TEST

1）The SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen Rapid Test Cassette (Colloidal Gold) is an acute-phase screening test for qualitative detection.

2）This reagent is designed to detect antigen in human nasal cavity,nasopharynx and oropharynx.

3）This reagent is a qualitative assay.It is not designed to determine the quantitative concentration of SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen.

4）The accuracy of the test depends on the sample collection process.Improper sample collection, improper sample storage, or repeated freezing and thawing of the sample will affect the test result.

5）The test results of this reagent are for clinical reference only,a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.

6）Limited by the method of antigen detection reagents, for negative test results,it is recommended to use nucleic acid detection or virus culture identification methods for review and confirmation.

PERFORMANCE

1）Detection Limit

The minimum detection limit of this reagent is as follows:

Strain	$TCID_{50}$/mL
SARS-CoV-2	3.5×10^2
RSV	1.07×10^4
Flu A	5.1×10^5
Flu B	1.5×10^6

2）Cross Reaction

No cross reaction has been confirmed of the SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen Rapid Test Cassette (Colloidal Gold) with the following pathogens:

①Bacteria

Acinetobacter baumannii	Bacteroids fragilis
Bordetella pertussis	Candida albicans
Candida glabrata	Cardiobacterium hominis
Eikeneus corrodens	Enterococuus gallinarum
Escherichia coil	Haemophilus phrophlus
Aemophilus influenzae	Haemophilus Parainfluenzae
Haemophilus Paraphrophilus	Kingella Kingae
Listeria Monocytogenes	Moraxella Catarrhalis
Neisseria Gonorrhoeae	Proteus Mirabilis
Proteus Vulgaris	Pseudomonas Aeruginosa
Serratia Marcescens	Staphylococcus Aureus
Staphylococcus Epidermidis	Streptococcus Pneumoniae
Streptococcus Pyogenes	Streptococcus Agalactiae
Streptococcus sp. Group c,g,f	Streptococcus Mutans

②Virus

No cross reaction with Adenovirus,Coxsackie virus Type A16,B1~5, Cytomegalovirus,Echovirus Type 3,6,9,11,14,18,30, Enterovirus Type 71, Mumps virus, Type I simple herpes virus Parainfluenza virus Type 1 ~ 3, Poliovirus Type 1~ 3,Rhinovirus Type 1A,13,14

③Mycoplasma etc.

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

3) Clinical Study Data Summary

A comparison study of the SARS-CoV-2&Respiratory Syncytial Virus&Flu A＆Flu B Antigen Rapid Test Cassette(Colloidal Gold) and Real Time PCR Kit . Compare the sensitivity and specificity between the two methods.

Table 1.1 Test result of SARS-CoV-2

Clinical sample		SARS-CoV-2 Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
SARS-CoV-2&Respiratory Syncytial Virus&Flu A& Flu B Antigen Rapid Test	Positive	138	0	138
	Negative	3	375	378
Total		141	375	516

Sensitivity: 97.87% (95% CI:93.91%-99.56%)
Specificity:100% (95% CI: 99.02%-100.00%)
Accuracy: 99.42%(95% CI:98.31%-99.88%)

Table 1.2 Test result of RSV

Clinical sample		RSV Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
SARS-CoV-2&Respiratory Syncytial Virus&Flu A& Flu B Antigen Rapid Test	Positive	112	2	114
	Negative	3	203	206
Total		115	205	320

Sensitivity: 97.39% (95% CI:92.57%-99.46%)
Specificity:99.02% (95% CI: 96.52%-99.88%)
Accuracy: 98.44%(95% CI:96.39%-99.49%)

Table 1.3 Test result of Flu A

Clinical sample		Flu A Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
SARS-CoV-2&Respiratory Syncytial Virus&Flu A& Flu B Antigen Rapid Test	Positive	57	1	58
	Negative	1	103	104
Total		58	104	162

Sensitivity:98.28% (95% CI:90.76% ~ 99.96%)

Specificity:99.04% (95% CI: 94.76% ~ 99.98%)

Accuracy: 98.77%(95% CI:95.61% ~ 99.85%)

Table 1.4 Test result of Flu B

Clinical sample		Flu B Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
SARS-CoV-2&Respiratory Syncytial Virus&Flu A& Flu B Antigen Rapid Test	Positive	34	1	35
	Negative	2	112	114
Total		36	113	149

Sensitivity: 94.44% (81.34%～99.32%)
Specificity: 99.12% (95.17%～99.98%)
Accuracy: 97.99% (94.23%～99.58%)

BIBLIOGRAPHY

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Code:GKPD028-1 Effective date: May 27, 2024

Index of Symbols

IVD	For in vitro diagnostic use only		Do not reuse
	Expiry date		See instruction for use
	Warning, please refer to the instructions in the annex		Manufacturer
2℃ 30℃	Temperature scope within which the product is reserved	LOT	Batch number
REF	Catalog #	Σ	Tests / box
EU REP	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
CE	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

Manufacturer:
Dezhou Guoke Medical Technology Co., Ltd
Add.: 28-31 axis,1 and 2 span, No.2 workshop, (Zhongyuan Science and Technology Innovation Park) No. 6596 Dongfanghong East Road, Yuanqiao Town, Economic and Technological Development Zone, Dezhou City, Shandong Province,China
E-mail: office@guoke-medical.com

EU REP **European Authorized Representative:**
Riomavix S.L.
Add.: Calle de Almansa 55,1D, Madrid 28039 Spain
E-mail: riomavix@gmail.com