

COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test Cassette (Colloidal Gold)

Cassette

Instructions for Use

An in vitro diagnostic test for the qualitative detection of COVID-19, influenza A and B viruses, respiratory syncytial virus (RSV), adenovirus, Mycoplasma pneumoniae (MP), and human metapneumovirus (HMPV) antigens in nasopharyngeal swab, oropharyngeal swab, and nasal swab specimens.



In Vitro Diagnosis For Professional Use

PRODUCT SPECIFICATION

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

INTENDED USE

The COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test Cassette (Colloidal Gold) is an in vitro diagnostic test for the qualitative detection of COVID-19, influenza A and B viruses, respiratory syncytial virus (RSV), adenovirus, Mycoplasma pneumoniae (MP), and human metapneumovirus (HMPV) antigens in nasopharyngeal swab, oropharyngeal swab, and nasal swab specimens, using the rapid immunochromatographic method.

PRINCIPLE

The COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test Cassette (Colloidal Gold) is based on the principle of Immunochromatography sandwich-like assay for determination of COVID-19/Flu A/B/RSV/ADV/MP/HMPV 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 COVID-19/Flu A/B/RSV/ADV/MP/HMPV 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 and dropper

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 handling 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 °C – 30 °C 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.

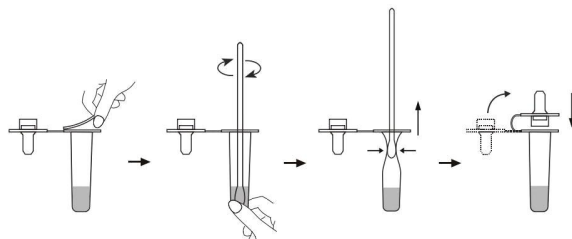
SAMPLE COLLECTION

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 °C – 8 °C for up to 8 hours, or they may be stored at -70 °C for long time.

SAMPLE PREPARATION PROCEDURE

1. Vertically transfer 0.5 mL – 1 mL of extraction buffer into the sample extraction tube.
2. Place the swab with collected secretions into the extraction tube. Rotate the swab for about 15 seconds while pressing the swab head against the inner wall of the tube to release antigen from the swab.
3. When removing the swab, squeeze the swab head against the inner wall to expel as much liquid as possible. Dispose of the swab according to biohazard waste disposal protocols.
4. Cap the extraction tube with the dropper tip.



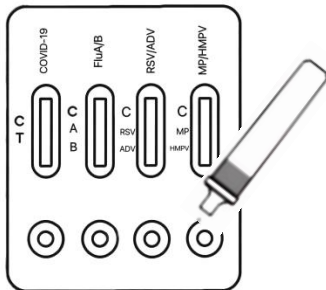
TEST PROCEDURE

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 the test device from the sealed pouch just before use and place it on a flat surface.
- 2) Firmly insert the dropper tip into the sample extraction tube.
- 3) Invert the extraction tube and squeeze to add 3 – 4 drops (approximately 80–100 µL) of the extracted specimen into the sample well.
- 4) Read the result at 15 minutes. Do not read after 20 minutes.



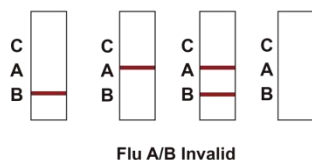
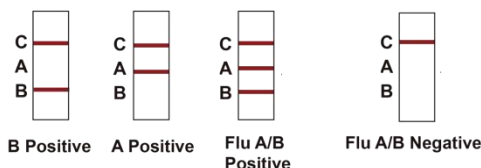
INTERPRETATION OF RESULT



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.

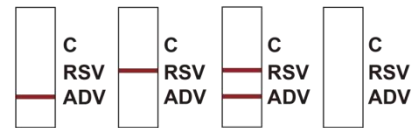
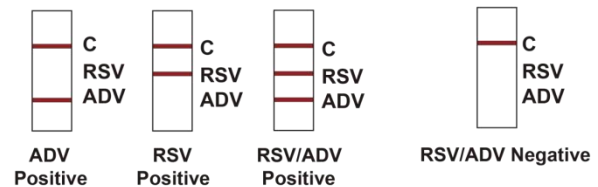


Interpretation of Flu A/B Results

Positive: A control line and at least one test line appear on the membrane. A test line for A indicates influenza A antigen; a test line for B indicates influenza B antigen. If both A and B lines appear, both antigens are present. The lower the antigen concentration, the fainter the test line.

Negative: A colored line appears in the control region (C). No visible line appears in the test line region, indicating that no influenza A/B antigen is detected.

Invalid: Control line is absent. Insufficient sample volume or incorrect procedure is the most likely cause. Review the procedure and retest with a new device. If the problem persists, discontinue use and contact your local distributor.

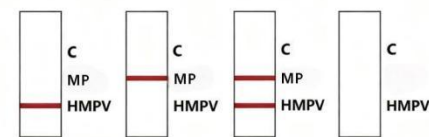
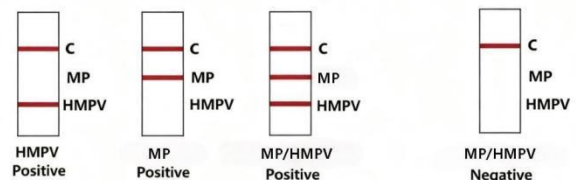


Interpretation of RSV/ADV Results

Positive: A control line and at least one test line appear on the membrane. The presence of an RSV test line indicates the presence of RSV antigen; the presence of an ADV test line indicates the presence of ADV antigen. If both RSV and ADV lines appear, it indicates that both RSV and ADV antigens are present. The lower the antigen concentration, the weaker the result line.

Negative: A colored line appears in the control region (C). No visible line appears in the test line region, indicating that no RSV/ADV antigen is detected.

Invalid: Control line is absent. Insufficient sample volume or incorrect procedure is the most likely cause. Review the procedure and retest with a new device. If the problem persists, discontinue use and contact your local distributor.



Interpretation of MP/HMPV Results

Positive: A control line and at least one test line appear on the membrane. The presence of an MP test line indicates the presence of MP antigen; the presence of an HMPV test line indicates the presence of HMPV antigen. If both MP and HMPV lines appear, it indicates that both MP and HMPV antigens are present. The lower the antigen concentration, the weaker the result line.

Negative: A colored line appears in the control region (C). No visible line appears in the test line region, indicating that no MP/HMPV antigen is detected.

Invalid: Control line is absent. Insufficient sample volume or incorrect procedure is the most likely cause. Review the procedure and retest with a new device. If the problem persists, discontinue use and contact your local distributor.

LIMITATIONS OF TEST

1) The COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo 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 COVID-19/Flu A/B/RSV/ADV/MP/HMPV 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
COVID-19	3.5×10^2
RSV	1.07×10^4
Flu A	5.1×10^5
Flu B	1.5×10^6
ADV	2.3×10^4
MP	2.5×10^2
HMPV	1×10^2

2) Cross Reaction

No cross reaction has been confirmed of the COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test Cassette (Colloidal Gold) with the following pathogens:

① Bacteria

Acinetobacter baumannii	Bacteroides fragilis
Bordetella pertussis	Candida albicans
Candida glabrata	Cardiobacterium hominis
Eikenella corrodens	Enterococcus gallinarum
Escherichia coli	Haemophilus phrophilus
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

② Virus

No cross reaction with 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.

③ Mycoplasma etc.

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

3) Clinical Study Data Summary

A comparative study was conducted between the COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test

Cassette (Colloidal Gold) and real-time PCR kits to evaluate the differences in sensitivity and specificity between the two methods.

Table 1.1 Test result of COVID-19

Clinical Sample		COVID-19 Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	59	1	60
	Negative	3	793	796
Total		62	794	856

Sensitivity: 95.20% (95% CI: 86.71% – 98.34%)

Specificity: 99.90% (95% CI: 99.29% – 99.98%)

Accuracy: 99.50% (95% CI: 98.80% – 99.82%)

Table 1.2 Test result of RSV

Clinical Sample		RSV Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	62	2	64
	Negative	2	790	792
Total		64	792	856

Sensitivity: 96.90% (95% CI: 89.30% – 99.14%)

Specificity: 99.70% (95% CI: 99.08% – 99.93%)

Accuracy: 99.50% (95% CI: 98.80% – 99.82%)

Table 1.3 Test result of Flu A

Clinical Sample		Flu A Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	59	1	60
	Negative	2	794	796
Total		61	795	856

Sensitivity: 96.70% (95% CI: 88.81% – 99.10%)

Specificity: 99.90% (95% CI: 99.29% – 99.98%)

Accuracy: 99.60% (95% CI: 98.97% – 99.88%)

Table 1.4 Test result of Flu B

Clinical Sample		Flu B Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	65	1	66
	Negative	3	787	790
Total		68	788	856

Sensitivity: 95.60% (95% CI: 87.81% – 98.49%)

Specificity: 99.90% (95% CI: 99.28% – 99.98%)

Accuracy: 99.50% (95% CI: 98.80% – 99.82%)

Table 1.5 Test result of ADV

Clinical Sample		ADV Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	60	3	63
	Negative	1	792	793
Total		61	795	856

Sensitivity: 98.40% (95% CI: 91.28% – 99.71%)

Specificity: 99.60% (95% CI: 98.90% – 99.87%)

Accuracy: 99.50% (95% CI: 98.80% – 99.82%)

Table 1.6 Test result of MP

Clinical Sample		MP Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP Antigen Combo Rapid Test	Positive	71	3	74
	Negative	3	779	782
Total		74	782	856

Sensitivity: 95.90% (95% CI: 88.75% – 98.61%)

Specificity: 99.60% (95% CI: 98.88% – 99.87%)

Accuracy: 99.30% (95% CI: 98.48% – 99.68%)

Table 1.7 Test result of HMPV

Clinical Sample		HMPV Real-time PCR Kit (RT-PCR)		Total
		Positive	Negative	
COVID-19 & Flu A/B & RSV & Adenovirus & MP & HMPV Antigen Combo Rapid Test	Positive	62	2	64
	Negative	3	789	792
Total		65	791	856

Sensitivity: 95.40% (95% CI: 87.29% – 98.42%)

Specificity: 98.80% (95% CI: 99.08% – 99.93%)

Accuracy: 99.40% (95% CI: 98.64% – 99.75%)

BIBLIOGRAPHY

- [1] World Health Organization: Clinical management of severe acute respiratory infection when novel coronavirus (nCoV-2019) infection is suspected: interim guidance. 12 January 2020.
- [2] Chen, Yu, Li Lanjuan et al. "COVID-19: viral dynamics and host response." Lancet Infectious Diseases, 2020, 20(5): 515-516.
- [3] Ruef C.: Diagnosing influenza-clinical assessment and/or rapid antigen testing?. Infection 2007; 35: 49-50.
- [4] Lode H: Respiratory tract infection: when is antibodies therapy indicated? Chin Ther 1991; 13: 149-156.
- [5] P. Pothier, G. A. Denoyel etc.: Use of Monoclonal Antibodies for Rapid Detection of Influenza A Virus in Nasopharyngeal Secretions. Eur. J. Clin. Microbiol., June 1986, p. 336-339.

Code: GKPD098-1 Effective Date: May 27, 2024
Index of Symbols

	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
	Temperature scope within which the product is reserved		Batch number
	Catalog #		Tests / box
	European union authorized representative		Keep dry
	Keep away from sunlight		Don't use the product when the package is damaged
	Biological risks		
	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

European Authorized Representative:


Riomavix S.L.

Add.: Calle de Almansa 55, 1D, Madrid 28039 Spain

E-mail: riomavix@gmail.com