Influenza type A and B (Flu A/B) Ag Rapid Test Cassette (Colloidal Gold)

Cassette

Instruction for Use

An immunochromatographic assay for the qualitative detection of influenza type A (including the subtype H1N1) and B nucleoprotein antigen extracted from nasopharyngeal (NP) swab, oropharyngeal swab, and nasal swab specimens.

CE IVD REF

In Vitro Diagnosis
For Professional Use

PACKAGING SPECIFICATION

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

INTENDED USE

Flu A/B Ag Rapid Test Cassette(Colloidal Gold) is an immunochromatographic assay for the qualitative detection of influenza type A (including the subtype H1N1) and B nucleoprotein antigen extracted from nasopharyngeal (NP) swab, oropharyngeal swab, and nasal swab specimens. It is intended to be used to aid in the differential diagnosis of influenza type A and B infection. The test is recommended for professional use only. All results must be interpreted together with other clinical information available to the physician.

SUMMARY

Influenza (commonly known as 'flu') is a highly contagious, acute viral infection of the respiratory tract. It is a communicable disease that is easily transmitted through the coughing and sneezing of aerosolized droplets containing live virus. Influenza outbreaks occur each year during the autumn and winter months. There are three types of influenza viruses: A, B, and C. Only influenza A viruses are further classified by subtype on the basis of the two main surface glycoproteins hemagglutinin (HA) and neuraminidase (NA). Influenza A subtypes and B viruses are further classified by strains.

Humans can be infected with influenza types A, B, and C viruses. Subtypes of influenza A that are currently circulating among people worldwide include H1N1, H1N2, and H3N2 viruses. Influenza B viruses can cause morbidity and mortality among humans, but in general are associated with less severe epidemics than influenza A viruses. Although influenza type B viruses can cause human epidemics, they have not caused pandemics. Influenza type C viruses cause mild illness in humans and do not cause epidemics or pandemics.

TEST PRINCIPLE

Flu A/B Ag Rapid Test Cassette is a rapid immunochromatographic test for the visual detection of influenza type A and B antigens (nucleoprotein) extracted from the nasopharyngeal (NP) swab, oropharyngeal swab, and nasal swab specimens .The test adopts double antibody sandwich method. When the extracted specimen is added into the test device, the specimen is absorbed into the device by capillary action, mixes with antibody-dye conjugate, and flows across the pre-coated membrane, in which influenza type A and B monoclonal antibodies are coated respectively.

When the influenza type A antigen levels are at or above the target cutoff (the detection limit of the test), type A antigen in the specimen binds to the specific antibody-dye conjugate and are captured by influenza type A monoclonal antibody immobilized in the relative site of test region "A" of the device. This produces a colored test band in the test region "A". When the influenza type A antigen levels are zero or below the target cut off, there is not a visible colored band in the test region "A" of the device. This indicates a negative result for influenza type A.

When the influenza type B antigen levels are at or above the target cutoff (the detection limit of the test), type B antigen in the specimen binds to the specific antibody-dye conjugate and are captured by influenza type B monoclonal antibody immobilized in the relative site of test region "B" of the device. This produces a colored test band in the test region "B". When the influenza type B antigen levels are zero or below the target cut off, there is not a visible colored band in the test region "B" of the device. This indicates a negative result for influenza type B.

To serve as a procedure control, a colored line will appear at the control region (C), if the test has been performed properly.

MATERIAL PROVIDED

Test devices, each cassette is Individual sealed in a foil pouch with a package of desiccant.
Extraction tubes.
Sterile Swabs.
Dropper Tips
Extraction Buffer.
Instruction for use.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

1. For professional and IN VITRO diagnostic use only.
2. The test should remain in the sealed pouch until use.
3. Do not use the kit if the foil pouch is punctured or not well sealed.
4. Do not reuse or use kits after the expiration date.
5. Do not mix components from kits with different lot number.
6. Avoid microbial contamination of reagents.
7. Wear gloves during the whole process and avoid reagents or specimen spilling-out. Wash hands thoroughly afterwards.
8. Dispose the used kit after decontamination of all liquids or solid wastes by following the local law or laboratory rule.
9. Avoid using blood samples.

STORAGE AND STABILITY

Store the kit in cool and dry places at a temperature between 2~30°C. **Do not freeze.** The shelf-life of the kit under these storage conditions is 24 months.

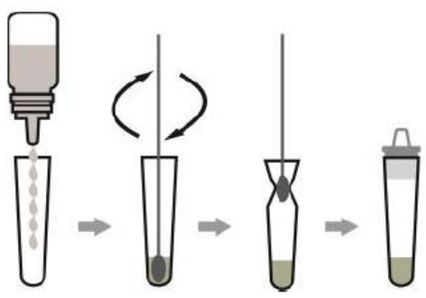
SPECIMEN COLLECTION AND PREPARATION

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.

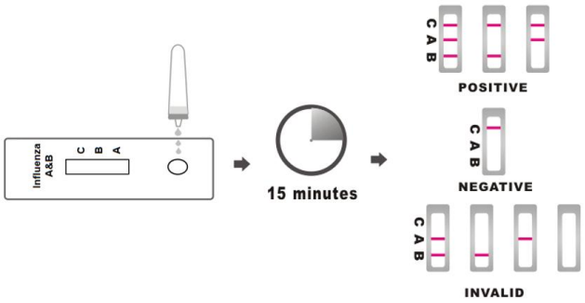
ASSAY PROCEDURES

1. Transfer 0.3 ml（about 10 drops) extraction buffer to the sample extraction tube vertically.
2. Insert the swab which has collected secretions into the specimen extraction buffer and rotate about 10 times to dissolve 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.



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

1. Remove the test cassette from the foil pouch and place it on a clean and level surface. Be sure to label the device with specimen's ID number.
2. Insert nozzle into sample extraction tube containing prepared test sample. Invert the tube, squeeze the tube gently to add 2-3 drops (approximately 60-80μL) of test sample into the samples well of the test cassette.
3. Start the timer. Results can be read at 15minutes. *Strong positive result may appear very shortly.* **Do not real results after 20 minutes.**



INTERPRETATION OF ASSAY RESULT

(Please refer to above illustration)

Negative Result

One red line appears in the control region "C", and no red line appears in the region "A" or the region "B".

Positive Result

FLU A positive: One red line appears in the control region "C", and the other red line appears in the region "A".

FLU B positive: One red line appears in the control region "C", and the other red line appears in the region "B".

FLU A&B positive: One red line appears in the control region "C", and the

other red lines appear in both region “A” and “B”.
Note: A faint test line (“A”) or (“B”) may appear. In this case, it shall be considered as positive result.
Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a positive determination is made.
Invalid Result
No red line appears in the control region “C”, regardless if the red line appears or not in the region “A” or the region “B”. Review the procedure and repeat the test with a new test device. If the problem persists, contact your local distributor.

QUALITY CONTROL
A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Good laboratory practice recommends the use of the control materials. Users should follow the appropriate federal state, and local guidelines concerning the frequency of assaying external quality control materials.

LIMITATIONS
1. As it is with any diagnostic procedure, a confirmed diagnosis should only be made after all clinical and laboratory findings have been evaluated.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test, or from improper sample collection.
3. Negative test results are not intended to rule-out other non-influenza viral infections.
4. Positive test results do not rule out co-infections with other pathogens and does not identify specific influenza A virus subtypes.
5. Performance of this test has not been established for monitoring antiviral treatment of influenza.

PERFORMANCE
Minimal detection limit:
For Flu A: $5.1\times10^{5}TCID_{50}$/mL For Flu B: $1.5\times10^{6}TCID_{50}$/mL

1. Accuracy:
A comparison study of Flu A/B Ag Rapid Test and method of cell culture was carried out. Compare the sensitivity and specificity between the two methods. The results for detection of influenza A are summarized in Table 2.1 and the results for detection of influenza B are summarized in Table 2.2.

Table 2.1 Test result of clinical samples

Clinical sample		Flu A Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
Flu A 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 2.2 Test result of clinical samples

Clinical sample		Flu B Real Time PCR Kit (RT-PCR)		Total
		Positive	Negative	
Flu B 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%)。

2. Analytical reactivity
Flu A/B Ag Rapid Test was tested with the following influenza A and B viral strains listed in Table 3. All showed positive results. Although the specific influenza strains causing infection in humans can vary year to year, all contain the conserved nucleoproteins targeted by the Flu A/B Ag Rapid Test.

Table 3: Influenza A and B viral trains

Flu A	Subtype of H1N1: 5 Strains, H2N2: 3 Strains, H3N2:7 Strains
Flu B	B/1715, B/1704, B/179, B/668, B/427, B/424, B/180, B/5, B/39

3. Cross-reactivity
1. The test for the influenza A has no cross-reativity with influenza B virus,and test for the influenza B has no cross-reativity with influenza A virus.
2. No cross reaction with following pathogens:
3. Adenovirus Type 1~8,11,19,37;Coxackie virus Type A16,B1~5, Cytomegalovirus, Echovirus Type 3,6,9,11,14,18,30; Enterovirus Type 71; HSV-1; Mumps virus; Parainfluenza virus Type 1~3; Poliovirus Type 1~3; Respiratory syncytical virus; Rhinovirus Type 1A, 13, 14.
4. No cross reaction with Chlamydia Pneumoniae, Chlamydia psittacl, Chlamydia Trachomatis, Mycoplasma Pneumoniae.
5. No cross reaction with following bacteria:

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

BIBLIOGRAPHY
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3. 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:GKPD027-1 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		

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