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"See Now" Influenza A+B Antigen Cassette Test

For in vitro Diagnosis Use
Product Code: SN 8.6

INTENDED USE

The ***"See Now"*** **Influenza A+B Antigen test** is used for the qualitative detection of Influenza type A and type B nucleoprotein antigens in nasopharyngeal swab, nasal swab and nasal aspirate samples.

PRINCIPLE

The ***"See Now"*** **Influenza A+B Antigen test** is a immunochromatographic membrane immunoassay that uses highly sensitive monoclonal antibodies to detect influenza type A and type B nucleoprotein antigens in nasopharyngeal swab, nasal swab and nasal aspirate samples. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane and absorbing pad. The reagent pad contains colloidal-gold conjugated with the monoclonal antibodies against Influenza virus A and B; the reaction membrane contains the secondary polyclonal antibodies either for virus A or for B, and the polyclonal antibodies against the mouse globulin.
When the sample is added into the sample window, conjugates dried in the reagent pad are dissolved and migrate along with the sample. If Influenza A presents in the sample, a complex formed between the anti-influenza A conjugate and the virus will be captured by the specific anti-influenza A monoclonal antibodies coated on the A region. If the sample contains influenza B, a complex formed between the anti-influenza B conjugate and the virus will be captured by the specific anti-influenza B monoclonal antibodies coated on the B region.

MATERIALS SUPPLIED

- Test Device, Desiccant, Test Instruction, Sample buffer.

MATERIALS REQUIRED BUT NOT SUPPLIED

- Sterilized swab, Extraction tube, Timer, Tube stand (for nasal aspiration)

STORAGE AND STABILITY

- The ***"See Now"*** **Influenza A+B Ag. test** should be stored between 4-30 ºC in the sealed pouch or desiccated container.
- Do not use it after the expiration date.
- Do not freeze.

PRECAUTIONS

- *FOR PROFESSIONAL AND IN VITRO DIAGNOSTIC USE ONLY.*
- The test device should remain in the sealed pouch until use.
- There should be no smoking or eating where antigen containing materials are being handled. Wear disposable gloves and lab coat while handling specimens. Wash hands thoroughly afterwards.
- Decontaminate and dispose of specimens and all potentially contaminated materials if they contain infectious agent.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test but should only be made by the physician after all clinical and laboratory have been evaluated.

SPECIMEN COLLECTION AND STORAGE/ PREPARATION

It is applicable to the diagnosis of the influenza virus A and B from the samples of nasal swabs, throat swabs or nasal aspirates. Use freshly collected samples for optimal test performance. Inadequate sample collection or improper sample handling may yield a false-negative result.

1）Nasal Swabbing

Completely insert the sterilized swab supplied in this kit into the nasal basin and swab several times to collect the epidermal cells of the mucus. **It is recommended to collect sample from nasal basin for more accurate results.**

2）Throat Swabbing

Deeply insert the sterilized swab into the throat and swab several times to collect the epidermal cells of the mucus. **Caution has to be paid to avoid the swab to be contaminated with saliva.**

3）Nasal Aspiration

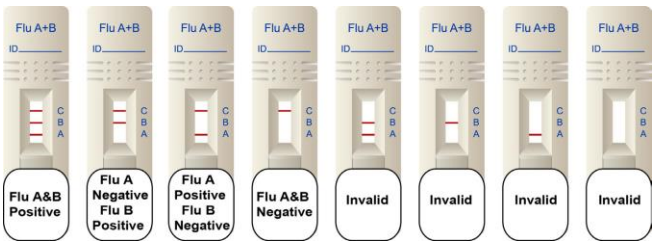
Collect nasal aspirate fluids using the specific aspirator as instructed.

Add **8 drops (about 0,4ml)** of the sample extraction buffer into the extraction tube. For Nasal and throat Swabs procedure: insert the swab into the extraction tube which contains 8 drops of buffer. After mixing, squeeze the tube several times with fingers from outside of the tube to immerse the swab. Remove the swab. The extracted solution will be used as test sample.

TEST PROCEDURE

- Remove the test device from pouch when ready to perform the test. Label the test device with patient or control identification
- Return the white cap assembly to the extraction tube.
- Reverse the sample extraction tube and add 3 drops (about 120 µl) of test sample by squeezing the extracted solution tube into the sample window.
- Read the results at 10 minutes. **The results after 10 minutes may not be accurate.**

INTERPRETATION OF RESULTS



Flu A POSITIVE:

One red line appears in the control region(C), and one red line in the A region (A). Positive result could be observed at 3 minutes as the earliest. The shade of color may vary but it should be considered positive whenever there is even a faint line.

Flu B POSITIVE:

One red line appears in the control region(C), and one red line in the B region(B). Positive result could be observed at 3 minutes as the earliest. The shade of color may vary, but it should be considered positive whenever there is even a faint line.

NEGATIVE:
One red line appears in the control region (C), and no line in the A region (A) or B region(B). The negative result indicates that there are no influenza A and B viral particles in the sample or the number of viral particles is below the detectable range.

INVALID:
No red line appears in the control region (C). The test is invalid even if there is a line in the A region (A) or B region(B). 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 Influenza A+B Rapid Test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATION OF PROCEDURE

The *"**See Now"*** Influenza A+B Antigen test 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 influenza.

The test detects both viable and non-viable influenza antigen. Test performance depends on antigen loaded 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.

QUALITY CONTROL

A procedural control is included in the test. A colored band appearing on the control region of the membrane indicates proper performance and reactive reagents.

For Flu A Control:

Positive Control (3.0～3.9×10^5 $TCID_{50}$/Test);

Weak Positive Control(3.0～3.9×10^4 $TCID_{50}$/Test);

Negative control (sample extraction buffer)

For Flu B Control:

Positive Control (1.5～1.9×10^6 $TCID_{50}$/Test);

Weak Positive Control (1.5～1.9×10^5 $TCID_{50}$/Test);

Negative control (sample extraction buffer)

PERFORMANCE CHARACTERISTICS

Influenza A

1）Analytical Sensitivity

The *"**See Now"*** Influenza A+B Antigen test has the analytical sensitivity of 3.0×10^4 $TCID_{50}$ on most of the influenza A strains.

2）Analytical Reactivity

The influenza A strain listed tested positive in the The *"**See Now"*** Influenza A+B Antigen test. Although the specific influenza strains causing infection in human can very, all contain the conserved nucleoproteins targeted by the *"**See Now"*** Influenza A+B Antigen test.

3）Clinical Study Data Summary

The *"**See Now"*** Influenza A+B Antigen test performance vs. cell culture for detection of **Flu A** type.

Test sensitivity			
Sample	+/+	-/+	%Sens
Nasal Swab	18	1	94.7
Throat Swab	9	4	69.2
Nasal Aspirate	52	7	88.1
Overall	79	12	86.8

Test Specificity			
Sample	+/+	-/+	%Spec
Nasal Swab	83	4	95.4
Throat Swab	63	4	94.0
Nasal Aspirate	106	8	93.0
Overall	252	16	94.0

Influenza B

1）Analytical Sensitivity

The *"**See Now"*** Influenza A+B Antigen test has the analytical sensitivity of 1.5×10^5 $TCID_{50}$ on most of the influenza B strains.

2）Analytical Reactivity

The *"**See Now"*** Influenza A+B Antigen test detects all nine influenza B strains.

Test sensitivity			
Sample	+/+	-/+	%Sens
Nasal Swab	17	4	81.0
Throat Swab	10	1	90.9
Nasal Aspirate	50	2	96.2
Overall	77	7	91.7
Test Specificity			
Sample	+/+	-/+	%Spec
Nasal Swab	84	1	98.8
Throat Swab	66	3	95.7
Nasal Aspirate	118	3	97.5
Overall	268	7	97.5

SPECIFICITY

The *"**See Now"*** Influenza A+B Antigen test has no cross reactivity with the following pathogens.

1) Virus other than influenza

No cross reaction with following pathogens:

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,

Parainfluenza virus Type 1～3, Poliovirus Type 1～3, Respiratory syncytial virus, Rhinovirus Type 1A,13,14.

2) Mycoplasma etc.

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

3) Bacteria

No cross reaction with following bacteria:

Acinetobacter baumannii, Bacteroides fragilis, Bordetella pertussis, Candida albicans, Candida glabrata, Cardiobacterium hominis, EikeneUa corrodens, Enterococcus gallinarum, Escherichia coli, Haemophilus phrophlus, aemophilus influenzae, Haemophilus parainfluenzae, Haemophilus paraphrophilus, Kingella kingae, Klebsiella pneumoniae, 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.