Sensit Influenza A+B Rapid Test

T1: Influenza A
T2: Influenza B
Cat No: S041-01

In-vitro Diagnostics

INTENDED USE

Sensit Influenza A+B Rapid Test Kit is a qualitative immunochromatographic assay for the detection of Influenza A and B antigens produced against Influenza Virus in nasal / throat / nasopharyngeal swab or nasal/nasopharyngeal aspirate specimens.

SUMMARY &TEST DESCRIPTION

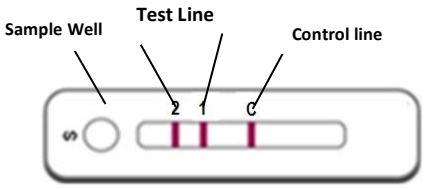
Influenza is a viral infection that affects mainly the nose, throat, bronchi, and, occasionally, lungs. Infection usually lasts for about a week and is characterized by sudden onset of high fever, aching muscles, headache and severe malaise, non-productive cough, sore throat, and rhinitis.

The virus is transmitted easily from person to person via droplets and small particles produced when infected people cough or sneeze. Influenza tends to spread rapidly in seasonal epidemics. Most infected people recover within one to two weeks without requiring medical treatment. However, in the very young, the elderly, and those with other serious medical conditions, the infection can lead to severe complications of the underlying condition, pneumonia, and death.

Influenza A+B Rapid Test utilizes Monoclonal Antibodies against Influenza A and Influenza B as the capture molecule. Colloidal gold conjugated Monoclonal Antibody against Influenza A and Influenza B is used as the detection antibody.

TEST PRINCIPLE

Influenza A+B Rapid Test works on chromatographic immunoassay. The basic components of each test strip include a) a Conjugate pad that contains colloidal gold conjugate; b) a nitrocellulose membrane strip containing three lines T1: Anti-Influenza A; T2: Anti-Influenza B and C: Goat Anti Mouse.



Test sample that is added to the sample well (S), with an adequate amount of buffer migrates from the sample pad along the conjugate pad where Influenza A and B antigen present in the sample will bind to Colloidal Gold conjugate to form a complex. The sample then continues to migrate across the membrane until it reaches the capture zones where the complex accordingly will bind to the immobilized antibodies (on the test line) producing a visible line on the membrane. If the respective antigen is not present in the sample, no reaction occurs in the capture zones and no test line is formed. The sample then migrates further along the strip until it reaches the control zone, where it produces another visible line on the membrane. This control line indicates that the sample has migrated across the membrane as intended.

REAGENTS & MATERIALS PROVIDED

1. Each is sealed in a foil pouch containing the following items:
   a. One test card with dropper
   b. Desiccant
2. Assay Diluent- In dropper bottle
3. Swab
4. Extraction tube
5. Instruction Leaflet

STORAGE & STABILITY

Store the test kit between 2-30°C till the expiration date indicated on the pouch/carton. DO NOT FREEZE. Ensure that the test device is brought to room temperature before opening.

PRECAUTIONS & WARNING

1. Use within 10 minutes after opening the pouch.
2. Do not touch the result window.
3. Use only the buffer supplied along with the kit.
4. Do not mix components from different kits.
5. Use only for in-vitro diagnostic purposes.

SAMPLE COLLECTION & PREPARATION

- Collect the nasal/throat/nasopharyngeal secretion using the swab provided.
- Add 10-12 drops of extraction buffer into the extraction tube provided (till the mark in the tube). Insert the swab into the assay diluent and agitate it sufficiently in order to ensure good sample extraction.
- If the specimen is not used for testing immediately, it should be refrigerated at 2-8°C.
- For a storage period longer than 5 days, freezing is recommended. Storeat -20^{0}C
- The specimen should be brought to room temperature prior to use.

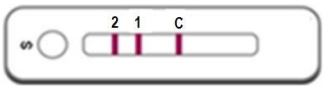
Treat the specimen as infectious and handle it with standard biosafety measures.

TEST PROCEDURE

1. Take out the test card from the foil pouch and place it on a horizontal surface.
2. Add 3-4 drops of the extracted sample (Prepared as mentioned above) using the dropper provided into the sample well (S) of the test device. Do not add particulate matter to theliquid.
3. Wait 10 minutes, read and interpret the results. The result is considered invalid after 15 minutes. All results where the control band does not appear areconsidered invalid.

INTERPRETATION OF TEST RESULT

Influenza A & B Positive



Color bands at position C, T1, and T2.

Influenza A Positive

Color bands at position C and T1.

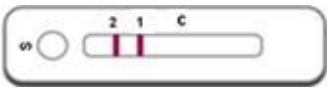
Influenza B Positive

Color bands at position C and T2.

Influenza A & B Negative

color band is only at position C.

Invalid



Color band does not appear at C.

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