Sensit Influenza A Rapid Test

Cat No. S017-01

In vitro Diagnostics

INTENDED USE

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

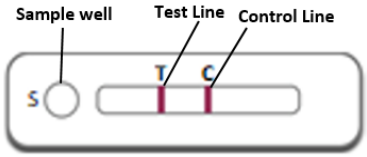
SUMMARY & TEST DESCRIPTION

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

TEST DESCRIPTION & PRINCIPLE

Influenza A 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 two lines T: Anti-Influenza A; 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 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.

MATERIALS PROVIDED

Each is sealed in a foil pouch containing the following items:
One test card with dropper
Desiccant
Assay Diluent- In dropper bottle
Swab
Extraction tube
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.

PRECAUTION & WARNING

1) Use within 10 minutes after opening pouch.
2) Do not touch result window.
3) Do not reuse test kit.
4) Do not use test kit beyond expiry date.
5) Use only for in-vitro diagnostic purpose.

SAMPLE COLLECTION

- 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.

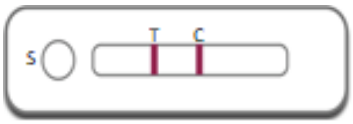
Treat the specimen as infectious and handle it with standard biosafety measures

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 the liquid.
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 are considered invalid.

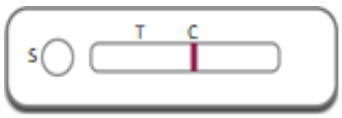
INTERPRETATION OF TEST RESULT

Positive: A clear pink control band ("C") and a detectable test band ("T") appear, indicating the presence of Influenza A in the sample.

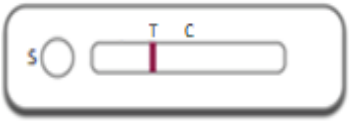


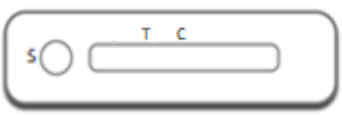
**Note: The intensity of the red color in the test region (T) will vary depending on the concentration of* Influenza A *present in the sample.*

Negative: A pink colored band appears only at control region ("C") indicating the absence *of* Influenza A in the sample.



Invalid: If the control line fails to appear within the result window, the result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be retested.





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LIMITATIONS

1. The test may not detect very low cortisol levels, limiting its use for early detection or subclinical conditions.
2. Non-specific binding or interference with other substances may result in false positives or negatives.
3. Inaccurate results may occur if the sample is contaminated or insufficient in volume.
4.Temperature, humidity, and storage conditions can affect test performance and lead to inaccurate results.
5. The kit provides semi-quantitative results (color changes), which may lack precision compared to laboratory-based methods.
6. Certain medications or medical conditions may interfere with cortisol levels and affect test accuracy.
7.The test has a limited shelf life, requiring proper storage and handling to ensure reliability.

DESCRIPTION OF SYMBOLS USED

The following graphical symbols used in Influenza A Rapid Test Kit for single-step detection of Influenza A are the most common signs appearing on medical devices and their packaging. They are explained in more detail in the European Standards EN 980: 2008 and INTERNATIONAL Standard ISO 15223-1:2016

Key to symbols used			
	Manufacturer		Expiration/use by date
	Do not reuse		Date of manufacture
	Consult IFU [Instructions For Use]	LOT	Batch code
	Temperature limitation 2-30°C	IVD	In Vitro diagnostic medical device
Σ X	Contains sufficient for 'X ' kits		Do not use if package is damaged
REF	Catalogue No		Keep dry

Please read the user manual carefully before operating to ensure proper use

Manufactured by,

ubio Biotechnology Systems Pvt Ltd
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