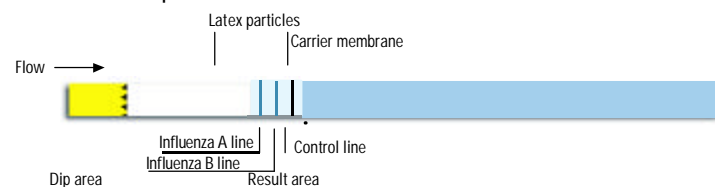


ENGLISH **actim™ INFLUENZA A&B**
Qualitative test for determination of influenza A&B in respiratory specimens

INSTRUCTIONS FOR USE

Structure of the dipstick



Intended use

The actim™ Influenza A&B test is a qualitative, one-step rapid test for detection of influenza type A and type B virus antigens in respiratory samples. The recommended sample types are nasal aspirates, nasal wash or nasal swab samples.

Kit components

The components of the actim™ Influenza A&B test kit 32832ETAC are:

- 20 dipsticks (32801ETAC) individually packed in sealed aluminum foil pouches with desiccant.
- One dropper bottle of Extraction Buffer (2ml) (32803ETAC). This solution contains surfactant, bovine serum albumin (BSA) and preservatives.
- One dropper bottle of Saline Solution (10ml) (32809ETAC).
- One lyophilized vial each of Influenza A Positive Control (32881ETAC) and Influenza B Positive Control (32981ETAC). Before use the vials need to be reconstituted with 6 drops of Saline solution. The Influenza A control contains strain A/Taiwan/1/86 (H1N1). The Influenza B control contains strain B/Qingdao/102/91.
- 20 polyester swabs for swab sample collection
- 20 test tubes for sample extraction
- Instructions for use

Pipettes may be needed for sampling (not provided in the test kit).

Storage

The test kit can be stored at +2...+25 °C. Storage at +2...+8 °C is recommended. Stored unopened, each component can be used until the expiry date marked on the component.

Use the dipsticks shortly after their removal from the aluminum foil pouch, because moisture damages them. Use the reconstituted controls during the same working day.

Principle of method

The test includes the extraction and detection of influenza type A and B virus antigens.

The test is based on immunochromatography. It involves monoclonal antibodies to influenza type A and type B virus antigens. Antibodies against both types are bound to blue latex particles (the detecting label). Antibodies against both types are immobilized on a carrier membrane to catch labeled particles and indicate a positive result.

When the dipstick is dipped into the sample, liquid starts to flow up the dipstick. If the sample contains influenza type A or B, the virus antigen binds to either of the antibodies attached to the latex particles. The particles are carried by the liquid flow and, if influenza virus antigen is bound to them, they bind to the corresponding catching antibody. A blue line (positive line) will appear in the lower part of the result area if the concentration of influenza type A in the sample exceeds the cut-off value for the test. A blue line (positive line) will appear in the middle of the result area if the concentration of influenza type B in the sample exceeds the cut-off value for the test. Appearance of the black control line confirms correct performance of the test.

Performance of test

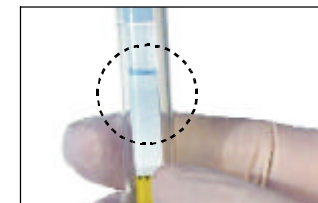
The cut-off value for influenza A&B test is such that the lowest detectable amount of influenza virus in the extracted sample is approximately 1,0 x 10⁴ TCID50/ml for influenza A/New Caledonia/20/99 (H1N1), 1,0x 10⁴ TCID50/ml for influenza A/Panama/2007/99 (H3N2) and 2,5 x 10⁴ TCID50/ml for influenza B/Yamanashi/166/98. These virus concentrations give weak positive results. Concentrations higher than approximately 2,5 x 10⁴ TCID50/ml for influenza



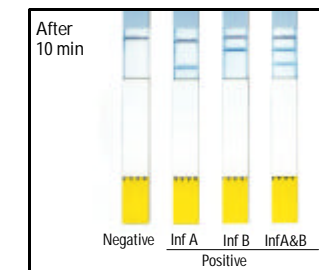
A. Addition of extraction buffer.



B. Dipping



C. Note liquid front



D. Interpretation of results

Brief instructions of use

A/New Caledonia/20/99 (H1N1), 2,5x 10⁴ TCID50/ml for influenza A/Panama/2007/99 (H3N2) and 5,0 x 10⁴ TCID50/ml for influenza B/Yamanashi/166/98 in the extracted sample give strong positive results.

Limitations of test

The test is intended only for in vitro diagnostic use. The test is intended for professional use only.

Specimen collection

The specimen is a respiratory sample. Collect a nasal swab sample or a nasal wash or a nasal aspirate sample. The samples should be tested as soon as possible after collection.

Nasal swab procedure:

- Invert the dropper bottle upside down and dispense 6 drops of saline into a test tube (= extraction tube).
- Invert the dropper bottle upside down and dispense 3 drops of Extraction Buffer into the same test tube. Mix the solutions well.
- Place the swab into the extraction tube. The specimen is extracted from the swab by swirling the latter vigorously for approximately 10 seconds.
- Leave the swab in the tube for 5 minutes. Swirl the swab vigorously in the buffer, press it against the wall of the tube and remove it from the tube.

Nasal wash/aspirate procedure:

- Dispense 300 µl of nasal wash or nasal aspirate solution into a test tube (= extraction tube).
- Invert the dropper bottle upside down and dispense 3 drops of Extraction Buffer into the same test tube.
- Mix the solutions well.
- Wait for 5 minutes.

Alternatively, if the aspirate volume is very small, a swab can be used to transfer the specimen to an extraction tube containing 6 drops of saline and 3 drops of Extraction Buffer. Proceed according to the nasal swab procedure.

Proceed to the assay procedure.

Assay procedure and interpretation of results

- Allow the aluminum foil pouch to reach room temperature. Open the foil pouch containing the dipstick by tearing. Do not touch the yellow dip area at the lower part of the dipstick. Identifying marks may be written on the upper blue part of the dipstick. The dipstick must be used shortly after its removal from the foil pouch.
- Place the yellow dip area (the lower end of the dipstick) into an extraction tube and **hold it there until you see the liquid front enter the result area** (in approximately 10 seconds). Remove the dipstick from the solution and place it in a horizontal position.
- Read the result **at 10 minutes**. A result can be interpreted as positive as soon as one or two blue and one black line become visible in the result area. If only one black line appears within 10 minutes, the result is interpreted as negative. **Do not pay attention to any lines appearing later than 10 minutes**
- Appearance of a black control line confirms that the test has been performed properly.

If, in addition to the black control line you see

- one blue line** in the lower part of the result area, the test result is **influenza A positive**.
- one blue line** in the middle part of the result area, the test result is **influenza B positive**.
- two blue lines** in the result area, the test result is **Influenza A and B positive**.
- no blue lines** in the result area, the test result is **Influenza A and B negative**

If the control line does not appear the test is invalid.

External quality control

The Controls may be used instead of patient samples for quality control purposes.

- Invert the dropper bottle upside down and dispense 6 drops of Saline Solution into the control bottles to reconstitute the controls. Wait for ten minutes.
- Invert the dropper bottle upside down and dispense 3 drops of Extraction Buffer into the control bottles. Mix the solutions well and wait for 5 minutes.
- Proceed to the assay procedure. Dip the dipsticks directly into the control vials. The reconstituted Controls should be used within the same working day.

Notes

- Nasal aspirate samples may be very mucous. Such samples should be pipetted carefully to ensure that the pipette absorbs 300 µl of sample. Very mucous samples are occasionally not absorbed by the dipstick. Such specimens may be diluted 1:2 with saline, and retested.
- If the sample needs to be diluted as described above, or if the sample needs to be transferred with the swab because of low sample volume, the amount of virus in the extracted sample may remain lower than usual, which may affect the test result. Also, nasal wash samples may be dilute and contain a low amount of virus. As a consequence, in these cases the results may be less strongly positive than usual, or even remain negative.
- When using the dropper bottles, ensure that the bottle is completely inverted upside down before dropping. This optimizes the drop size.
- Care must be taken when placing the dipstick in the sample. The upper part of the dipstick must stay dry.
- Do not use a dipstick that has become wet before use, because moisture damages the test.
- Do not use a dipstick if you notice a blue or black coloring in the result area before testing.
- When dipping, be careful to hold the dipstick in position (with the dip area in the sample extract) until the sample liquid front reaches the result area. Do not leave the dipstick in the sample too long. The test will not work properly if the amount absorbed is too small or too large.
- The blue positive lines are in the lower and middle part, the black control line in the upper part of the result area of the dipstick. Appearance of a control line confirms correct performance of the test. If a control line does not appear the test is invalid, and should be repeated using another dipstick.
- If the test result cannot be interpreted clearly (e.g. if the lines are blotched or uneven) it is recommended that the test be repeated with another dipstick.
- The result of a test should be interpreted as negative only after 10 minutes have elapsed. A faint blue line appearing after 10 minutes indicates a low influenza virus antigen concentration, below the cut-off value for the test.
- As with all diagnostic tests, results must be interpreted in the light of other clinical findings.
- All biological specimens and materials must be treated as potentially hazardous, and disposed of in accordance with local authority guidelines.

Literature

- Cox N.J. Influenza Lancet 1999; 354:1277-82
- Heikkinen T. Comparative study of nasopharyngeal aspirate and nasal swab specimens for detection of influenza BMJ (2001) 322:138
- Sintchenko V. Treat or test first? Decision analysis of empirical antiviral treatment of influenza virus infection versus treatment based on rapid test results. J. Clin Virol(2002) 25:15-21



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