SPECTRUM
MEDICAL DIAGNOSTICS

Influenza A+B Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- The Influenza A+B Rapid Test Cassette (Swab/Nasal Aspirate) is intended for professional in vitro diagnostic use only.
- Follow the specimen collection and preparation instructions carefully, and make sure all materials are at room temperature before testing.

Intended Use

- The Influenza A+B Rapid Test Cassette is a professional in vitro diagnostic tool for detecting the presence of Influenza A and B viruses.
- It is intended to aid in the rapid differential diagnosis of influenza A and B viral infections.
- Results can be obtained within 15 minutes, enabling timely decision-making for patient intervention.

Quality Control

- Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control.
- It confirms sufficient specimen volume and correct procedural technique.
- A clear background is an internal negative procedural control.
- If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.
- Controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP) positive/negative controls are recommended.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use it beyond the expiration date.

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Limitations, Warnings & Precautions

1. For professional in vitro diagnostic use only. Do not use after the expiration date, this test should remain in the sealed pouch until ready to use.
2. All specimens should be considered potentially hazardous and handled in the same manner as an infected agent.
3. Used tests should be discarded according to local regulations.
4. The Influenza A+B Rapid Test Cassette is designed for nasopharyngeal swab, throat swab, or nasal aspirate specimens and should not be used with other types of samples.
5. Improper specimen collection or storage may result in false negative results. Follow the specimen collection and preparation instructions carefully.
6. Excess blood or mucus on the swab specimen may interfere with test performance and yield false positive results.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with test results, leading to either invalid or incorrect results.
8. A positive result for influenza A and/or B does not exclude the possibility of an underlying co-infection with another pathogen. Consider the possibility of an underlying bacterial infection.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
10. Keep the test out of the reach of children and unauthorized personnel.
11. Follow local regulations and guidelines for the use and disposal of diagnostic test kits.
12. If the control line fails to appear, it may indicate insufficient specimen volume or incorrect procedural techniques. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit and contact your local distributor.
13. A negative result obtained from this kit should be confirmed by culture if clinical suspicion of influenza remains.
14. Store the test as packaged at room temperature or refrigerated (2-30°C) and do not freeze. The test must remain in the sealed pouch until use. Do not use beyond the expiration date.
15. The test does not determine the quantitative value or rate of increase in influenza A and/or B virus concentration.
16. Please read all the information in this package insert before performing the test.

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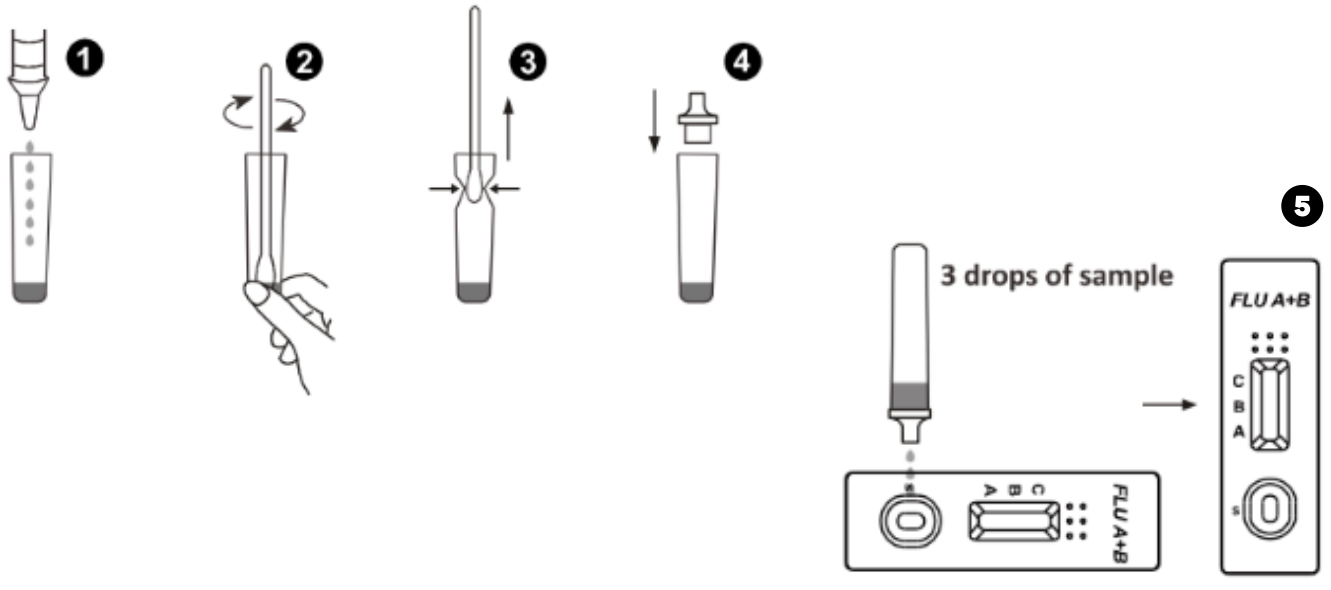
Test Procedure

1. Allow the test cassette, specimen, and extraction buffer to equilibrate to room temperature (15-30°C) prior to testing.
2. Remove the test cassette from the sealed foil pouch and use it as soon as possible. The best results will be obtained if the assay is performed immediately after opening the foil pouch.
3. Place the Extraction Tube in the workstation. Hold the extraction reagent bottle upside down vertically. Squeeze the bottle and let the solution drop into the extraction tube freely without touching the edge of the tube. Add 10 drops of solution (Approx. 400ul) to the Extraction Tube. **Refer to illustration 1.**
4. Place the swab specimen in the Extraction Tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab. **Refer to illustration 2.**
5. Remove the swab while squeezing the swab head against the inside of the Extraction Tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol. **Refer to illustration 3.**
6. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. **Refer to illustration 4.**
7. Add three drops of the solution (approx. 120ul) to the sample well on the test cassette. **Refer to illustration 5.**
8. Start the timer and read the result at 15 minutes. Do not interpret the result after 20 minutes.



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Positive Result:

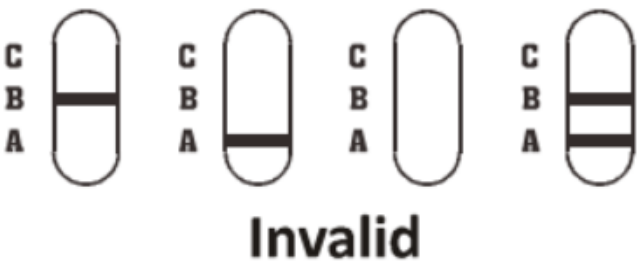
- **Influenza A:** If two distinct colored lines appear, with one colored line in the control region (C) and another colored line in the Influenza A region (A), it indicates the presence of Influenza A antigen in the sample.
- **Influenza B:** Similarly, if two distinct colored lines appear, with one colored line in the control region (C) and another colored line in the Influenza B region (B), it indicates the presence of Influenza B antigen in the sample.
- **Influenza A and Influenza B:** If three distinct colored lines appear, with one colored line in the control region (C) and two colored lines in the Influenza A region (A) and Influenza B region (B), it indicates the presence of both Influenza A and Influenza B antigens in the sample.
- **Note:** The intensity of the color in the test line regions may vary based on the amount of the respective antigens present in the sample.

Negative Result:

- If only one colored line appears in the control region (C) and there is no apparent colored line in the test line regions (A or B), it indicates a negative result, indicating that Influenza A and B antigens were not detected in the sample.

Invalid Result:

- If the control line fails to appear, it indicates an invalid result. This could be due to reasons such as insufficient specimen volume or incorrect procedural techniques.
- It is important to review the procedure and repeat the test with a new test cassette.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com



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Influenza A+B Rapid Test Training Quiz

True or False: Influenza A outbreaks are typically more prevalent than Influenza B outbreaks.
a) True
b) False

What is the intended use of the Influenza A+B Rapid Test Cassette?
a) Qualitative detection of Influenza A and B antibodies
b) Qualitative detection of Influenza A and B antigens
c) Quantitative measurement of Influenza viral load

What is the recommended reading time for the test result?
a) 5 minutes
b) 10 minutes
c) 15 minutes

What is the principle behind the Influenza A+B Rapid Test Cassette?
a) Polymerase Chain Reaction (PCR)
b) Chromatographic immunoassay
c) Cell culture

What should be done if the control line fails to appear?
a) Repeat the test with a new kit and proper procedural techniques
b) Interpret the result as negative
c) Continue using the test kit with caution

True or False: The Influenza A+B Rapid Test Cassette can determine the quantitative value or rate of increase in Influenza A and B virus concentration.
a) True
b) False

True or False: The Influenza A+B Rapid Test Cassette has been compared with a leading commercial RT-PCR test, showing a correlation of over 97%.
a) True
b) False