Avonchem Rapid Influenza A/B Test Panel
For Nasal Swab Specimen

INTENDED USE

Influenza A&B is a rapid qualitative in vitro assay that detects influenza type A **(including the H1N1 sub-strain)** and B antigens (nucleoprotein) extracted from the respiratory specimens. The test is designed to detect nucleoproteins of A and B core subtypes, independent of H and N surface proteins. For professional use only.

KIT STORAGE

The Rapid Influenza A/B test kits should be stored at room temperature in the original sealed pouch. The expiration date was determined under normal laboratory conditions.

MATERIALS PROVIDED

1. Rapid Influenza A/B test panel.
2. Instructions.
3. Swab.
4. Test tube
5. Extraction Buffer.

PRECAUTIONS

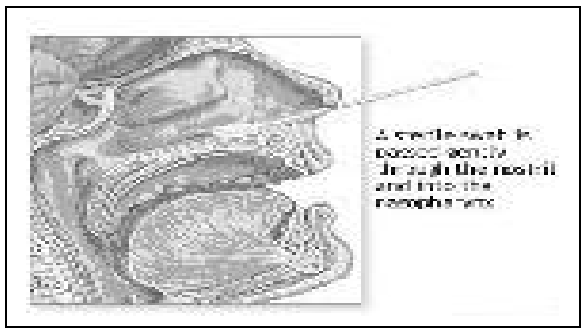
The Rapid Influenza A/B test kits should be stored at room temperature 4-30ºC (40-86ºF). The test panel is sensitive to humidity as well as to heat. Perform the test immediately after removing the test panel from the foil pouch. Do not use it beyond the expiration date.

WARNINGS

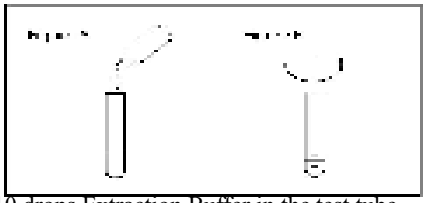
1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.

SPECIMEN COLLECTION

1. Insert the sterile swab into nostril which shows the most secretion.
2. Very gently rotate and push the swab until resistance is met at level of the turbinates.
3. Gently rotate the swab against nasal wall for a few times.



SPECIMEN PREPARATION

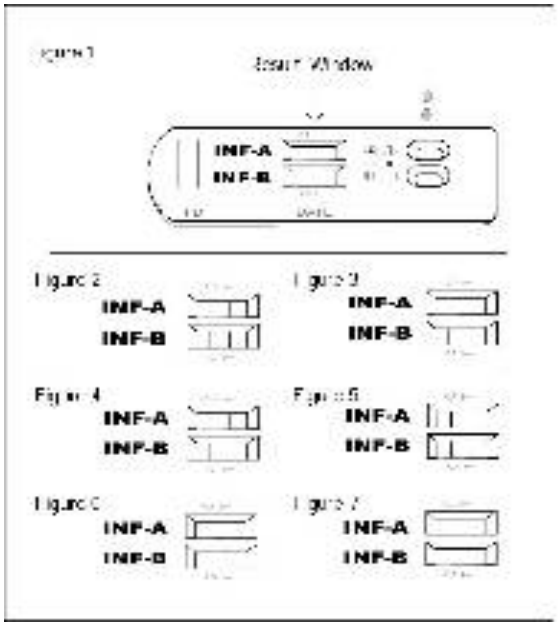


1. Put 10 drops Extraction Buffer in the test tube.
2. Place the specimen swab in the tube and swirl it vigorously to mix the reagents for at least 1 minute.
3. Then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab. Mix the contents of the tube by gentle swirling. The mixture is ready to test.

PROCEDURE OF TEST

1. Remove the test panel from the foil packet, and place it on a flat, dry surface.
2. Holding the sample dropper above the test panel, squeeze 3 drops of the mixed specimen into the sample well (Figure 1). Wait until each drop is absorbed, before adding additional drops. If after the first drop, the drop is not absorbed within 30 seconds, follow it up with 2 buffer drops directly from the buffer bottle, and require no additional specimen drops.
3. As the test begins to work, you will see purple colour move across the Result Window in the center of the test panel.
4. Interpret test results at 10 minutes. Do not interpret test results after 15 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30 ºC. If your room temperature is significantly lower than 15 ºC, then the interpretation time should be properly increased.



INTERPRETATION OF THE TEST

1. A colour band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Band.
2. The right section of the Result Window indicates the test results. If another colour band appears at the right section of the Result Window, this band is the Test Band.

POSITIVE RESULT: TWO COLOUR BANDS

The presence of two colour bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result in either or both Inf-A/Inf-B panel, indicating positive for Inf-A and/or Inf-B respectively (Figure 2, 3 and 4). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the "T" band will be very faint.

NEGATIVE RESULT: ONE COLOUR BAND

The presence of only one colour band within the Result Window indicates a negative result (Figure 5).

INVALID RESULT:

If after performing the test, no colour bands are visible within the Result Window, the result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit (Figure 6 and 7).

Note: A positive result will not change once it has been established at 15 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after 15 minutes.

USER QUALITY CONTROL

Control standards are not supplied with this kit; however, it is recommended that a control be tested as good laboratory testing practice.

LIMITATIONS OF THE TEST

Although the Rapid Influenza A/B is accurate in detecting Influenza A/B virus, false results can occur. Other clinically available tests are required if questionable results are obtained. The Rapid Influenza A/B test is qualitative assay. The amount of Influenza A or B present in the specimen cannot be estimated by the assay. The assay results distinguish positive from negative samples only. 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 findings have been evaluated.

REFERENCES:

1. Murphy, B.R., and R.G. Webster, 1996, Orthomyxoviruses, pp. 1397–1445. In: Fields, Virology, 3rd edition, B.N. Fields, D.M. Knipe, P.M. Howley, et al. (eds.), Lippincott-Raven, Philadelphia.
2. Biosafety in Microbiological and Biomedical Laboratories, 4th Edition. U.S.Department of Health and Human Services, CDC, NIH, Washington, DC (1999).
3. CDC website: http://www.cdc.gov/flu/

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