PreventID® **Influenza A plus B**

Manual (FOR PROFESSIONAL USE)

REF KST50112GP

Intended Use

The **PreventID® Influenza A plus B** is a rapid qualitative in vitro assay that detects Influenza type A and B antigens (nucleoprotein) extracted from the respiratory specimens. The test has been shown to detect various Influenza A subtypes including the subtypes H3N2 and H1N1. For professional use only.

Test Principle

The test is a sandwich immunoassay. In the region of the test line (T) is an immobilised mouse anti-Influenza antibody, in the control region (C) there is an immobilised goat anti-Mouse antibody. After application, the sample passes through the region where gold-conjugated mouse anti-Influenza antibodies are located. This conjugate reacts with the sample. If the sample is positive, i.e. contains influenza viruses, a complex of immobilised mouse anti-influenza - influenza antigen in the sample - gold conjugate antibody forms at (T) and can be seen as a coloured line. At (C) the band is formed by a complex of immobilised goat anti-mouse antibody - gold conjugated mouse anti-influenza antibody. This coloured control line thus indicates that sample application, migration and test run has been correct and the result is valid.

Materials

Materials Provided

- test devices (with sample droppers), individually packed TEST
- swabs
- tubes
- rack for tubes
- bottles with extraction buffer BUF
- manual

Materials Required but not Provided: Timer or stop watch

Storage and Stability

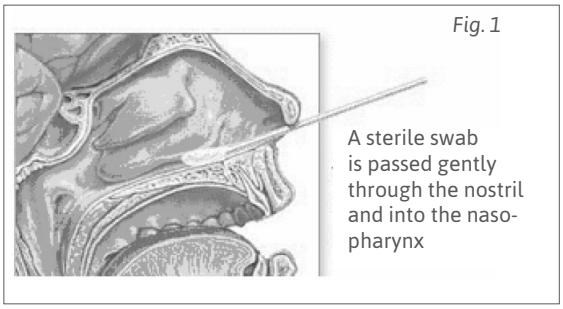
The **PreventID® Influenza A plus B** test devices should be stored at room temperature (4–30 °C). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the pouch. Do not use it beyond the expiry date.

Precautions

1. For *in vitro* diagnostic use only.
2. Do not eat or smoke while handling specimen.
3. Wear protective gloves and wash hands thoroughly after performing the test.
4. Avoid splashing or aerosol formation while handling specimen and performing the test.
5. All samples and materials used should be treated as potentially infectious and disposed in a biohazard container. Clean all contaminated objects and surfaces carefully.
6. Do not use test if the pouch is torn or if the membrane of the test device is visibly damaged. Do not use the test after expiry date.
7. Do not mix reagents from different lots.
8. Read the instruction carefully before performing the test.
9. If you have any questions please contact Preventis GmbH.

Specimen Collection and Preparation

Insert the sterile swab into nostril which shows the most secretion *(Fig. 1)*. Very gently rotate and push the swab until resistance is met at level of the turbinates.



1. Gently rotate the swab against nasal wall for a few times. Put 12 drops extraction buffer into the tube *(Fig. 2a)*.
2. Place the specimen swab in the tube and swirl it vigorously to mix the reagents for at least 1 minute *(Fig. 2b)*
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.
4. Mix the contents of the tube by gentle swirling. The mixture is ready to test.

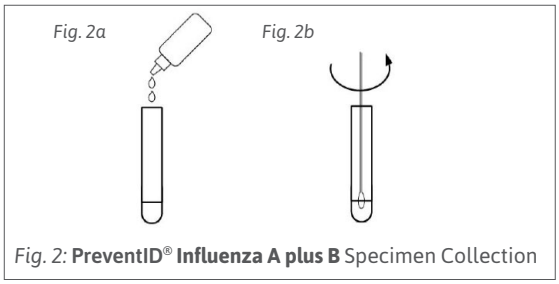


Fig. 2: **PreventID® Influenza A plus B** Specimen Collection

Test Procedure

1. Remove the test device from the pouch and place it on a flat, dry surface.

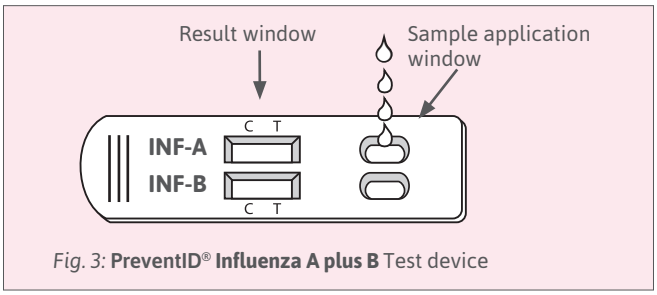


Fig. 3: **PreventID® Influenza A plus B** Test device

2. Holding the sample dropper above the test device squeeze **4 drops of the mixed specimen** into each sample application window *(Fig. 3)*. Wait until each drop is absorbed, before adding additional drops.
   Note: If the drops may contain many air-bubbles, then the actual specimen volume may be less than the minimum volume required. So if there is no red-dye migrating to the result window in about 30 seconds, add 1–2 additional drop or drops of **buffer**.
3. As the test begins to work, you will see purple colour move across each result window in the center of the test device.
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°C.

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Test Interpretation *(Fig. 4)*

The test result is indicated by the appearance or non-appearance of one or two coloured **test lines (T)** in the test areas at the right section of the result window.
A coloured **control line (C)** in the control area at the left section of the result window indicates that the test has run correctly.

Positive:
The presence of two colour lines (T and C) within the result window, regardless of which line 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 *(Fig. 4a-c)*.

Negative:
The presence of only the control line (C) within the result window indicates a negative result *(Fig. 4d)*.

Invalid:
If after performing the test no colour lines are visible within the result window, the test is considered invalid *(Fig. 4e-f)*. The directions may not have been followed correctly or the test may have deteriorated. It is recommended to re-test the specimen with another test device.

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.

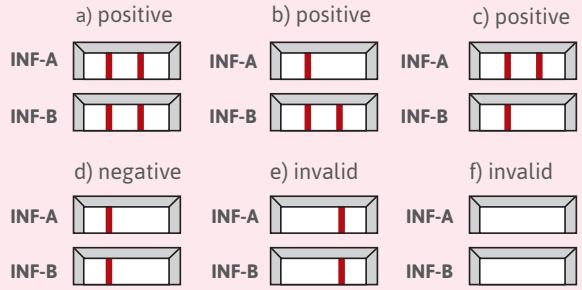

Fig. 4: **PreventID® Influenza A plus B** Test interpretation

Test Characteristics

Analytical Specificity

Specificity testing of the **PreventID® Influenza A plus B** test using negative and positive control samples spiked with various microorganisms, viruses, drugs, and other substances showed no interference with the test.

The samples were spiked with

- Microorganisms:
  Acinetobacter calcoaceticus / Bacteroides fragilis / Bordetella pertussis / Branhamella catarrhalis (ATCCâ 43628) / Candida albicans (ATCCâ 14053) / Corynebacterium diptheriae (ATCCâ 9015) / Enterococcus faecalis / Escherichia coli (ATCCâ 25922) / Gardnerella vaginalis / Haemophilus influenzae (ATCCâ 35056) / Klebsiella pneumonia (ATCCâ 13883) / Mycoplasma pneumonia / Neisseria gonorrhorea (ATCCâ 9826) / Neisseria menigitidis, serogroup B (ATCCâ 13090) / Neisseria sp. (ATCCâ 43831) / Pseudomonas aeruginosa (ATCCâ 27853) / Proteus vulgaris / Serratia marcescens (ATCCâ 8100) / Staphylococcus aureus (ATCCâ 29213 & 25923) / Staphylococcus epidermidis (ATCCâ 12228) / Streptococcus Group B (ATCCâ 12386) / Streptococcus Group C (ATCCâ 12388) / Streptococcus Group D (ATCCâ 12389) / Streptococcus Group F (ATCCâ 12393) / Streptococcus Group G (ATCCâ 12394) / Streptococcus pneumoniae (ATCCâ 9163, 6306 & 10015) / Staphylococcus aureus
- Viruses:
  Adenovirus 5 (Ad. 75) /Adenovirus 7 (Gomen) / Adenovirus 10 (J.J.) / Adenovirus 18 (D.C.) / Coronavirus OC43 / Coxsackievirus A9 (Bozek) / Coxsackievirus B5 (Faulkner) / Cytomegalovirus (Towne) / Echovirus 2 (Cornelis) / Echovirus 3 (Morrisey) / Echovirus 6 (D'Amori) / Herpes simplex virus 1 / Herpes simplex virus 2 / Human Rhinovirus 2 (HGP) / Human Rhinovirus 14 (1059) / Human Rhinovirus 16 (11757) / Measles (Edmonston) / Mumps (Enders) / Parainfluenza virus 1 (Sendai) / Parainfluenza virus 2 (CA/Greer) / Parainfluenza virus 3 (C243) / Respiratory Syncytial virus / Rubella (RA 27/3) / Respiratory Syncytial virus (A-2) / Varicella-Zoster (Ellen)
- Substances:
  Acetamiophen, Acetyl salicyl acid, Ascorbic acid, Atropine, bilirubin, caffeine, creatinine, gentesic acid, glucose, ketones, Mestranol, nitrite, Penicillin, sodium- and lithium heparin.

None of the above tested substances showed any interference with neither a clinically defined negative nor a positive specimen. Negative specimen samples with supplementation of potentially interfering substances gave consistently negative test results, whereas specimen samples positive to Flu-A/B scored consistently positive.

Analytical Sensitivity

Virus titration in embryonated chicken eggs is used to determine Analytical Sensitivity. Depending on the strain, the sensitivity was between $6{,}1x10^1$ and $3{,}6x10^5$ viruses.

Clinical Sensitivity and Specificity

This test is compared against RT-PCR for its relative sensitivity and specificity:
The RT-PCR relative sensitivity/specificity of **PreventID® Influenza A plus B** is 84.4 %/94.7 % for A strains and 84.3 %/95.5 % for B strains.
The test is compared with viral culture (n = 300):
The sensitivity of **PreventID® Influenza A plus B** is 76 % (114/150) and specificity is 92 % (138/150).

Test Limitations

Use the test only once. Test results are only reliable if you follow the instructions for use carefully. Although the **PreventID® Influenza A plus B** is accurate in detecting Influenza A/B viruses, false results can occur. Other clinically available tests are required if questionable results are obtained.

The **PreventID® Influenza A plus B** test is a qualitative assay. The amount of Influenza A or B antigen 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.

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Status: 2019-08-13

US: all products: Research Use Only. Not for use in diagnostic procedures.

Temperature limitation	Manufacturer
In vitro diagnostic device	Lot number
Catalogue number	Expiry date
Read user instructions	Do not reuse
Contains sufficient for <n> tests	

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