

# BinaxNOW<sup>®</sup>

## Influenza A & B

Rapid Test

**IMPORTANT: See Product Insert, including QC section, for complete use instructions and performance claims**

### COMPLEXITY: WAIVED

Any modifications by the laboratory to the test system or FDA cleared test system instructions will result in the test no longer meeting the requirements for waived categorization. You must have a CLIA Certificate of Waiver to perform this test. To obtain a Certificate of Waiver, please contact your state health department.

**NOTE:** Test positive and negative control swabs provided once with each kit. Use of visibly bloody samples is not recommended with this test kit.

## PART 1 - SAMPLE PREPARATION PROCEDURE

### Nasal Wash/Aspirate:

Nasal wash/aspirate samples do not need preparation. Go to PART 2.

### Nasopharyngeal Swabs:

Remove sample from swab in 0.5 to 3.0 ml of saline or transport fluid by vigorously rotating the swab in the liquid. Go to PART 2. To use Binax Elution Solution to elute swab, follow the Swab Elution procedure below.

### Swab (Control and Patient) Elution using Binax Elution Solution:

1. Twist off the test vial cap.
2. Put the swab to be tested into test vial. Rotate the swab vigorously (without making a lot of bubbles) three (3) times **in the liquid.**
3. Press the swab against the side of the vial and turn as you remove it from the vial. This removes sample from the swab.
4. Discard the swab into a container intended for contagious material.
5. Test the liquid sample (from the test vial) in the BinaxNOW<sup>®</sup> Test as soon as possible. Go to PART 2.



Manufactured by:

 **inverness medical**  
professional diagnostics



Store kits at room temperature  
(15-30°C, 59-86°F)



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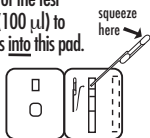
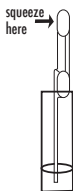
Rev. 3/11/28/06  
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## PART 2 - TEST PROCEDURE

**WARNING: INVALID RESULTS** can occur when too little sample is added to the test. Be sure that the lower part of the pipette is full and does not have any air spaces in it before you add the sample to the Sample Pad. If there are air spaces, put the sample back into the container by squeezing the top bulb. Redraw the sample from the bottom of the container into the pipette. Use a new pipette if needed.

1. Remove device from the pouch just prior to testing and lay flat on work bench.
2. Fill pipette by firmly squeezing the top bulb and then placing pipette tip into sample. Slowly release bulb while tip is still in sample. This will pull liquid into the pipette. Make sure there are no air spaces in the lower part of the pipette.
3. See arrow on test device to find the **WHITE** sample pad at the top of the test strip. **SLOWLY** (drop by drop) add entire contents of the pipette (100  $\mu$ l) to the **MIDDLE** of this pad such that all of the sample volume absorbs into this pad. **DO NOT** add sample to the pink/purple colored pad.
4. Immediately peel off the adhesive liner from the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device.



## PART 3 - RESULT INTERPRETATION

NOTE: Do not read test results before or after 15 minutes as they may not be correct.

For a **NEGATIVE SAMPLE**, the BLUE Control Line in the **BOTTOM THIRD** of the window turns a pink to purple color. No other line appears.



For a **FLU A POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color. A **SECOND** pink to purple Sample Line appears above it in the **MIDDLE THIRD** of the window. Any shade of a pink to purple Sample Line indicates a positive result.



For a **FLU B POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color. A **SECOND** pink to purple Sample Line appears above it in the **TOP THIRD** of the window. Any shade of a pink to purple Sample Line indicates a positive result.



For a **FLU A and FLU B POSITIVE SAMPLE**, the BLUE Control Line turns a pink to purple color, **AND** two pink to purple Sample Lines appear above it in the **MIDDLE and TOP** thirds of the window. Any shade of pink to purple Sample Lines indicate positive results.



A test is **INVALID** if the Control Line remains **BLUE** or is not present at all, whether a Sample Line(s) is present or not. Repeat **Invalid** tests.

