

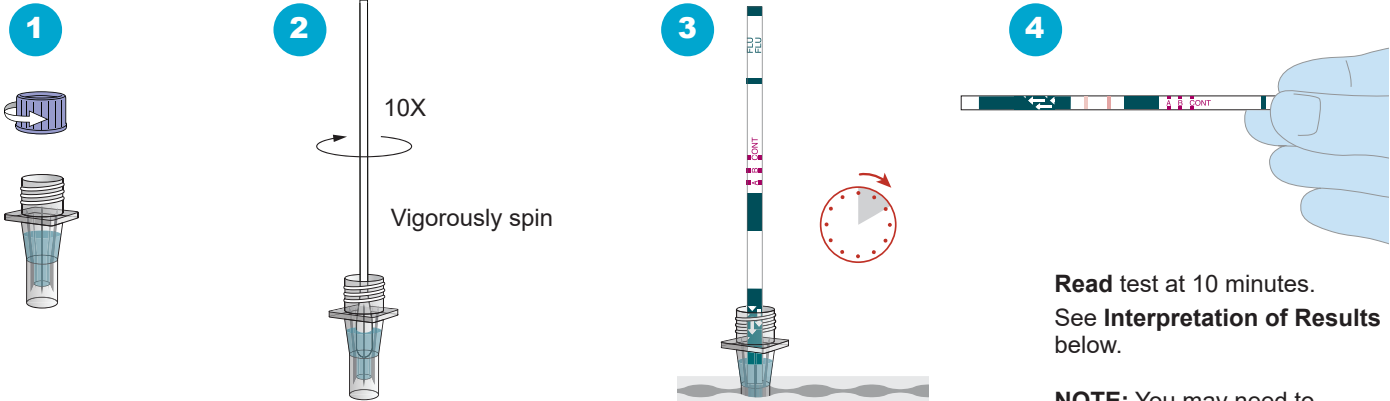
For use with nasal and nasopharyngeal swab specimens.
A Certificate of Waiver is required to use the test.



IMPORTANT: Read and follow the complete test procedure before performing the test. Refer to the Instructions for Use (IFU) for more complete information.

Users must follow manufacturer's instructions; failure to follow the instructions or modification to the test procedure will result in the test no longer meeting the requirements for waived classification.

TEST PROCEDURE:



1
Twist cap off the Extraction Buffer vial.

2
Insert the swab through the ridges into the liquid.

Spin swab 10 times to mix the specimen.

NOTE: Nasal swabs may not reach the bottom of the vial. Ensure that the swab is fully immersed in the liquid when mixing.

3
Discard the swab.

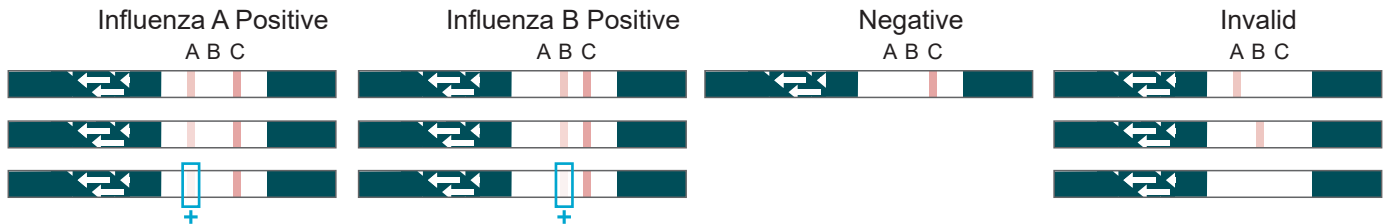
Insert Test Stick (arrows pointing downward) into the vial.

Start timing.

4
Read test at 10 minutes.
See Interpretation of Results below.

NOTE: You may need to remove the Test Stick to read the test results.

INTERPRETATION OF RESULTS:



+ LOOK CLOSELY WHEN INTERPRETING THE RESULTS!

The Control Line must be present for the result to be valid.

The appearance of **ANY** shade of a very light or faint pink to purple line at the **A Test Line and/or B Test Line** along with a **C Control Line** indicates a positive result for the presence of influenza A and/or B viral antigen.

Even if you see a very light or faint pink to purple Test Line, as long as the Control Line is present, it is a positive test result.

EXTERNAL QUALITY CONTROL PROCEDURE:

To perform a positive or negative control test, complete the steps in the Test Procedure section, treating the control swab in the same manner as a patient swab.

Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

For technical questions or assistance, please contact Technical Services at (800) 332-1042 or SDADiagnosticsTSDL@sekisuidiagnostics.com

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