Test Name/Equipment:	QuickVue Influenza A+B Test

Date Initiated : 12/15/2014 Date Amended: 04/12/2019 Date Reviewed: 07/06/2022

Intended Use

The QuickVue Influenza A + B test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab, nasal aspirate, and nasal wash specimens. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B viral infections. This test is not intended to detect influenza type C antigens. Negative results do not preclude influenza virus infection and should not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

Principle of the Test

The QuickVue Influenza A+B Test involves the extraction of influenza A and B viral antigens. The patient specimen is placed in the Reagent Tube, during which time the virus particles in the specimen are disrupted, exposing internal viral nucleoproteins. After extraction, the Test Strip is placed in the Reagent Tube where nucleoproteins in the specimen will react with the reagents in the Test Strip. If the extracted specimen contains influenza A or B antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. The Test Line for influenza A or B will develop at separate specified locations on the same Test Strip. If influenza A or B antigen are not present, or are present at very low levels, only the blue procedural Control Line will appear.

Specimen collection and handling:

Proper specimen collection, storage, and transport are critical to the performance of this Test

Nasal Swab Sample: **ONLY** use a foam nasal swab provided in the kit. It is important to obtain as much secretion as possible. Therefore, to collect a Nasal Swab sample, insert the sterile Swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the Swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the Swab a few times against the nasal wall.

Kit Storage and Stability:

Store the kit at room temperature, 59°F to 86°F (15°C to 30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

TEST PROCEDURE

Important: Use of proper hand hygiene and wearing gloves is required when preforming any testing.

Procedure instructions by step (to be completed in this order)

1. Verify that Extraction test tube (glass tube) has lyophilized reagent in bottom of tube.
2. Dispense all of the Reagent Solution from the Reagent Tube into the test tube. Gently swirl the Extraction Tube to dissolve its contents.
3. Place the patient swab with sample into the Reagent Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Reagent Tube.
   Leave the swab in the Reagent tube for 1 minute.
4. Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.
5. Place the Test Strip into the Reagent Tube with the arrows on the Test Strip pointing down. Do not handle or remove the Test Strip until the test is complete and ready for reading.
6. Read result at ten (10) minutes. Some positive results may appear sooner. Do not read after ten (10) minutes.

Interpretation of Results

- ***Positive Result:** At ten (10) minutes, the appearance of **ANY** shade of a pink-to-red Test Line either above or below the blue Control Line **AND** the appearance of a blue procedural Control Line indicates a positive result for the presence of the influenza A and/or B viral antigen.

  Hold the test strip with the arrows pointed down.
  •If the red line is above the blue Control Line, the test result interpretation is positive for type A.
  •If the red line is below the blue Control Line, the test result interpretation is positive for type B.

  *A positive result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.

- ****Negative Result:** At ten (10) minutes, the appearance of **ONLY** the blue procedural Control Line indicates influenza A and B viral antigen were not detected. A negative result should be reported as a presumptive negative for the presence of influenza antigen.

  **A negative result does not exclude influenza viral infection. Negative results should be confirmed by cell culture.

- **Invalid Result: If at ten (10) minutes, the blue procedural Control Line does not appear,** even if any shade of a pink-to-red Test Line appears, **the result is considered invalid**. If at 10 minutes, the background color does not clear and it interferes with the reading of the test, the result is considered invalid. If the test is invalid, a new test should be performed with a new patient sample and a new Test Strip.

Reporting and Documentation of Results

The nurse will report the results verbally to the Telehealth provider during a consultation, document manually on the Patient Result log located in the clinic, and on the School Telehealth nurse website electronic POC Testing form.

QUALITY CONTROL

Built-in Control Features

The QuickVue Influenza A+B Test contains built-in procedural control features. The manufacturer's recommendation for daily control is to document these built-in procedural controls for the first sample tested each day. The two-color result format provides a simple interpretation for positive and negative results. The appearance of a blue procedural Control Line provides several forms of positive control by demonstrating sufficient flow has occurred and the functional integrity of the Test Strip was maintained. If the blue procedural Control Line does not develop at 10 minutes, the test result is considered invalid. A built-in negative control is provided by the clearing of red background color, verifying that the test has been performed correctly. Within 10 minutes, the result area should be white to light pink and allow the clear interpretation of the test result. If background color appears and interferes with interpretation of the test result, the result is considered invalid. Should this occur, review the procedure, and repeat the test with a new Test Strip.

External Quality Control

External controls may also be used to demonstrate that the reagents and assay procedure perform properly. Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits – provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures, and in accordance with Local, State, and Federal regulations or accreditation requirements.

Limitations of the test method

See manufacturer's package insert.

Expected values, performance characteristics, clinical studies, and literature references

See manufacturer's package insert.

Warnings and Precautions

See manufacturer's package insert.

Quidel QuickVue Influenza A+B Acknowledgement

I have read, reviewed, and certify that I am knowledgeable of the above policy and procedure. I agree to follow the steps required in order to perform the procedure correctly.

_____	_____
School	**District**

_____	_____	_____
Trainee Name	**Trainee Signature**	**Date**
_____	_____	_____
Trainee Name	**Trainee Signature**	**Date**
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Trainee Name	**Trainee Signature**	**Date**