

Quidel® QuickVue Influenza A/B Test

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CLIAwaived™ Inc.



Quidel® QuickVue Influenza A/B Test

The QuickVue test is the first CLIA-waived rapid influenza test. The QuickVue Influenza test combines speed, simplicity and accuracy all in one test. 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 wash and/or nasal aspirate specimens. The test is intended as an aid in the rapid differential diagnosis of acute influenza type A and type B virus infection. (Not approved for home use!)

BENEFITS:

- Differentiated results for type A and type B
- Simple 3-step procedure
- Easy to read test results
- Results in 10 minutes
- Room temperature storage
- 12-18 month shelf life
- Built-in procedural control features
- FDA Cleared and CLIA waived

Ordering Information:	
Product Description	Catalog #
Quidel® QuickVue Influenza A/B Tests (25 Tests)	QDL-20183
Quidel® QuickVue Influenza A/B Tests (25 Tests)	QDL-20317
Reimbursement Information:	
CPT Code #	National Limit Amount
87804QW*	\$16.76

*It is always the provider's responsibility to establish appropriate coding & charges. Reimbursement shown indicates National Average. It is recommended provider bill 87804QW for Influenza A and 87804QW for Influenza B. Total combined reimbursement \$33.52.

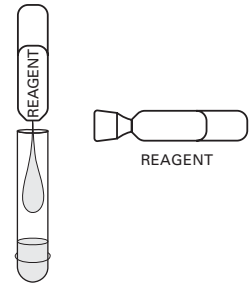
TEST PROCEDURE

All clinical specimens must be at room temperature before beginning the assay.

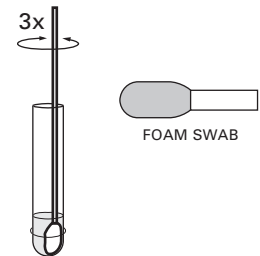
Expiration date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Nasal/Nasopharyngeal Swab Procedure

1. Dispense all of the Extraction Reagent Solution from the Reagent Tube. Gently swirl the Extraction Tube to dissolve its contents.



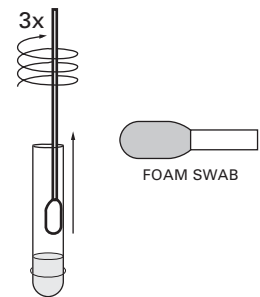
2. Place the patient swab with sample into the Extraction Tube. Roll the swab at least three (3) times while pressing the head against the bottom and side of the Extraction Tube.



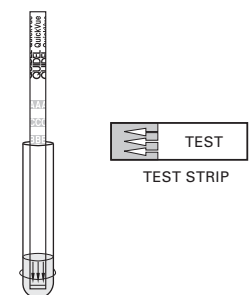
Leave the swab in the Extraction Tube for one (1) minute.



3. Roll the swab head against the inside of the Extraction Tube as you remove it. Dispose of the used swab in accordance with your biohazard waste disposal protocol.



4. Place the Test Strip into the Extraction Tube with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.

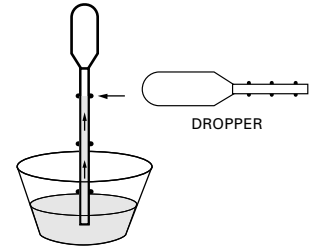


5. Read result at ten (10) minutes. Some positive results may appear sooner. Do not read result after ten (10) minutes.

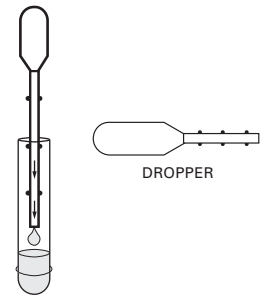


Nasal Wash/Nasal Aspirate Procedure

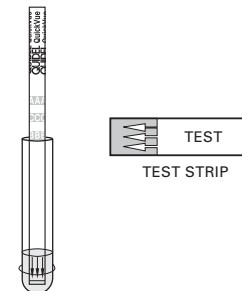
1. Fill the dropper to the top/uppermost notch with nasal wash or nasal aspirate sample.



2. Add entire contents of the dropper to the Extraction Tube. Swirl the Extraction Tube gently to dissolve its contents.



3. Place the Test Strip into the Extraction Tube with the arrows on the Test Strip pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.



4. Read result at ten (10) minutes. Some positive results may appear sooner. Do not read after ten (10) minutes.



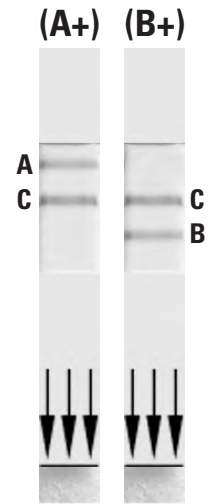
INTERPRETATION OF RESULTS

Positive Result:

At ten minutes, **ANY** shade of a pink-to-red Test Line forms, 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 influenza A and/or B viral antigen.

Hold the test strip with the **arrows pointed down**.

- If the red line is **above** the Control Line, the test results are positive for type A. See image to the immediate right (A+).
- If the red line is **below** the Control Line, the test results are positive for type B. See image to the far right (B+).



Negative Result:

At ten minutes, the appearance of **ONLY** the blue procedural Control Line indicates the sample is negative for influenza A and B viral antigen. A negative result should be reported as a presumptive negative for the presence of influenza antigen.



Invalid Result:

If at ten 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 ten 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.

