



Influenza A & B Screening

CHAPTER 8: INFLUENZA TYPE A AND B

Procedure: Nasal Swab for Influenza type A and B by Quidel influenza test

PRINCIPLE:

The QuickVue Influenza test allows for the rapid, qualitative detection of influenza type A and type B antigens directly from nasal swab, nasal wash and/or nasal aspirate specimens. This test is intended for use as an aid in the rapid diagnosis of acute influenza virus infection. The test is not intended to detect influenza C antigens or antigens of other viruses.

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-strand RNA viruses known as influenza viruses. There are three types of influenza viruses: A, B, and C. Type A viruses are the most prevalent and are associated with most serious epidemics. Type B viruses produce a disease that is generally milder than that caused by type A. Type C viruses have never been connected with a large epidemic of human disease. Both type A and B viruses can circulate simultaneously, but usually one type is dominant during a given season.¹

The QuickVue Influenza test involves the extraction of influenza A and B viral antigens. The patient specimen is placed in the Extraction 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 Extraction Reagent Tube where nucleoproteins in the specimen will react with the reagents in the Test Strip. If the extracted specimen contains influenza antigens, a pink-to-red Test Line along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. If influenza type A or type B antigens are not present, or are present at very low levels, only a blue procedural Control Line will appear.

REAGENTS AND MATERIALS SUPPLIED:

- 25-Test kit, Catalog Number 00317
- 25 Individually Packaged Test Strips: Mouse monoclonal anti-influenza A and anti-influenza B antibodies.
- 25 Extraction Reagent Solution (250 µL each) Salt solution
- 25 Extraction Tubes: Lyophilized buffer with detergents and reducing agents
- 25 Disposable Droppers
- 25 Sterile Swabs
- Positive Influenza Type A Control Swab
- Positive Influenza Type B Control Swab
- Negative Control Swab: Formalin-fixed *Streptococcus C* antigen
- Direction Insert and Procedure Card

MATERIALS NOT SUPPLIED:

- Specimen containers
- Timer or watch

WARNINGS AND PRECAUTIONS:

- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Use appropriate precautions in the collection, handling, storage and disposal of patient samples and used kit contents.² Discard used material in a proper biohazard or sharps containers.
- The Test Strip must remain sealed in the protective foil pouch until use.
- The Extraction Reagent solution contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
- To obtain accurate results, you must follow the Direction Insert.

KIT STORAGE AND STABILITY

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

SAMPLE COLLECTION AND STORAGE:***Nasal Swab Sample:***

For proper test performance, use the swabs supplied in the kit.

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.

Nasal Wash or Aspirate Sample***For Older Children and Adults:***

With the patient's head hyper-extended, instill about 2.5 mL of sterile, normal saline into one nostril with a syringe. To collect the wash, place a clean, dry specimen container directly under the nose with slight pressure on the upper lip. Tilt the head forward and allow the fluid to run out of the nostril into the specimen container. Repeat for the other nostril and collect the fluid into the same specimen container.

For Younger Children:

The child should sit in the parent's lap facing forward, with the child's back against the parent's chest. The parent should wrap one arm around the child in a manner that will restrain the child's body and arms. Fill an aspiration bulb or bulb syringe with up to 2.5 mL of sterile, normal saline (depending on the size of the child), and instill the saline in to one nostril while the head is tilted back. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen into a clean, dry specimen container. Repeat the process for the child's other nostril and transfer the specimen into the same specimen container.

SAMPLE TRANSPORT AND STORAGE:

Samples should be tested as soon as possible after collection. Do not use any kind of transport media to store or transfer samples. Samples may be stored refrigerated (2-8°C) in a clean, dry, closed container for up to one hour.

QUALITY CONTROL:***Built-in Control Features***

The QuickVue Influenza test contains built-in procedural control features. These built-in procedural controls are to be documented for each sample tested. The appearance of a blue procedural Control Line demonstrates that sufficient capillary flow has occurred and 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 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:

In addition to the procedural controls or calibrators, external controls must be used to demonstrate that the reagents and assay procedure is performed properly. External positive and negative Control Swabs are supplied in the test kits and should be tested using the Swab Procedure. Controls should be tested with **each new lot or shipment** of test materials, or whenever there is any question about kit storage, operator technique, or other aspect of system

performance. **If the controls do not perform as expected, repeat the test or contact your POCT site supervisor, the POCT clinical coordinator, or the Department of Pathology UDL central administrative office. Correct control results must be obtained before testing patient samples.**

TEST PROCEDURES:

Expiration date: check expiration on each individual test package (tray or outer box) before using. *Do not use any test past the expiration date on the label. All test packages should be initialed by the operator who opens them, and the expiration date for the kit should be clearly noted on the box.*

Nasal Swab Procedure

1. Dispense all of the Extraction Reagent Solution from the yellow capped Reagent Tube into the Extraction Tube. Gently swirl the Extraction Tube to dissolve its contents.
2. Place the swab with the patient 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
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 pointing down. Do not handle or move the Test Strip until the test is complete and ready for reading.
5. Read result after ten (10) minutes. Some positive results may appear sooner.

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 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 earlier.

INTERPRETATION OF RESULTS:

Positive Result:

At ten minutes ANY shade of a pink-to-red Test 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.

Negative Result:

At ten minutes, the appearance of ONLY the blue procedural Control Line indicates the sample is negative for the presence of 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 10 minutes, the background color does not clear and it interferes with the reading of the test, the result is considered invalid. If the result is invalid, a new test should be performed with a new patient sample and a new Test Strip.

LIMITATIONS:

- The contents of this kit are to be used for the qualitative detection of influenza A and B antigen from nasal swab, nasal wash and nasal aspirate specimens. This test does not differentiate between influenza types A and B.

- Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
- Test results must be evaluated in conjunction with other clinical data available to the physician.
- A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or from improper sample collection.
- Negative test results do not rule-out non-influenza viral infections.

PERFORMANCE CHARACTERISTICS:

The performance of the QuickVue Influenza test was compared to cell culture methods in a multi-center field clinical study. A total of 370 specimens were tested from 275 patients [274 nasal swabs and 96 nasal wash/aspirate specimens].

The following tables summarize the results:

For Nasal Swab Specimens:

- Compared to culture and confirmed for influenza A or B by DFA, the QuickVue Influenza test correctly identified 79/108 (73%) positive specimens and 159/166 (96%) negative specimens.

		Culture Results	
		Pos	Neg
QuickVue Results	Pos	79	7
	Neg	29	159

Sensitivity: 79/108 = 73%
 Specificity: 159/166 = 96%
 Pred. Value (+): 79/86 = 92%
 Pred. Value (-): 159/188 = 85%
 Accuracy: 238/274 = 87%

For Nasal Wash or Nasal Aspirate Specimens:

- Compared to culture and confirmed for influenza A or B by DFA, the QuickVue Influenza test correctly identified 22/27 (81%) positive specimens and 68/69 (99%) negative specimens.

		Culture Results	
		Pos	Neg
QuickVue Results	Pos	22	1
	Neg	5	68

Sensitivity: 22/27 = 81%
 Specificity: 68/69 = 99%
 Pred. Value (+): 22/23 = 96%
 Pred. Value (-): 68/73 = 93%
 Accuracy: 90/96 = 94%

ANALYTICAL SPECIFICITY AND CROSS-REACTIVITY:

The QuickVue Influenza test was evaluated with a total of 62 bacterial and viral isolates. Bacterial isolates were evaluated at a concentration between 10⁷ and 10⁹ org/mL. Viral isolates were evaluated at a concentration of at least 10⁴ - 10⁶ TCID₅₀/mL. Adenovirus 18 and Parainfluenza virus 3 were test at 10² TCID₅₀/mL. None of the organisms or viruses listed below gave a positive result in the QuickVue Influenza test.

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|---------------------------|------------------------------|-----------------------------|
| Adenovirus 5 (Ad. 75) | Coxsackievirus B5 (Faulkner) | Herpes simplex virus 2 |
| Adenovirus 7 (Gomen) | Cytomegalovirus (Towne) | Human Rhinovirus 2 (HGP) |
| Adenovirus 10 (J.J.) | Echovirus 2 (Cornelis) | Human Rhinovirus 14 (1059) |
| Adenovirus 18 (D.C.) | Echovirus 3 (Morrisey) | Human Rhinovirus 16 (11757) |
| Coronavirus OC43 | Echovirus 6 (D'Amori) | Measles (Edmonston) |
| Coxsackievirus A9 (Bozek) | Herpes simplex virus 1 | Mumps (Enders) |

Parainfluenza virus 1 (Sendai)	Respiratory Syncytial virus (A-2)	Long chain
Parainfluenza virus 2 (CA/Greer)	Respiratory Syncytial virus (Subgroup A,	Rubella (RA 27/3)
Parainfluenza virus 3 (C243)		Varicella-Zoster (Ellen)

ASSISTANCE:

If you require assistance, please contact your POCT site supervisor, the POCT clinical coordinator, or the Department of Pathology UDL central administrative office. If necessary, they will contact Quidel Technical Support. Quidel Technical Support is only available after 7AM Pacific Time, 10AM Eastern Time

REFERENCES:

1. Murphy, B.R. and R.G. Webster. 1996 Orthomyxoviruses, pp. 1397-1445. In: Field's Virology, 3rd edition, B.N. Fields, D.M Knipe, P.M. Howley, Et. al. (eds.), Lippincott-Raven, Philadelphia.
2. Recommendations for the Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Centers for Disease Control, August 21 1987.

Written by: POCT Committee.

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