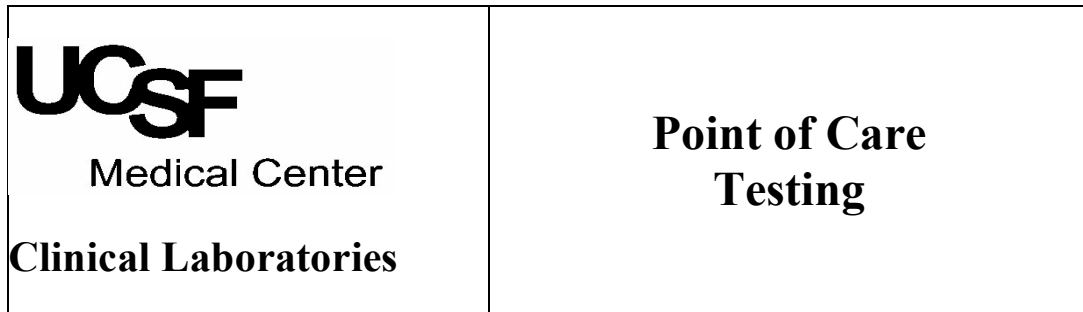


Director Approval \_\_\_\_\_ Date \_\_\_\_\_



### QuickVue® Influenza Test

#### PURPOSE

QuickVue Influenza test provides qualitative detection of Influenza Type A and Type B antigens from nasal specimens (swab, wash or aspirate), to aid in the detection of acute influenza virus infection. It is recommended that negative test results be followed up with confirmatory testing.

#### SCOPE

The test provides detection of Influenza Type A and Type B antigen only. The test is not intended to detect influenza C antigens.

#### PRINCIPLE

Influenza antigens may be detected in clinical specimens by immunoassay. The QuickVue Influenza Test is a lateral-flow immunoassay using highly sensitive monoclonal antibodies that are specific for influenza antigens. The test is specific to influenza types A and B antigens with no known cross-reactivity to normal flora or other known respiratory pathogens.

The QuickVue Influenza Test involves the extraction of the 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.

## PERSONNEL

Intended for use by clinical personnel who have been trained and demonstrated competency in this procedure. In the hospital setting, this includes:

- Registered Nurses,
- Nurse Practitioners,
- Physician Assistants, and
- Physicians.

In the ambulatory setting, this includes

- Hospital Assistants,
- Licensed Vocational Nurses,
- Registered Nurses,
- Nurse Practitioners,
- Physician Assistants, and
- Physicians.

Individuals who are color blind must demonstrate their ability to read the test results.

## REAGENTS, EQUIPMENT, AND MATERIALS

- Test Kit containing
  - Test Strips
  - Extraction Reagent Solution vials ( 250 microliters each)
  - Extraction tubes containing powdered buffer
  - Disposable Sterile Swabs
  - Disposable pipettes
  - Positive A, Positive B and Negative controls
- Disposable syringe or bulb syringe
- Specimen container
- Sterile Saline
- Gloves
- Gowns or laboratory coats
- Eye protection
- Facemask
- Timer or watch
- Storage and Handling
  - Test kits stored at room temperature, 59-86° F (15-30° C), out of direct sunlight will remain stable until the expiration date printed on the outer box.
  - Do not freeze.
  - Do not mix components from different kit lots.

## SPECIMEN REQUIREMENTS

Appropriate personal protective equipment (PPE) or splash protection, such as gowns or laboratory coats, gloves, eye protection and facemasks, are required for minimizing risks associated with splash for Influenza tests.

Nasal swab, wash or aspirate specimens may be used for testing. Specimens should be tested as soon as possible after collection. If testing is not performed immediately by the person collecting the specimen, then the sample must be labeled in the presence of the patient, using two forms of patient identification.

The following methods are suggested for specimen collection:

A. **Nasal Swab Sample**

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

Insert sterile swab into the nostril that presents the most secretion under visual inspection. Gently rotate the swab inward, 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.

B. **Nasal Wash or Aspirate Sample**

1. **For Older Children and Adults**

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

2. **For Younger Children**

Sit child on 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 into 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 specimen container. Repeat the process for the child's other nostril and transfer the specimen into the same specimen container.

As part of our Bloodborne Pathogen Exposure Control Plan, standard precautions must be followed when handling specimens. Gloves should be worn while collecting or testing the specimen.

## CONTROLS

A. Built-in Procedural Controls (positive and negative)

Proper performance of the procedural controls must be documented on the first sample tested each day of patient testing.

1. A positive procedural control is included in each test strip. The appearance of the blue band in the upper region of the membrane demonstrates that sufficient capillary flow has occurred and that the functional integrity of the Test Strip has been maintained.

**NOTE: If the blue procedural Control Line does not develop at 10 minutes, the test is considered invalid.**

2. A negative procedural 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.

**NOTE: If background color appears and interferes with interpretation of the test result, the result is considered invalid.**

3. Document proper performance of positive and negative procedural controls each day of patient testing on the QC log sheet.

B. External Quality Control (2 positive and 1 negative)

External Positive and Negative Quality Controls must be performed and documented each time a new kit of 25 QuickVue Influenza tests is opened.

1. Control swabs are supplied in each kit and quality control should be performed prior to patient testing with materials from the new kit,
2. Using the Swab Procedure, document QC results on the QC log sheet.
3. Date and initial box when QC is performed.
4. Document external quality control results on the QC log sheet.

## QUALITY CONTROL PROCEDURE

- Check expiration dates on control pouches (Positive A, Positive B, and Negative controls), test strips, extraction reagent vials and extraction tubes.
- Dispense all the solution from an extraction reagent vial into an extraction tube, which contains a powdered buffer.
- Gently swirl extraction tube to dissolve contents.
- Place the Positive A Control swab into the extraction tube, pushing the swab at least three times against the bottom and sides of the extraction tube.
- Remove the swab, pressing the head of the swab against the side of the tube as you remove it.
- Dispose of the swab in a sharps container or biohazard bin.
- Place a test strip into the extraction tube, with the arrow pointing down.
- DO NOT handle or move the test strip until the test is complete and ready for reading.
- Wait ten (10) minutes to read results.
- Repeat for Positive B control and the Negative control.
- A positive result for Positive A Control and Positive B Control is indicated by a red band in the test region along with the blue procedural band (which indicates proper functioning of the test strip).
- A negative result for the Negative Control is confirmed when only one blue procedural control band appears on the test strip. No red band will appear in the test region.
- Proper positive and negative procedural functioning is indicated by the appearance of the blue band and by the fading of the reddish background, so that test results may be interpreted.
- Record result in QC log.
- Write the date and "QC performed" on the box
- If the controls do not perform as expected, repeat the test. A new test should be performed with a new patient sample and a new Test Strip. Do not report patient result until the control problem is resolved.
- Contact the Point-of-Care Testing Coordinator at 353-1630, or the vendor's Technical Support number (800) 874-1517, for aid in evaluating the problem.

## TESTING PROCEDURE

- Splash protection (gloves, gown eye protection, facemask) is required when performing testing.
- Using two patient identifiers, verify patient identification and explain procedure to patient and/or family.
- Obtain nasal swab, wash or aspirate specimen.
- Check expiration dates on Test strips, extraction reagent vials and extraction tubes.
- Dispense all the solution from an extraction reagent vial into an extraction tube, which contains a powdered buffer. .
- Gently swirl extraction tube to dissolve contents.
- Nasal Swabs:
  - Place the swab into the extraction tube, pushing the swab at least three times against the bottom and sides of the extraction tube.
  - Remove the swab, pressing the head of the swab against the side of the tube as you remove it.
  - Dispose of the swab in a sharps container or biohazard bin.

OR

- Nasal Wash or Aspirate
  - Using the dropper provided in the kit, fill the dropper to the upper most notch with the nasal wash/ aspirate sample, collected in the specimen cup.
  - Place entire contents of dropper into the extraction tube, swirling gently to dissolve contents.
- Place a test strip into the extraction tube, with the arrow pointing down.
- DO NOT handle or move the test strip until the test is complete and ready for reading.
- Wait ten (10) minutes to read results.
- A positive result is indicated by a red band in the test region, along with the appearance of the blue procedural band (which indicates proper functioning of the test strip).
- A negative result is interpreted when only one blue procedural control band appears on the test strip. No red band will appear in the test region. It is recommended that negative test results be followed up with confirmatory testing.
- Proper positive and negative procedural functioning is indicated by the appearance of the blue band and by the fading of the reddish background, so that test results may be interpreted.
- Record only valid results in patient's medical record.
- Report result to provider.

## INTERPRETING RESULTS

Report only "Positive" or "Presumptive Negative" Result. Do not report results of invalid tests.

- POSITIVE:** At ten minutes, the appearance of **ANY** shade of 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:** 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 negative for the presence of influenza antigen.
  - Negative results should be confirmed by Laboratory testing.
- INVALID RESULT:**

1. 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.
2. If at ten minutes, the background color does not clear and it interferes with the reading of the test, the result is considered invalid.
3. If the test is invalid, a new test should be performed with a new patient sample and a new Test Strip.

## PROCEDURAL NOTES

- A. The QuickVue Influenza Test is for *in vitro* diagnostic use.
- B. Do not use the kit contents beyond the expiration date printed on the outside of the box.
- C. Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents. Discard used material in a proper biohazard or sharps container.
- D. The Test Strip must remain sealed in the protective foil pouch until use.
- E. The Extraction Reagent Solution contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
- F. To obtain accurate results, you must follow the procedure.

## LIMITATIONS

- A. The test is to be used for the qualitative detection of influenza A and B antigen from nasal swab, wash or aspirate specimens. This test does not differentiate between influenza types A and B.
- B. Test results must be evaluated in conjunction with other clinical data available to the physician.
- C. 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.
- D. Negative test results are not intended to rule-out other non-influenza viral infections.

## DOCUMENTATION

Lot numbers and expiration dates of all kit materials should be recorded on QC logs.

## RECORD MAINTENANCE

Retired records containing laboratory worksheets and logs are kept in an accessible area for three years as required by law.

## REFERENCES

- Quidel QuickVue Influenza Test Package Insert, 02/07.
- Murphy, B.R. and Webster, R.G. 1996. Orthomyxoviruses, pp. 1397-1445. In: Fields Virology, 3<sup>rd</sup> edition, B.N. Fields, D.M. Knipe, P.M. Howley, Et al. (eds.), Lippincott-Raven, Philadelphia.
- Recommendations for the Prevention of HIV Transmission in Health Care Settings, Morbidity and Mortality Weekly Report, Centers for Disease Control, August 21, 1987.