Title: Rapid Flu AB Procedure

Contents

Purpose ......................................................................................................................................................................2
Scope .........................................................................................................................................................................2
Policy and Procedure Statement ................................................................................................................................2
Test Principle ..........................................................................................................................................................2
Regulatory Requirements ...........................................................................................................................................2
Limitations/Interferences ............................................................................................................................................3
Test Kit/Supplies/Equipment ......................................................................................................................................3
Competency Assessment ...........................................................................................................................................3
Specimen Collection (Nasal Swab) ............................................................................................................................4
Quality Control Monitoring ..........................................................................................................................................4
Test Procedure ...........................................................................................................................................................4
Interpretation of Results .............................................................................................................................................5
Expected Results .......................................................................................................................................................6
Documentation ...........................................................................................................................................................7
Reference ...................................................................................................................................................................7

Written by: Gino Pagnani Date: 5/2006
Approved by: Kent Lewandrowski, MD Date: 5/2006
Purpose

This document outlines policies and procedures that deal with Rapid Influenza A/B testing. In an effort to be concise some information may be excluded from the manufacturer’s recommended procedure. It is recommended that operators familiarize themselves with the manufacturer’s product information that accompanies each package and their manual if one exists.

Scope

Level of Personnel: All RN’s, NP’s, PCA’s, MA’s, who have successfully completed Initial training and maintained annual competency.

Testing Site: All sites approved and on file with the Pathology Services POCT Division

Policy and Procedure Statement

The QuickVue Influenza A+B 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. The test is intended for use as an aid in the rapid differential diagnosis of acute influenza type A and type B virus infection. The test is not intended to detect influenza C antigens. Negative test results should be confirmed by cell culture.

Test Principle

The QuickVue Influenza A+B 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 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 type B antigens will develop at separate specified locations on the same Test Strip. If influenza A or type B antigens are not present, or are present at very low levels, only the blue procedural Control Line will appear.

Regulatory Requirements

I. Each testing site must have a documented quality control program, which is developed in collaboration with or has been approved by the MGH Pathology Service.

II. All test results must be maintained in patient records with all required information for four years

Required information:

1. Patient’s name
2. Medical Record Number
3. Patient’s gender
4. Patient’s age or date of birth
5. Date & time test collected, performed and reported
6. Ordering Physician
7. Responsible physician (if not 6)
8. Reference or Target Range
9. Test Performed
10. Test units
11. Lab name

III. Additional information that must be retained for four years:

1. Testing personnel records
2. Quality control results
3. Product information (i.e. serial number, lot numbers, expiration dates, etc.), information on quality control and any remedial action
4. QC charts, maintenance sheets, reference and critical ranges

IV. Other
1. Universal precautions must be observed when handling any patient specimen.
2. A physician’s order or standing order is required prior to performing test.
3. The Hospital Hand Hygiene policy must be adhered to at all times.

**Limitations/Interferences**

1. The Test Strip must remain sealed in the protective foil pouch until use.
2. Dispose of all used materials in a proper biohazard container.
3. The Extraction Reagent Solution contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.
4. Internal Quality Controls must be performed and documented with each test.
5. External Quality Controls must be performed and documented with each box of 25 test kits.
6. Only Quidel swabs may be used to obtain the sample and perform the test.
7. 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.
8. Failure to follow the Test Procedure and Interpretations of Test Results may adversely affect test performance and/or invalidate the Test Result.
9. Test Results must be evaluated in conjunction with other clinical data available to the physician.
10. A negative test may occur if the level of antigen in a sample is below the detection limit of the test or from improper sample collection.
11. Negative test results are not intended to rule-out other non-influenza viral infections.
12. Positive test results do not identify specific influenza A virus subtypes or rule out co-infections with other pathogens.
13. Individuals who received nasally administered influenza A vaccine may have positive test results for up to three days after vaccination.

**Test Kit/Supplies/Equipment**

<table>
<thead>
<tr>
<th>Product</th>
<th>Quidel #</th>
<th>Vendor</th>
<th>Fisher #</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Instant-Recall Memory Timer</td>
<td></td>
<td>Fisher Scientific</td>
<td>02-401-7</td>
<td>Package of 25</td>
</tr>
<tr>
<td>Quidel QuickVue Influenza A+B Test</td>
<td>20183</td>
<td>Fisher Scientific</td>
<td>23 043 058</td>
<td>Store at Room Temp (15 – 30°C)</td>
</tr>
<tr>
<td>Quidel swabs</td>
<td>0476900</td>
<td>Fisher Scientific</td>
<td>NC 9682121</td>
<td>Package of 25</td>
</tr>
</tbody>
</table>

**Reagents and Materials Provided with Kit:**

<table>
<thead>
<tr>
<th>Components</th>
<th>Quantity Provided</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individually packaged Test Strips: Mouse monoclonal anti-influenza A and anti-influenza B antibodies.</td>
<td>25</td>
</tr>
<tr>
<td>Extraction Reagent Solution: 340ul of salt solution</td>
<td>25</td>
</tr>
<tr>
<td>Extraction Tubes: Lyophilized buffer with detergents and reducing agents</td>
<td>25</td>
</tr>
<tr>
<td>Disposable droppers</td>
<td>25</td>
</tr>
<tr>
<td>Sterile swabs</td>
<td>25</td>
</tr>
<tr>
<td>Positive Influenza Type A Control Swab: swab is coated with non-infectious recombinant influenza A antigen</td>
<td>1</td>
</tr>
<tr>
<td>Positive Influenza Type B Control Swab: swab is coated with non-infectious recombinant influenza B antigen</td>
<td>1</td>
</tr>
<tr>
<td>Negative Control Swab: Swab is coated with formalin-inactivated, non-infectious Streptococcus C antigen</td>
<td>1</td>
</tr>
<tr>
<td>Package Insert</td>
<td>1</td>
</tr>
<tr>
<td>Procedure Card</td>
<td>1</td>
</tr>
</tbody>
</table>

**Competency Assessment**

Competency is assessed after initial training and annually (within 365 days) using at least two of the following methods:
1. Performing a test on a blind specimen.
2. Supervisor observes performance of routine work.
3. Each user's quality control performance is monitored.
4. Written testing specific to the method.

Operators that have not completed annual competency should not perform patient testing.

### Specimen Collection (Nasal Swab)

*For proper test performance, swabs supplied with the kit must be used.*

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 nostril wall.

For optimal results, samples should be tested as soon as possible after collection. Samples that are obviously dried out or diluted by excess liquid should not be tested due to decreased test sensitivity.

### Quality Control Monitoring

#### Internal Quality Controls

Positive Internal Control

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.**

Negative Internal Control

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

Results of the Positive and Negative Internal Controls must be documented with each test performed. Should the internal quality controls fail, review the procedure and repeat the test with a new Test Strip.

#### External Quality Controls

Three control swabs (Negative, Positive A and Positive B) are included with each box of 25 tests. Controls are run at the following frequency using the nasal swab procedure:

- Each time a new box is opened or a new shipment is received.
- Each new untrained operator.

External QC results are documented on the Patient/Quality Control Log. If the controls do not perform as expected, repeat the test or contact the POCT program (email: MGH POCT Coordinators or page 35058) for assistance before testing patient samples. The POCT staff will contact Quidel Technical Support if required.

### Test Procedure
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 Reagent Solution into the Reagent Tube. Gently swirl the tube to dissolve its contents.

2. 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 one (1) minute.

3. 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.

4. Place the Test Strip into the Reagent 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.

Interpretation of Results
Expected Results

Negative for Influenza A + B

Seasonal outbreaks of influenza occur worldwide in both the northern and southern hemispheres causing widespread illness each winter. The average attack rate of influenza is 26-33 cases per 100 people per year. The risk of hospitalization is roughly 1/300 of those infected among the very young and elderly. Approximately 20,000 deaths in the U. S. are attributed to influenza or its complications each year.
**Documentation**

The patient’s results and the internal quality control results must be recorded concurrently in one of the following manners:

1. in the patient’s record, or
2. on the rapid flu testing Quality Control / Test Result Log or
3. on another approved permanent record.

All records must be retained and retrievable for 4 years.

**Reference**

Quidel QuickVue Influenza A+B Test package insert 1063807 (10/09)