Quest Diagnostics

TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	1/2/2013
Department:	Micro	**Due Date:**	1/31/2013

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Influenza Antigen Detection GEC.M02, SGAH.M10, WAH.M10 v003

Description of change(s):

Section	Reason
4.2	Change name of Extraction Tube to Reagent Tube and Extraction Solution to Reagent Solution Added temperature range (15-30ºC)
10.4	Added invalid results

Document your compliance with this training update by taking the quiz in the MTS system.

Approved draft for training all sites (version 003)

Technical SOP

Title	**Influenza Antigen Detection**	
Prepared by	Ron Master	Date: 8/10/2009
Owner	Ron Master	Date: 8/10/2009

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Annual Review		
Print Name	**Signature**	**Date**

Form revised 3/31/00

TABLE OF CONTENTS

1. Test Information....3
2. Analytical Principle....4
3. Specimen Requirements....4
4. Reagents....5
5. Calibrators/Standards....6
6. Quality Control....6
7. Equipment And Supplies....7
8. Procedure....7
9. Calculations....8
10. Reporting Results And Repeat Criteria....8
11. Expected Values....10
12. Clinical Significance....10
13. Procedure Notes....10
14. Limitations Of Method....10
15. Safety....11
16. Related Documents....11
17. References....11
18. Revision History....11
19. Addenda....12

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Influenza A and B Antigen Detection	Lateral –flow immunoassay	INFLU

Synonyms/Abbreviations
Flu test

Department
Microbiology

2. ANALYTICAL PRINCIPLE

The QuickVue Influenza 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 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 in very low levels, only a blue procedural Control Line will appear.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Nasal wash or aspirate: Specimen Collection	**For older children and adults:** With the patient's head hyper-extended, instill about 2.5 mL 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. **For younger children:** With the patient's head hyper-extended, instill about 2.5 mL of sterile, normal saline into one nostril with a bulb syringe. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen to a sterile container. Repeat the process on the other nostril and transfer the specimen into the same specimen container.
Nasal Swab: **Specimen Collection**	**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.
Other	N/A

Form revised 3/31/00

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Nasal wash or aspirate, Nasal swab None
Collection Container	See section 3.1
Volume - Optimum **- Minimum**	2.5 ml 0.5 ml
Transport Container and Temperature	Collection container at room temperature
Stability & Storage Requirements	Room Temperature: Up to 8 hours
	Refrigerated: Up to 8 hours
	Frozen: Unacceptable
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	Do not use any type of transport media to store or transport samples. Reject samples submitted in transport medium.
Compromising Physical Characteristics	N/A
Other Considerations	N/A

4. REAGENTS

Refer to the Material Safety Data Sheet (MSDS) supplied with the reagents for complete safety hazards. Refer to the section in this procedure covering "SAFETY" for additional information.

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
QuickVue Influenza Test kit	Quidel # 101156 (25 tests per kit)

4.2 Reagent Preparations and Storage

NOTES: Date and initial all reagents upon opening. Each container must be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, (6) any special storage instructions; check for visible signs of degradation.
Refer to the Material Safety Data Sheet (MSDS) for a complete description of hazards. If a specific hazard is present, it will be noted in this procedure when the hazard is first encountered in a procedural step.

Precautions:
1. **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.**
2. **The Test Strip must remain sealed in the protective foil pouch until use.**

Form revised 3/31/00

3. **The Reagent Solution contains a salt solution. If the solution contacts the skin or eye, flush with copious amounts of water.**
4. **To obtain accurate results, you must follow the Direction Insert.**

QuickVue Influenza Test Kit	
Components	Sterile swabs
	Disposable pipettes
	Reagent Tubes
	Reagent Solution (ready for use)
Storage Stability	Room temperature, 15-30ºC (out of direct sunlight). Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

Reagent Controls	Positive Influenza Type A control swab
	Positive Influenza Type B control swab
	Negative control swab
Storage/Stability/ Preparation	Room temperature, 15-30ºC (out of direct sunlight). Kit contents are stable until the expiration date printed on the outer box. Do not freeze. Controls are supplied ready to use.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Built-in Control Features
The QuickVue Influenza Test contains built-in procedural control features. These built-in procedural controls will be documented for each patient test.

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 capillary flow has occurred and the functional integrity of the Test Strip was maintained. **If the blue procedural Control Line does not develop in 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 results, 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 performed properly.

External positive and negative Control Swabs are supplied with the kit and should be tested using the Swab Procedure. Controls should be tested with each new kit opened.

6.2 Frequency

Internal Controls are performed and documented for each patient tested.
External positive and negative controls are tested with each new kit opened.

6.3 Tolerance Limits

If the controls do not perform as expected, repeat the test and notify the supervisor before testing patient specimens. Call Quidel Technical Support 1-800-874-1517 Monday – Friday 7:00 am – 5:00 pm Pacific Time with any questions.

6.4 Review Patient Data

N/A

6.5 Documentation

Record Quality Control and patient data on appropriate worksheet.

6.6 Quality Assurance Program

The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

N/A

7.3 Supplies

Timer

8. PROCEDURE

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection is required minimum personal protective equipment. Report all accidents to your supervisor.

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

8.1	Nasal Swab Procedure
1.	Dispense all of the Reagent Solution from the Reagent Tube into the gray-capped Reagent Tube. Gently swirl the Reagent Tube to dissolve its contents. When opening the Reagent Tube hold it up straight so the content does not spill.
2.	Place the patient swab sample into the Reagent Tube. Roll the swab at least 3 times while pressing the head against the bottom and side of the Reagent Tube.
3.	Roll the swab head against the inside of the Reagent Tube as you remove it. Dispose of the swab in the biohazard trash.
4.	Place the Test Strip into the Reagent Tube with the arrows on the strip pointing down. Do not handle or move the strip until the test is complete and ready for reading.
5.	Read results at 10 minutes in a well-lit area. Some positive results may appear sooner.

8.2	Nasal Wash Procedure
1.	Fill the dropper to the top/uppermost notch with the well-mixed nasal wash.
2.	Add the entire contents of the dropper to the gray-capped Reagent Tube (you do not need to use the yellow-capped Reagent Solution when using a nasal wash). Swirl the Reagent Tube gently to dissolve its contents.
3.	Place the Test Strip into the Reagent Tube with the arrows on the strip pointing down. Do not handle or move the strip until the test is complete and ready for reading.
4.	Read results at 10 minutes in a well-lit area. Some positive results may appear sooner.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

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

Invalid Result: If at 10 minutes, the blue procedural Control Line does not appear, even if any shade of 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 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.

Notify the supervisor of any control failures or invalid test results. Do not report patient results if the controls fail.

10.2 Rounding / Units of Measure

N/A

10.3 Clinically Reportable Range (CRR)

N/A

10.4 Repeat Criteria and Resulting

If the result is…	Then ….
Any shade of a pink-to-red Test Line AND the appearance of a blue procedural Control Line	Positive
The appearance of ONLY the blue procedural line.	Negative The sensitivity of this Direct Antigen Immunoassay is ≤ 70% for influenza A compared to culture and may be lower for pandemic H1N1 influenza than for seasonal influenza A viruses. This may also hold true for influenza B. Therefore, a negative result does not exclude influenza virus infection.
No blue procedural Control Line at 10 minutes, even if any shade of pink-to-red Test Line appears.	The result is considered invalid. A new test should be performed with a new patient sample and a new Test Strip. Notify the supervisor of an invalid test result.
The background color does not clear and it interferes with reading of the test.	The result is considered invalid. A new test should be performed with a new patient sample and a new Test Strip. Notify the supervisor of an invalid test result.

10.5 Reporting

Result using function MEM using worksheet WIM2, SIM2 or GIM2

Outpatient positives will be called to the physician via call list.
Inpatient positives will be called to the unit by the resulting technologist following laboratory Critical Value policy.
There is no need to call ERD with results as they are reviewed immediately. These results will also appear on epidemiology reports that print the following day.

Form revised 3/31/00

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

Positive

12. CLINICAL SIGNIFICANCE

Influenza is a highly contagious, acute, viral infection of the respiratory tract. The causative agents of the disease are immunologically diverse, single-stranded 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 associated with a large epidemic of human disease. Both type A and type B viruses can circulate simultaneously, but usually one type is dominant during a given season.

13. PROCEDURE NOTES

- **FDA Status:** Approved/cleared
- **Validated Test Modifications:** None

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

The total, with-in run, and between-run performance of the QuickVue Influenza Test was evaluated for precision. A panel consisting of two different levels of Influenza A antigen and two different levels of influenza B antigen were repeated five times with a single lot of QuickVue Influenza Test on three different days. One hundred per cent (100%) accuracy was obtained for all specimens tested.

14.3 Interfering Substances

Whole blood, and several over-the-counter (OTC) products and common chemicals were evaluated and did not interfere with the QuickVue Influenza Test at the levels tested.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Nasal swab: sensitivity 73%; specificity 96%
Nasal was or aspirate: sensitivity 81%; specificity 99%

15. SAFETY

You, the employee, have direct responsibility to avoid injury and illness at work. Nearly all-harmful exposures to infectious substances and chemicals, and other injuries, can be avoided with effective training and consistent safe work practices.

Become familiar with the Safety Manual to learn requirements on working safely and protecting the environment from harm. Although lab work typically focuses on the hazards of working with specimens and chemicals, we must also control other important hazards.

- Slips, trips, and falls cause many serious injuries. Please ensure that spills are cleaned quickly (to avoid slippery floors) and that you can see and avoid obstacles in your path.
- Ergonomic injuries result from performing tasks with too much repetition, force, or awkward position. Ergonomic injuries include strains and back injuries. Learn about ergonomic hazards and how to prevent this type of injury.
- Scratches, lacerations, and needle sticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.
- Warnings of other specific hazards are noted in this procedure. Please comply with the requirements to reduce your risk of injury."

Report all accidents and injuries to your supervisor or the Safety Officer.

16. RELATED DOCUMENTS

Critical Value, Laboratory policy
Current product kit insert

17. REFERENCES

Quite, 10165 McKellar Ct. SanDiego, CA 92121. “QuickVue Influenza Test” Package Insert 10/02.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SOP M004.003		
000	9/28/2009	10.4	Add comment for negative result	R. Master	R. Master
001	10/13/2010	6.1,6.2	Internal QC frequency	R. Master	R. Master
		11.2	Title change to local terminology	L. Barrett	R. Master
		16	Moved Current PI to related docs	R. Master	R. Master

Form revised 3/31/00

002	11/9/2012	4.2	Change name of Extraction Tube to Reagent Tube and Extraction Solution to Reagent Solution Added temperature range (15-30ºC)	R. Master	R. Master
		10.4	Added invalid results	R. Master	R. Master

19. ADDENDA

Influenza QC Log (see Attachment Tab of Infocard)