TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/11/2018
Department:	Core Lab	**Due Date:**	8/7/2018
		Implementation:	**8/7/2018**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Influenza A and B Antigen Detection, Immunoassay, X/pect® Flu A & B SGAH.QDMI800 v1.6

Xpect® Flu A&B QC Log AG.F399.2

Description of change(s):

IQCP completed to allow reduction in QC frequency

Section	Reason
6.3	Changed QC frequency

QC Log revised to match SOP

This revised SOP and FORM will be implemented on August 7, 2018

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

Technical SOP

Title	**Influenza A and B Antigen Detection, Immunoassay, X/pect® Flu A & B**
Prepared by	P.L. Cerwinka MSc. RM (AAM, ASCP) Date: 4/29/2009

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

Review		
Print Name and Title	**Signature**	**Date**

Corporate Approval		
Owner/BPT Chair	Dale Schwab Ph.D., D.(ABMM)	Date: 4/29/2009
BPT Medical Advisor	Herman Hurwitz, MD	
Signature	*On file*	Date: 2/26/2010
Chief Laboratory Officer/Designee	William M Miller, MD	
Signature		Date: 3/2/2010
Corporate Issue Date	4/5/2010	

Form revised 2/2/07

Quest Diagnostics Incorporated
Site: Shady Grove Medical Center, Washington Adventist Hospital, Germantown Emergency Center
Title: **Influenza A and B Antigen Detection, IA**

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	**Method/Instrument**	**Local Code**
Influenza A and B Antigen Immunoassay	Manual Membrane Immunochromatography	INFAB

Synonyms/Abbreviations
Rapid Flu A and B Antigen Test; Influenza A and B Direct Antigen Detection; Influenza A and B; Influenza A & B

Department
Microbiology

Form revised 2/2/07

2. ANALYTICAL PRINCIPLE

Xpect® Flu A&B is a rapid *in vitro* immunochromatographic test for the direct, qualitative detection of influenza A and influenza B viral antigen (nucleoprotein) from nasal wash, nasal swab, and throat swab specimens from symptomatic patients. The test is intended as an aid in the rapid diagnosis of influenza A and influenza B viral infections.

The Xpect® Flu A&B test device incorporates separate membrane strips for influenza A and for influenza B. To perform the test, the patient specimen is diluted and added to the sample wells of the device. The mixture moves along the membranes by capillary action. If present, influenza A or B viral antigens in the patient sample bind anti-influenza A or B conjugated antibodies. A visible line forms as a complex of antibody-antigen-antibody coated colored particles is captured in the test region (T). Antibody coated colored particles not bound at the test line are later captured in the control region (C) containing goat anti-mouse antibody. A visible line will always appear in the control region indicating that the test is working properly. The presence of a control line combined with the absence of a visible test line is interpreted as a negative test result.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	None
Specimen Collection and/or Timing	It is recommended that specimens be obtained early in the course of the illness and be tested as soon as possible.
Special Collection Procedures	Nasopharyngeal (NP) swab: Immobilize the patient's head and insert swab through a nostril. Push forward using gentle downward pressure to keep the swab on the floor of the nasal cavity until the tip reaches the posterior wall of the nasopharynx. Rotate gently for a few seconds and remove. Submit swab in V-C-M transport medium. For collection of Nasopharyngeal or Nasal Washings refer to the Quest Diagnostics Directory of Service.
Other	None

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Nasopharyngeal (NP) swabs and washes, nasopharyngeal aspirates, lower nasal (turbinate) swabs and washes.
-Other Acceptable	Throat swabs
Collection Container	For NP swabs, Flocked Nylon, Dacron polyester or rayon-tipped swabs with flexible shaft are recommended and placed into Viral, Chlamydia and Mycoplasma (V-C-M) medium vials or equivalent, such as M4, EMEM or PBS with gelatin or albumin. See package insert for complete list of validated transport media. Washes and aspirates should be added to an equal amount of V-C-M medium.
Volume - Optimum	One swab or 2-3mL of washings/aspirate
- Minimum	One swab or 1mL of washings/aspirate
Transport Container & Temperature	V-C-M medium or equivalent transported on cold packs. Note: As a point of care test, no transport media is required.
Stability & Storage Requirements	Room Temperature: Not acceptable
	Refrigerated: 3 days
	Frozen: Six months at –20ºC or below in a non-defrosting freezer. Avoid multiple freeze-thaw cycles.
Timing Considerations	Specimens obtained early in the course of illness will contain the highest virus titers.
Unacceptable Specimens & Actions to Take	Calcium alginate swabs must not be used. Swabs with cotton tips and wooden shafts are not recommended. (Only flocked nylon or polyester-tipped swabs with aluminum or plastic shafts are to be used with this test). Specimens at room temperature, unless tested at point of care as a fresh specimen. Reject the above unacceptable specimens.
Compromising Physical Characteristics	None
Other Considerations	Excessive dilution of wash or aspirates into transport medium may result in decreased test sensitivity.

The following transport media have been evaluated and found to be compatible with Xpect® FLU A&B test:

Amies Medium
Bartels Viral Transport Medium
BD™ Universal Viral Transport System
Cary Blair Medium
Copan Universal Transport Medium
Earle's Minimum Essential Medium (EMEM)
EMEM with 1% Bovine Serum Albumin
EMEM with 1% Lactalbumin Hydrolysate

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Hank's Balanced Salt Solution
Liquid Stuarts Medium
M4®
M4RT®
M5®
M6™
Phosphate Buffered Saline (PBS)
PBS with 0.5% Bovine Serum Albumin
PBS with 0.5% Gelatin
Saline (normal)
Sucrose Phosphate
Tryptic Soy Broth w/ 0.5% Bovine Serum Albumin
Tryptic Soy Broth w/ 0.5% Gelatin
Veal Infusion Broth
Veal Infusion Broth w/ 0.5% Bovine Serum Albumin

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits or reagents must be reviewed for any changes before the kit is used.

4.1 Reagent Summary

Reagents / Kits	Supplier, Catalog Number and Stock Clerk Number
Xpect Flu A/B kit, 20 tests/ea)	Remel, Catalog # R42600 Stock Clerk # 151641
Lab Validation panel	Remel, Catalog# R246005, Stock Clerk # 151644

Individual Reagents	Supplier, Catalog & Stock Clerk Number	Quantity
Quality Control Swab Package	Remel, R246003, SC # 151645	20 swabs; 10 flu A and 10 flu B

4.2 Reagent Preparation and Storage

The Xpect Flu A/B kit must be stored at room temperature (15-25°C) or refrigerated (2-8°C) until the expiration date printed on the box. Do not freeze or overheat. If stored refrigerated, allow components to come to room temperature before use.

5. CALIBRATORS/STANDARDS

Quest Diagnostics Incorporated
Site: Shady Grove Medical Center, Washington Adventist Hospital, Germantown Emergency Center
Title: **Influenza A and B Antigen Detection, IA**

5.1 Calibrators/Standards Used

Not Applicable

6. QUALITY CONTROL

6.1 Controls Used

- **Internal Controls:** A procedural control is included in the test membrane.
  - A colored band appearing on the control band (C) region is considered an **internal positive** procedural control, indicating proper performance and reactive reagents.
  - A clear background in the results area is considered an **internal negative control**. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.
- **External Controls:** Quality Control (QC) swabs that are Flu A+/B- and Flu A-/B+ are provided with the kit. Additional QC swabs are provided in the Quality Control Swab Package (see section 4.1).
  NOTE: Alternatively, previously tested positive samples may be used as an external positive control. These samples must be stored at -70°C and are stable for 30 days.
  - **Flu A (+)/B (-) control swab**: A dry swab containing inactivated influenza A antigen
  - **Flu B (+)/A (-) control swab**: A dry swab containing inactivated influenza B antigen

6.2 Control Preparation and Storage

- Process QC swabs in accordance with Procedure Step 8.2 (as for fresh swab specimens without transport media.
- Refer to the control insert sheet provided in the Quality Control Swab Package for preparation, storage and handling instructions.

6.3 Frequency

- External Controls (Flu A+/B- and Flu A-/B+) must be tested with each new kit lot or shipment for proper reactivity or every 31 days, whichever is more frequent.

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6.4 Tolerance Limits and Criteria for Acceptable QC

Control	Expected Results
Internal Negative Control	A clear background in the results area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will clear to give a discernible result.
Internal Positive Control	A colored band appearing on the control band (C) region is considered an internal positive procedural control, indicating proper performance and reactive reagents
External Flu A or B Positive Control	A positive test is indicated by two blue-colored bands; one in the test (T) region and one in the control (C) region. A complete, blue, clearly visible test line of any intensity should be interpreted as positive.

- Refer to Section 10.1 for an illustration of regions T and C on the test device.
- If internal or external controls do not perform as expected, do not report patient results.
- The QC failure must be brought to the attention of the supervisor (or designee) for a second review and further action.
- All steps taken in response to QC failures must be documented, including: the unacceptable condition, the root cause of the problem, actions taken to correct the problem, how patient samples were handled, and the date and initials of the person recording the information.
- Refer to the Quality Control Program SOP for more details.

6.5 Review Patient Data

Review patient results for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal results, or unusually high percentage of negative or positive results. Computer aided tools should be used when available.

6.6 Documentation

- Documentation of all controls is required.
- Refer to local policies and procedures for QC documentation and to Quest Diagnostics records management program for record retention requirements.

6.7 Quality Assurance Program

Refer to National and local policies and procedures for other quality assurance activities applicable to this procedure.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Solid phase, lateral flow, Immunochromatographic test device

7.2 Equipment

Vortex

7.3 Supplies

Timer

8. PROCEDURE

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

8.1	Specimen Preparation for N/P and Nasal Washes and Swabs Transported in > 0.3 ml of Liquid Media:
1.	**All testing must be done under a Class II biological safety cabinet**. Dispense 5 drops (approximately 0.1 ml) of Specimen Diluent into the dilution tube provided. **NOTE**: For mucoid specimens, double dilution may be required. See section 10.1 "Invalid Test Results".
2.	Mix specimen well (vortex suggested) and use the transfer pipette provided in the kit to transfer 0.1 ml (first molded graduated mark from the tip) of liquid specimen (nasal wash or specimens in transport medium) into the dilution tube provided.

8.2	Specimen Preparation for Quality Control Swabs Provided with the kit and with fresh Point of Care Specimens (undiluted in transport media)
1.	**All testing must be done under a Class II biological safety cabinet**. Dispense 25 drops (approximately 0.6 ml) of Specimen Diluent into a dilution tube. **NOTE**: For mucoid specimens, double dilution may be required. See section 10.1 "Invalid Test Results".
2.	Place the swab specimen in the tube.
3.	Mix thoroughly or vortex to release bound antigenic material from the swab.
4.	Rotate the swab firmly against the tube walls then squeeze the sides of the tube while removing the swab.

8.3	Test Procedure
1.	Use a transfer pipette to dispense 0.1 ml (first molded graduated mark from tip of pipette) of specimen into the Flu A sample well and 0.1 ml into the Flu B sample well of the appropriately labeled Xpect test device.
2.	Read and record the test results visually after 15 minutes according to section 10: REPORTING RESULTS section. (Strong positive results may be apparent sooner than 15 minutes.)

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

Not Applicable

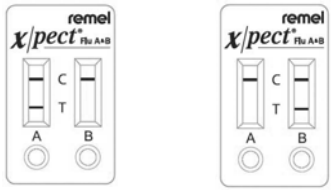
10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

The test device has two separate read windows; the one on the left is for Flu A, and the one on the right is for Flu B as depicted.

Positive Test (antigen present):
A positive test is indicated by two blue-colored bands; one in the (T) region and one in the (C) region. A complete, blue, clearly visible test line of any intensity should be interpreted as positive.

Flu A Positive **Flu B Positive**



Negative Test (antigen not present):
A negative test is indicated by only one blue-colored band in the control (C) region.

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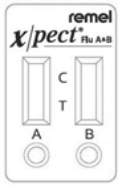
Uninterpretable Test Results:
Uninterpretable test results occur when the test band is partial or incomplete, or the control band is absent or incomplete. Uninterpretable results due to excessively mucoid specimens may be repeated using twice the normal volume of Specimen Diluent during the dilution step. Refer to Sections 8.1 and 8.2

(Uninterpretable)



10.2 Rounding

Not applicable

10.3 Units of Measure

Not applicable

10.4 Clinically Reportable Range (CRR)

Not applicable, Qualitative test

10.5 Resulting and Repeat Criteria

- Invalid results due to excessively mucoid specimens should be repeated. Refer to Sections 8.1 and 8.2. If results are uninterpretable after dilution, another specimen should be requested.

If The Result is	Message	LIS Code or Mnemonic
Positive for A	Detected	DET
Positive for B	Detected	DET
Negative for A and/ or B	Not Detected	NTD
Uninterpretable after repeat testing	Uninterpretable, may be due to interference, please repeat sample	UNINP

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Use LIS function **MEM** to enter results.

Enter Shift: (1, 2, or 3)
Worksheet: Use WIM2 for WAH, SIM2 for SGMC, or GIM2 for GEC
Test: <Enter>
Enter "A" (Accept)
Enter Accession number
Press <Enter> until Result screen is displayed

Enter Results using above codes

11. EXPECTED VALUES

11.1 Reference Ranges

Not Detected

11.2 Critical Values

None established

11.3 Standard Required Messages

The following comment is automatically added to the report by the LIS when the result is not detected:

The sensitivity of this Direct Antigen Immunoassay is < or equal to 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

12. CLINICAL SIGNIFICANCE

Influenza is an acute viral disease that is seasonal in incidence, usually occurring in the colder months. The illness classically presents with sudden onset of fever, chills, headache, myalgia, and a non-productive cough. Influenza A or B virus cause the majority of clinically significant disease, with influenza C virus being responsible only for mild, predominately upper respiratory tract illness. Epidemic and pandemic influenza represent special challenges to public health and our laboratories may be asked to change procedures for reporting and handling of isolates and specimens for further characterization. Consult with you state health department or check the CDC website http://www.cdc.gov/flu/Pandemic/ for more information.

Patients who present with suspected influenza may benefit from treatment with antiviral agents. Amantadine[i] and rimantadine[i] are available for both the prevention and

treatment of influenza A disease only. Zanamivir[i] and Oseltamivir[i] are available for the treatment of both influenza A and B disease. In adults, therapy with these agents may reduce the severity and duration of illness if given within the first 48 hours of onset of illness. Since the therapeutic options have expanded to include options for the treatment of influenza B disease, it is important to rapidly distinguish influenza A from influenza B in order to allow physicians a choice in selective antiviral intervention. Moreover, since only amantadine and rimantadine have indications for influenza prophylaxis, it is important to determine if influenza A is causing symptomatic disease in a particular institution (e.g., nursing home) or community, so that appropriate preventative intervention can be taken for susceptible individuals. It is therefore important to not only rapidly determine whether influenza is present, but also which type of influenza virus is present.

Procedures used to diagnose influenza type A and B infections include rapid immunoassay, direct specimen immunofluorescence assay, reverse transcription-polymerase chain reaction (RT-PCR), serologic assay, and culture isolation with confirmation.

13. PROCEDURE NOTES

- **FDA Status:** FDA Cleared
  Validated Test Modifications: None
- The performance characteristics of the Xpect® Flu A&B test have not been established for use in monitoring antiviral treatment or for cell culture confirmation/identification methods.
- A positive test does not rule out the possibility of co-infection with another pathogen. The performance characteristics of the Xpect® Flu A&B test have not been established for use in monitoring antiviral treatment or for cell culture confirmation/identification methods.
- Additional testing is required to differentiate any specific influenza A subtypes or strains.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

Qualitative test, reported as Detected or Not Detected

14.2 Precision

Not Applicable

14.3 Interfering Substances

None known

14.4 Clinical Sensitivity/Specificity/Predictive Values

Both viable and nonviable influenza A and B viruses are detectable with the Xpect® Flu A&B test.

Due to low levels of virus shedding, inadequate specimen collection, or improper handling or transport, a negative test result does not rule out the presence of influenza virus. Consequently, the results from the Xpect® Flu A&B test should be used in conjunction with other clinical findings to establish a diagnosis.

Refer to Package Insert for specific information regarding Sensitivity and Specificity of assay and detection limits observed with various strains of Influenza virus, including A (H1N1).

15. SAFETY

This testing must be performed under a class II biological safety cabinet.

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

- Training and Competency documents for Influenza A and B Detection by X/pect® Flu A & B
- Quest Diagnostics Incorporated Specimen Collection section in the *Directory Of Services.*
- Quest Diagnostics Incorporated Priority Results Procedure QDMED704
- Quest Diagnostics Incorporated Records Management Program for Record Retention Requirements.
- Biosafety, local Microbiology SOP
- Current package insert for Remel X/pect Flu A and B
- Xpect® Flu A&B QC Log (AG.F399)

17. REFERENCES

- Lieberman, D, Lieberman, d., Shimoni, A., Keren-Naus, A., Steinberg, R., and Shemer-Avni, 2009. Identification of Viruses in Adults: Nasopharyngeal versus Oropharyngeal Sampling. J. of Clini, Microbiology, vol 47. No11, pp. 3439-3443.
- Remel X/pect Flu A and B Package Insert (IFU 24600, Revised July 9, 2013) Lenexa KS, 66215
- Walsh, Paul, et al. 2000. Physician's Desk Reference, Medical Economics Company, New Jersey.
- Kaiser, L., Couch, R.B., Galasso, G.J., Glezen, W.P., Webster, R.G., Wright, P.F., and Hayden, F.G. 1999. First international symposium on influenza and other respiratory viruses: summary and overview Kapalua, Maui, Hawaii, December 4-6, 1998. Antiviral Res., *42*:149-176.
- Cox, N.J., and Bender, C.A. 1995. The molecular epidemiology of influenza viruses. Virology, *6*:359-370.

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- McElhaney, J.E., Gravenstein, S., Krause, P., Hooton, J.W., Upshaw, C.M., and Drinka, P. 1998. Assessment of markers of the cell-mediated immune response after influenza virus infection in frail older adults. Clin. Diag. Lab. Immunol. *5*:840-844.
- Fan, J., Henrickson, K.J., and Savatski, L.L. 1998. Rapid simultaneous diagnosis of infections with respiratory syncytial viruses A and B, influenza viruses A and B, and human parainfluenza virus types 1, 2, and 3 by multiplex quantitative reverse transcription-polymerase chain reaction-hybridization assay (hexaplex). Clin. Infect. Diseases *26*:1397-1402.
- Wright, K.E., Wilson, G.A.R., Novosad, D., Dimock, C., Tan, D., and Weber, J.M. 1995. Typing and subtyping of influenza viruses in clinical samples by PCR. J. Clin. Microbiol. *33*:1180-1184.
- Kendal, A.P. 1985. Influenza Viruses. p.341-357. Laboratory Diagnosis of Viral Infections, *In* H. Lennette, (ed.) Marcel Dekker, Inc., New York.
- McQuillen, J., Madeley, C.R., and Kendal, A.P. 1985. Monoclonal antibodies for the rapid diagnosis of influenza A and B virus infections by immunofluorescence. Lancet. *ii*:911-914.
- Guenthner, S. H., and Linnemann, C.C., Jr. 1988. Indirect immunofluorescence assay for rapid diagnosis of influenza virus. Laboratory Medicine. *19*:581-583.
- Schmidt, N.J., Ota, M., Gallo, D., and Fox, V.L. 1982. Monoclonal antibodies for rapid, strain specific identification of influenza virus isolates. J. Clin. Microbiol. *16*:763-765.
- Shu, L.L., Bean, W.J., and Webster, R.G. 1993. Analysis of the evolution and variation of the human influenza A virus nucleoprotein gene from 1933 to 1990. J. Virol. *67*:2723-2729.
- Covalciuc K., Webb K., and Carlson C. 1999. Comparison of Four Clinical Specimen Types for detection of Influenza A and B Virus by Optical Immunoassay (FLU OIA TEST) and Cell Culture Methods. J.Clin. Microbiol. *37*: 3971-3974.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
1.1	8/20/09	10.5	Revised FLAB message test to indicate negative results do not exclude infection and sensitivity changed to less than.	P. Cerwinka	H. Hurwitz
1.2	9/28/09	7.1, 7.2	Clarified method as Immunochromatographic and added vortex equipment	P. Cerwinka	H. Hurwitz
1.2	11/10/09	3.1	Edited Collection procedures to standard	P. Cerwinka	H. Hurwitz
1.2	9/28/09	3.2	Added validated transport media	J. Cromien	P. Cerwinka
1.2	9/28/09	6.1	Added note to external controls to allow use of previously tested positive patient samples	J. Cromien	P. Cerwinka
1.2	10/30/09	6.3	Changed requirement for QC once each shift to once each day.	L. Wolff	P. Cerwinka

Version	Date	Section	Reason	Reviser	Approval
1.2	9/28/09	13.0	Added comment per package insert regarding ability to differentiate strains.	J. Cromien	P. Cerwinka
1.2	9/28/09	14.4	Statement added regarding sens/ specificity for detection of A (H1N1)	J. Cromien	P. Cerwinka
1.2	9/28/09	17.0	Updated reference for Package Insert and preferred specimen type	J. Cromien	P. Cerwinka
1.3	1/6/10	1.0	Corrected assay name from EIA to immunoassay	J. Cromien	P. Cerwinka
1.3	1/6/10	10.5	Corrected verbiage for FLAB comment	J. Cromien	P. Cerwinka
1.3	1/17/18	Cover	Deleted 12 month review	L Barrett	R Master
	1/17/18	1	Deleted QD order code	L Barrett	
	1/17/18	3.4	Deleted QLS TNP message	R Master	
	1/17/18	4, 6	Updated reagent labeling statement to current general BPT format	L Barrett	
	1/17/18	6.3	Deleted corporate SOP & QC rotation	L Barrett	
	1/17/18	6.4	Added local QC SOP	L Barrett	
	1/17/18	8.4.2	Added step from manufacturer's instructions	R Master	
	1/17/18	10.5	Added comment to request another specimen if repeat uninterpretable. Change LIS result codes to local codes. Added LIS resulting	R Master L Barrett	
	1/17/18	11.2	Changed to local terminology, deleted instruction to call	L Barrett	
	1/17/18	11.3	Moved comment from 10.5	L Barrett	
	1/17/18	15	Updated to current BPT statement	L Barrett	
	1/17/18	16	Deleted corporate SOPs and inserted local versions, added PI and log	L Barrett	
	1/17/18	17	Update package insert date	R Master	
	1/17/18	19	Moved package insert to section 16	L Barrett	
	1/17/18	Footer	Updated to current BPT format	L Barrett	
1.4	2/7/18	10.5	Corrected code for 'not detected'	L Barrett	R Master
1.5	6/27/2018	6.3	Changed QC frequency	R. Master	R. Master

19. ADDENDA

None

Quest Diagnostics™

Xpect® FLU A&B QUALITY CONTROL LOG

☐ Germantown Emergency Center
☐ Shady Grove Medical Center
☐ Washington Adventist Hospital

1. **External Controls** (Flu A+/B- and Flu A-/B+ swabs) are tested and documented with each new kit lot number or shipment or every 31 days, whichever is more frequent.
2. **Internal controls** must be documented each time the test is performed (Y or Yes indicates acceptable performance, N or No indicates unacceptable).
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.
4. Record patient and external QC results as **NTD** (not detected) or **DET** (detected). Use code UNINP for uninterpretable results; refer to SOP for repeat instructions.

Date	**Patient Name / MR#**	**Patient Result** DET / NTD		**Kit**	**Internal Neg QC**		**Internal Pos QC**		**External Control / Type A Pos**			**External Control / Type B Pos**			**Tech**
		A	**B**	**Lot # / Expire**	Clear (**Y** or **N**) **A**	**B**	Blue line (**Y** or **N**) **A**	**B**	**Lot # / Expire**	**Result** DET / NTD **A**	**B**	**Lot # / Expire**	**Result** DET / NTD **B**	**A**	
Weekly review:				Weekly review:						Weekly review:					
Weekly review:				Weekly review:						Monthly review:					