TRAINING UPDATE

Lab Location:	GEC, SGAH & WAH	**Date Distributed:**	5/22/2014
Department:	Core Lab / Micro	**Due Date:**	6/30/2014
		Implementation:	**7/1/2014**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

RSV Testing by Binax NOW GEC/SGAH/WAH.M01 v2
RSV Quality Control Log AG.F33.2

Influenza Antigen Detection GEC.M02,SGAH/WAH.M10 v4
Influenza Quality Control Log AG.F32.4

Streptococcus Group A Antigen with Reflex to Culture QDHOS706v1.2
STREP Group A Quality Control Log AG.F35.4

C Diff Quik Chek Complete SGAH.M34 / WAH.M32 v1
C Diff Quik Chek Complete Quality Control Log AG.F69.2

Rotavirus Antigen Detection SGAH.M32 v3
Rotavirus Quality Control Log AG.F34.2

Description of change(s):

All of the above SOPs:

Section 6	Change external QC frequency to require testing **every 30 days,** standardized wording for required testing with receipt of new lots or shipments
Section 10	Add detail for LIS reporting

For RSV, Flu and Strep Group A:
Removed requirement to call any results

All of the QC forms:

- standardized wording for external QC frequency and added requirement to run every 30 days
- added instruction for QC failures

These revised SOPs and logs will be implemented on July 1, 2014

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

Technical SOP **Approved draft for training**

Title	**RSV Testing by Binax NOW®**
Prepared by	Wendell R. McMillan II Date: 11/17/2008
Owner	Ron Master Date: 11/17/2008

Laboratory Approval	**Local 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**

Form revised 2/2/07

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Binax NOW® RSV test	Lateral-flow immunoassay	RSV

Synonyms/Abbreviations
Respiratory Syncytial Virus

Department
Microbiology

Form revised 2/2/07

2. ANALYTICAL PRINCIPLE

The Binax NOW® RSV Test is an immunochromatographic membrane assay used to detect RSV fusion protein antigen in nasal wash and nasopharyngeal swab specimens from symptomatic patients. This test is intended for *in vitro* diagnostic use to aid in the diagnosis of respiratory syncytial virus infections in neonatal and pediatric patients under the age of five. This assay was validated in our facility and found to be effective for use with patients over the age of 5 years. Anti-RSV antibody, the Sample Line, is adsorbed onto nitrocellulose membrane. Control antibody is adsorbed onto the same membrane as a second stripe. Both anti-RSV and control antibodies are conjugated to visualizing particles that are dried onto an inert fibrous support. The resulting conjugate pad and the striped membrane are combined to construct pad and the striped membrane are combined to construct the test strip. The test strip is mounted on the right side of a cardboard, book shaped hinged test device.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Nasal Wash or Aspirate Collection Procedures	With the patient's head hyper-extended, instill about 2.5 mL 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.
Other	N/A

3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Fresh nasopharyngeal swab or nasal wash specimen. None
Collection Container	Sterile swab or sterile container for washes
Volume - Optimum **- Minimum**	3.0 mL 0.5 mL N/A for swabs
Transport Container & Temperature	• Swabs should be eluted within one hour of collection. Eluted liquid swab samples can be stored at room temperature for up to 4 hours or at 2-8ºC for up to 48 hours, before testing. Allow samples to warm to room temperature and swirl gently before testing. • Use a sterile container for nasal wash specimens.

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Criteria		
	• The following transport media were tested and found to be acceptable for use in the Binax NOW® test: Amies Media, Binax Elution Solution, Hank's Balanced Salt Solution, M4 Media, M4-RT Media, M5 Media, Saline, and Stuart's Media.	
Stability & Storage Requirements	Room Temperature:	Swab: Deliver within 1 hour of collection; eluted swab samples can be stored at room temperature for up to 4 hours Nasal Wash: 4 hours
	Refrigerated:	Swab: eluted swab samples can be stored at 2-8ºC up to 48 hours Nasal Wash: 2-8ºC up to 24 hours
	Frozen:	Unacceptable
Timing Considerations	Samples should be tested as soon as possible after collection.	
Unacceptable Specimens & Actions to Take	Excessively bloody and or mucoid specimens should not be tested with the Binax NOW® test. If the sample is too mucoid to pipette, add a **FEW DROPS** of saline to break up the mucus. If it is still too mucoid to pipette, request a new sample.	
Compromising Physical Characteristics	N/A	
Other Considerations	Do not centrifuge specimens prior to use with the Binax NOW® test	

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
Binax NOW® RSV	Binax, Inc. #430-000
Optional: Nasopharyngeal (NP) Swab Specimen Accessory Pack	Binax, Inc. #400-065

4.2 Reagent Preparation 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.

Assay Kit	
Test Devices:	A membrane coated with mouse antibody specific for RSV antigen and with control line antibody is combined with mouse anti-RSV and control line antibody conjugates in a hinged test device. The membrane of an untested device contains a blue line at the control line area.
Transfer Pipettes:	Fixed volume (100 µL) transfer pipettes used to transfer sample to the test devices. Use only pipettes provided by Binax or a calibrated pipette capable of delivering 100 µL sample volume.
Positive Control Swab:	Inactivated RSV dried onto swab.
Negative Control Swab:	Inactivated *Streptococcus* Group A dried onto swab.
Elution Solution Vials for Control Swabs:	Vials contain a fixed volume (0.5 mL) of elution solution used to prepare control swabs for testing. Do not use other elution solutions with the NOW® test.
Storage/Stability	Store at room temperature (15º-30ºC).
Preparation	Refer to 6.2 for positive and negative control preparation.

Optional Item -Nasopharyngeal (NP) Swab Specimen Accessory Pack	
Nasopharyngeal Swabs:	Sterile foam swabs for use in the Binax NOW® RSV test.
Elution Solution Vials for Swab Specimens:	Vials containing a fixed volume of elution solution (0.5 mL) used to prepare swab specimens for testing.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

The NOW® RSV test has built-in procedural controls that are recorded for each test run.

6.1.2 Procedural Controls

A. An untested device has a blue line at the “Control” position. If the test flows and the reagents work, this blue line will always turn pink in a tested device.

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B. The clearing of background color from the result window is a negative background control. The background color in the window should be light pink to white within 15 minutes. Background color should not hinder reading of the test.

6.1.3 External Positive and Negative Controls

NOW® test kits contain Positive and Negative Control Swabs. These swabs will monitor for substantial reagent failure. The Positive Control will not ensure precision at the assay cut-off. External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	External Positive and Negative Controls
Preparation	1. The test kit contains test vials pre-filled with elution solution. Twist off the test vial cap. 2. Put control swab to be tested into test vial. Rotate the swab three (3) times in the liquid. 3. Press the swab against the side of the vial and turn as you remove it from the vial. This removed sample from the swab. 4. Discard the swab.
Storage/Stability	Test the liquid sample (from the test vial) in the NOW® test as soon as possible. Refer to section 8.

6.3 Frequency

6.3.1 Internal QC provided with each test.
6.3.2 External QC is run with each new kit lot number or shipment or every 30 days, whichever is more frequent.

6.4 Tolerance Limits

- Negative control swab should yield a negative result (pink control line, no line in sample area.
- Positive control swab should yield a positive result (pink control line and pink line in the sample area).
- Do not use kit if the external controls do not yield expected results and do not use the test devices if the internal control does not yield a pink line.
- Re-analyze in accordance with Laboratory Quality Control Program.
- Corrective action must follow the Laboratory Quality Control Program.

6.5 Review Patient Data

N/A

6.6 Documentation

Record Quality Control and patient data on the RSV Quality Control log sheet.

6.7 Quality Assurance Program

The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

N/A

7.3 Supplies

Binax NOW® RSV kit
Timer
(Optional) Calibrated pipette capable of delivering 100 µL sample volume.

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.

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	Specimen/Test Run
1.	Remove device from the pouch just prior to testing and lay flat on work bench.
2.	Fill pipette by firmly squeezing the top bulb and placing pipette tip into sample. Release bulb while tip is still in sample. This will pull liquid into the pipette. Make sure there are no air spaces in the lower part of the pipette.
3.	See arrow on test device to find White Sample Pad. **SLOWLY** add entire contents (100 µl) of pipette to the **MIDDLE** of this pad by squeezing the top bulb.

8.1	Specimen/Test Run
4.	Immediately peel off adhesive liner from the test device. Close and securely seal the device. Read result in window 15 minutes after closing the device. Results read before or after 15 minutes may be inaccurate. Note: When reading test results, tilt the device to reduce glare on the result window if necessary.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

10.1.1 For a **NEGATIVE SAMPLE**, the BLUE Control Line in the lower half of the window turns a PINK-TO-PURPLE color. No other line appears.

10.1.2 For a **POSITIVE SAMPLE**, the BLUE Control Line turns a PINK-TO-PURPLE color. A second PINK-TO-PURPLE Sample Line appears above it.

10.1.3 A test is **INVALID** if the Control Line remains BLUE or is not present at all. Repeat Invalid tests with a new test device.

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria

N/A

10.6 Resulting

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

Enter Shift: (1, 2, or 3)

Worksheet: Use WIM2 for WAH, SIM2 for SGAH, or GIM2 for GEC

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Test: <Enter>

Enter "A" (Accept)

Enter Accession number

Press <Enter> until Result screen is displayed

Enter Results as listed below:

IF the result is …	THEN report with LIS code
Positive	POS
Negative	NEG

There is no need to call results as they are transmitted electronically.

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

Respiratory Syncytial Virus (RSV) causes upper and lower respiratory tract infections, and is generally recognized as the most frequent agent for lower respiratory tract infections including bronchiolitis, and a major cause of infant mortality. Approximately 90% of children have had one, and 50% of children have had two RSV infections by the age of two. RSV was the leading cause of infant hospitalization from 1997 to 2000 with charges totaling more than 2.6 billion dollars for those three years. The high risk groups include infants born prematurely, children with chronic lung or congenital heart disease, and those with compromised immune systems.

13. PROCEDURE NOTES

- **FDA Status:** Approved/Modified
- **Validated Test Modifications:** Validated to enable reporting on patients greater than 5 years of age.

1. For *in vitro* Diagnostic Use.
2. Leave test device sealed in its foil pouch until just before use.
3. Do not use kit past its expiration date.
4. Do not mix components from different kit lots.
5. The white sample pad at the top of the test strip contains reagents that extract the target antigen from the virus. To ensure optimum performance, add the sample **SLOWLY** to the **MIDDLE** of this pad such that all of the sample volume absorbs into the pad.
6. The RSV Positive Control Swab has been prepared from RSV-infected tissue culture cells that have been inactivated and subsequently tested by bioassay procedures. Use universal precautions when performing the assay. Samples may be infectious. Proper handling and disposal methods should be established according to local, state, and federal regulations.
7. **INVALID RESULTS** can occur when an insufficient volume of specimen is added to the test device. To ensure delivery of an adequate volume, make certain that the lower shaft of the transfer pipette is full and does not contain air spaces before dispensing contents of the pipette onto the Sample Pad of the device. If air spaces are present, expel the specimen back into the container by squeezing the top bulb and redraw the specimen into the pipette. Use a new pipette if necessary.

14. LIMITATIONS OF METHOD

Inadequate specimen collection or low levels of virus shedding may result in suboptimal performance and my yield false negative results.

A negative test result does not exclude infection with RSV nor is it intended to rule out other microbial-cause respiratory infections.

Results obtained with this assay, particularly in the case of weak test lines that are difficult to interpret, should be used in conjunction with other clinical information available to the physician.

Monoclonal antibodies may not detect all antigenic variants or new strains of RSV.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

Binax test performance has not been evaluated in patients who have been treated with palivisumab. However, an analytical study has demonstrated that palivisumab interferes with the ability of the Binax NOW® Test to detect RSV.

The potential for interference from antimicrobials and interferon has not been established.

See product insert for list of substances tested and found not to affect test performance.

14.4 Clinical Sensitivity/Specificity/Predictive Values

Nasopharyngeal swab: Sensitivity 93%, specificity 93%
Nasal wash: Sensitivity 89%, specificity 100%

The Binax NOW® RSV Test detects both viable and non-viable RSV. Test performance depends on antigen load in the specimen and may not correlate with cell culture performed on the same specimen.

15. SAFETY

The employee has 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 Environmental Health and Safety (EHS) Manual. Learn the 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.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Current package insert Binax NOW® RSV Test Procedure
RSV Quality Control Log (AG.F33)

17. REFERENCES

Binax NOW® RSV Test Procedure. Binax, Inc., d.b.a Inverness Medical Professional Diagnostics. Revision 1 4/21/08.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	4/15/11	3.2	Clarified Stability	R. Master	R. Master
000	4/15/11	10.6	Deleted statement concerning epidemiology report	R. Master	R. Master
000	4/15/11	11.2	Update title to local terminology	L. Barrett	R. Master
000	4/15/11	14.2	Precision N/A	R. Master	R. Master
000	4/15/11	14.3	Interfering substances, refer to product insert	R. Master	R. Master
000	4/15/11	14.4	Added sensitivity and specificity	R. Master	R. Master
000	4/15/11	16	Add current package insert	L. Barrett	R. Master
000	4/15/11	19	Remove package insert	L. Barrett	R. Master
001	4/22/14	6.1.3, 6.3	Changed external QC frequency	R. Master	R. Master
001	4/22/14	10.6	Removed requirement to call positive results, added detail for LIS reporting	R. Master	R. Master
001	4/22/14	16	Log moved from section 19	L. Barrett	R. Master
001	4/22/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics

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

RSV QUALITY CONTROL LOG

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 30 days, whichever is more frequent.
2. **Internal controls** must be documented each time the test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	Patient Name / MR#	Patient Result	Kit	Internal Control	External Positive Control		External Negative Control		Tech
			Lot # / Expire	Valid / Invalid	Lot # / Expire	Result	Lot # / Expire	Result	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Approved draft for training

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.		

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

Form revised 10/31/02

TABLE OF CONTENTS

1. TEST INFORMATION

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

Synonyms/Abbreviations
Flu test

Department
Microbiology

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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

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	Nasal wash or aspirate, Nasal swab	
-Other Acceptable	None	
Collection Container	See section 3.1	
Volume - Optimum	2.5 ml	
- Minimum	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.**

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 are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

6.2 Frequency

Internal Controls are performed and documented for each patient tested.

External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

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. Discard the swab in 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.

If the result is…	Then ….
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

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

Enter Shift: (1, 2, or 3)

Worksheet: Use WIM2 for WAH, SIM2 for SGAH, or GIM2 for GEC

Test: <Enter>

Enter "A" (Accept)

Enter Accession number

Press <Enter> until Result screen is displayed

Enter Results as listed below:

IF the result is …	THEN report with LIS code
Positive	POS
Negative	NEG

Calling of positive results not required as results are transmitted through the LIS to HIS interface.

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

11.3 Priority 3 Limit(s)

None established

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 wash or aspirate: sensitivity 81%; specificity 99%

15. SAFETY

The employee has 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 Environmental Health and Safety (EHS) Manual to learn the 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 needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Current product kit insert
Influenza QC Log (AG.F32)

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
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
003	4/18/2014	6.1,6.2	Changed external QC frequency	R. Master	R. Master
		10.5	Removed requirement to call positive results, added detail for LIS reporting	R. Master	R. Master
		11.3	Removed reference to Priority 3	R. Master	R. Master
		16	Removed Critical Value policy, moved QC form from addenda	R. Master	R. Master
		Footer	Version # leading zero’s dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics

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

INFLUENZA QUALITY CONTROL LOG

1. **External Positive (A&B)** and **Negative Controls** are tested and documented with each new kit lot number or shipment or every 30 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.

Date	Patient Name / MR#	Patient Result	Kit	Internal Neg QC	Internal Pos QC	External Pos Control / Type A		External Pos Control / Type B		External Neg Control		Tech
			Lot # / Expire	Clear background (Yes or No)	Blue line (Yes or No)	Lot # / Expire	Result	Lot # / Expire	Result	Lot # / Expire	Result	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Technical SOP **Approved draft for training**

Title	***Streptococcus*** **Group A Antigen with Reflex to Culture**
Prepared by	Ron Master Date: 5/12/2012

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	**Corporate Issue Date:** 5/25/2012	
Print Name and Title	**Signature**	**Date**
Lori Loffredo **Hospital BPT Chair**	*Approval on file*	**5/18/2012**
Dianne Zorka **NQA Manager (QC/ FDA Review)**	*Approval on file*	**5/17/2012**
R. Schlesinger, M.D. **BPT Medical Advisor**	*Approval on file*	**5/16/2012**
Stephen Suffin, M.D. **Chief Medical Officer, VP/Corporate**	*Approval on file*	**5/24/2012**

Retirement Date:	
Reason for retirement/replacement:	

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	*Streptococcus* Group A Antigen with Reflex to Culture
Method	Immunochromatography
Instrument	Not applicable
Synonyms	Rapid Strep, OSOM® Strep A, GAS Antigen
Department	Microbiology

Order Code	**Test Name**
QSTRP	*Streptococcus* Group A Ag with Reflex to Culture

2. ANALYTICAL PRINCIPLE

The Genzyme OSOM® Strep A uses color immunochromatographic dipstick technology with rabbit antibodies coated on the nitrocellulose membrane. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A *Streptococcus*. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A *Streptococcus* is present in the sample, it will form a complex with the anti-Group A *Streptococcus* antibody conjugated color particles. The complex will then be bound by the anti-group A streptococcus capture antibody and a visible blue test line will appear to indicate a positive result.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Two swabs should be submitted for this test. Use the sterile culture swabs to sample the back of the throat (posterior pharynx), tonsillar crypts, and between the tonsillar pillars and uvula. Avoid touching the lips, cheeks, tongue, and uvula.
Special Collection Procedures	Throat specimens should not be collected if the patient may have epiglottitis, a rapidly progressing infection with potential to cause complete airway obstruction. If epiglottitis is suspected, prompt otolaryngologic consultation for airway management is recommended.
Other	Refer to the Quest Diagnostics Incorporated *Directory of Services* for instructions on specimen collection and transport.

3.2 Specimen Type & Handling

Criteria	
Type -Preferred	Two swabs in liquid media such as Amies (BD red cap) or modified Stuart's medium.
-Other Acceptable	None.
Collection Container	Swabs in liquid media such as Amies or modified Stuart's medium. Do not use a collection system containing charcoal or semisolid (gel) transport media.
Volume - Optimum	Two swabs are preferred. One is for the antigen test and the second for culture if necessary.
- Minimum	1 swab

Criteria		
Transport Container & Temperature	BD red cap rayon, in liquid bacterial transport medium. (This swab has been validated by Quest Diagnostics).	
Stability & Storage Requirements	Room Temperature:	Process swabs as soon as possible after collection. Swabs in liquid transport media may be stored up to 2 days.
	Refrigerated:	Swabs in liquid transport media up to 2 days.
	Frozen:	Not validated
Timing Considerations	None	
Unacceptable Specimens & Actions to Take	Reject • Specimens from other sources than the throat or nasopharynx • Swabs with wooden shafts, calcium alginate, or cotton tips • Frozen specimens • Specimens in expired transport devices • Specimens in viral transport medium or in Gen-Probe collection devices • Beyond stability (>48 hrs. old)	
Compromising Physical Characteristics	Throat specimens should not be collected if the patient may have epiglottitis, a rapidly progressing cellulitis with potential to cause complete airway obstruction. Epiglottitis is typically caused by *H. influenzae* type b, but occasionally by *S. aureus* or *S. pneumoniae*. Epiglottitis should be considered in a febrile patient who has a severe sore throat, dysphagia, high-pitched breathing noises or progressive respiratory distress, and minimal findings on visualization of the oropharynx. If epiglottitis is suspected, prompt otolaryngologic consultation for airway management is suggested.	
Other Considerations	If only one swab is received, first streak the culture plate (refer to Plating SOP) before starting the OSOM® Strep A procedure. The extraction reagent will render the specimen nonviable for culture. Alternatively, if two swabs are received, process one for the antigen test and use the second for culture.	

4. REAGENTS

4.1 Reagent Summary

Reagents / Kits	Supplier & Catalog Number
OSOM® Strep A	Genzyme Diagnostics Cat# 141

4.2 Reagent Preparation and Storage

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.

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.

Genzyme Diagnostics OSOM® Strep A Kit	
Reagent 1	2 M Sodium Nitrite Caution: Toxic
Reagent 2	0.3 M Acetic Acid Caution: Corrosive
Positive Control	Nonviable Group A Streptococci, in 0.1% Sodium Azide.
Negative Control	Nonviable Group C Streptococci, in 0.1% Sodium Azide.
Container	Store in manufacturer's original container.
Storage	Store at Room Temperature (15° to 30°C)
Stability	Do not use Test Sticks or Reagents after expiration date.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Not applicable

5.2 Calibrator Preparation and Storage

Not applicable

5.3 Calibration Criteria and Procedure

Not applicable

6. QUALITY CONTROL

6.1 Controls Used

Three levels of internal procedural controls are automatically performed with each test. The results of these internal controls must be documented each time the test is performed. These controls verify that:

1) The Extraction Reagents were mixed properly (indicated by a pink to light yellow color when mixed).
2) The Test Stick is working properly (indicated by the red Control Line), and
3) That there are no interfering substances in the specimen (indicated by a clear background).

Quality Control	**Supplier**
Internal Reagent Control	Reagents 1 & 2. Supplied in the kit.
Internal Positive Control	Each test device. Supplied in the kit.
Internal Negative Control	Each test device. Supplied in the kit.
External Positive Control (includes control of the extraction)	Supplied in the kit.
External Negative Control	Supplied in the kit.

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

Control	**Internal Procedural Controls**
Contents	Nitrocellulose membrane device coated with rabbit antibodies. Reagent 1 and Reagent 2 (Refer to Section 4.1 for contents).
Preparation	None
Storage	Store at 15-30° C
Stability	Stable until manufacturer's expiration date

Control	**External Positive Control**
Contents	Nonviable Group A Streptococci, 0.1% Sodium Azide
Preparation	None
Storage	Store at 15-30° C
Stability	Stable until manufacturer's expiration date

Control	**External Negative Control**
Contents	Nonviable Group C Streptococci, 0.1% Sodium Azide
Preparation	None
Storage	Store at 15-30° C
Stability	Stable until manufacturer's expiration date

6.3 Frequency

- The results of these internal controls must be documented each time the test is performed.
- *External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.* These controls verify the extraction step and test devices are working properly and that the analyst is performing the test correctly.

6.4 Tolerance Limits

Step	Tolerance Limits
Internal Reagent Control	Color change from pink to light yellow after the addition of Reagents 1 & 2, in each tube.
Internal Positive Control	Red line in the Control line area of each test device.
Internal Negative Control	Clear background in the Control Line area of each test device.
External Positive Control (includes extraction)	Blue test line and red control line.
External Negative Control	Red control line only.

- Refer to package insert illustration for test result interpretation.
- Each time the controls exceed the acceptable criteria specified above, the run is considered to be out of control (failed) and patient results must not be reported. The run must be brought to the attention of supervisor (or designee) for second review and further action.
- The following are guidelines for failed controls:

IF …	THEN…
The red (Internal Positive Control) line does not appear for an External Control	That QC test is invalid. Hold patient results until corrective action is performed.
If the background (Internal Negative Control) is not clear and interferes with the result of an External Control	That QC test is invalid. Hold patient results until corrective action is performed.

If one or both External Control tests are invalid BUT all patient tests are valid (i.e., presence of a red Control line and clear background on all patients). 1. If the repeat control test is valid … 2. If the repeat control test is invalid …	Repeat the failed External Control test to verify that the original test was performed correctly. 1. Report the patient results. 2. **DO NOT release patient results when controls do not meet tolerance limits.** Investigate and take corrective action for all unacceptable controls. Corrective action must be documented.

6.5 Documentation

Refer to local policies and procedures for QC documentation and to Quest Diagnostics records management program for record retention requirements.

All steps taken in response to QC failures must be documented, including: a description of the QC failure, the root cause of the problem, actions taken to correct the problem, how patient samples were handled if applicable, and the date and initials of the person recording the information.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

- Test device supplied with kit

7.2 Equipment

- None

7.3 Supplies

- Timer or watch
- Marking pen

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.

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

8.0	Ordering
1.	When a *Streptococcus* Group A Antigen test is ordered, the accessioner will order both the rapid antigen test and culture. Sunquest can not automatically reflex microbiology tests. If the Antigen test is positive, the culture must be cancelled by the technologist performing the antigen test.

8.1	Specimen Preparation
1.	Specimens received for this test should be sorted into two groups of accessions prior to beginning testing: (1) dual swab submissions, and (2) single swab submissions.
2.	**If a single swab is submitted, streak the culture plate before starting the OSOM® Strep A procedure. Once a specimen has been used for this test, it is no longer acceptable for culture.**
3.	If two swabs are submitted, use one for the OSOM® Strep A test and reserve the second for the reflex culture if necessary.

8.2	Test Run
1.	Just before testing, add 3 drops of Reagent 1 (pink to light red) and 3 drops of Reagent 2 to one Test Tube for each patient and each external control. (The solution should turn light yellow).
2.	Immediately put each patient swab into a Test Tube.
3.	**Negative and Positive External Controls**: Vigorously mix the control contents. For each control, add 1 free falling drop from the dropper bottle to a tube containing reagents 1 and 2. Place a clean swab from the test kit into each of the control tubes.
4.	Vigorously mix each solution by rotating the swab forcefully against the side of the Tube at least ten (10) times. Best results are obtained when specimen is vigorously extracted in the solution. Let stand one minute.
5.	Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn. Discard the swab into bio-hazard waste.
6.	Remove a Test Stick from the container; recap the container immediately.
7.	Place the Absorbent End of a Test Stick into each of the extracted samples.
8.	Read the results at 5 minutes. Positive results may be read as soon as the red Control Line appears.
9.	Results are invalid after the stated read time. The use of a timer is recommended.

9. CALCULATIONS

Not applicable

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

Note: A blue or red line which appears uneven in color density is considered a valid result. In cases of moderate or high positive specimens, some blue color behind the Test Line may be seen; as long as the Test Line and Control are visible, the results are valid.

Result	Interpretation
A blue Test Line and a red Control Line. Note that the blue line can be any shade of color.	Positive for Group A streptococcal antigen.
A red Control Line but no blue Test Line is visible.	Presumptive Negative for Group A streptococcal antigen.
No red Control Line appears or background color makes reading the red Control Line impossible.	Invalid result.

10.2 Rounding

Not applicable

10.3 Units of Measure

Not applicable

10.4 Analytical Measurement Range (AMR)

Not applicable. This is a qualitative test reported as Detected or Not Detected.

The OSOM® Strep A is a qualitative test for the detection of Group A Streptococcal antigen. This test does not differentiate between viable and nonviable Group A Streptococci.

10.5 Review Patient Data

- Review patient results for unusual patterns, trends or distribution.
- Report atypical or unexpected results or trends for this test to appropriate supervisory personnel, prior to releasing results.

10.6 Repeat Criteria and Resulting

IF the result is …	THEN…
Negative	1. Issue Final report as: "Not Detected" 2. Perform the Throat Culture / Group A *Streptococcus* Culture. **See also section 8.1**
Positive	1. Issue Final report as: " Detected" 2. Cancel the Throat Culture / Group A *Streptococcus* Culture order.
Invalid Result	1. Issue final report as: "invalid result" using code INVD. The comment "Please repeat test if clinically indicated" will be appended to the result by the LIS. 2. Perform the Group A *Streptococcus* Culture. **See also section 8.1**

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

Enter Shift: (1, 2, or 3)

Worksheet: Use WIM2 for WAH, SIM2 for SGAH, or GIM2 for GEC

Test: <Enter>

Enter "A" (Accept)

Enter Accession number

Press <Enter> until Result screen is displayed

Enter Results as listed below:

Result Message	Sunquest Result Code
Detected	DET
Not Detected	NTD
Invalid	INVD

11. EXPECTED VALUES

11.1 Reference Ranges

Not Detected

11.2 Critical Values

None established

11.3 Standard Required Messages

Not applicable

12. CLINICAL SIGNIFICANCE

Group A *Streptococcus* (*S. pyogenes*) is the most common cause of bacterial pharyngitis ("Strep throat") causing local pharyngeal pain, adenopathy, and fever. In addition, it is important to treat infections caused by this virulent organism in order to avoid potential, morbid complications including peritonsillar and retropharyngeal abscesses, bacteremia, rheumatic fever, and acute glomerulonephritis. Group A *Streptococcus*, however, may also be isolated in small numbers as part of the oropharyngeal flora of asymptomatic carriers.

13. PROCEDURE NOTES

- **FDA Status:** FDA Waived /Cleared or Approved
- **Validated Test Modifications:** None

- Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Streptococcal pharyngitis displays a seasonal variation and is most prevalent during winter and early spring. The highest incidence of this disease is found in crowded populations such as military bases and in school-age children.
- A negative result may be obtained if the specimen is inadequate or if the antigen concentration is below the sensitivity of this test.
- The American Academy of Pediatrics states [5]. "Several rapid diagnostic tests for GAS pharyngitis are available. The specificities of these tests generally are very high, but the reported sensitivities vary considerably. As with Throat cultures, the accuracy of these tests is most dependent on the quality of the throat specimen, which must contain tonsillar and pharyngeal secretions. Therefore, when a patient suspected of having GAS pharyngitis has a negative rapid streptococcal test, a throat culture should be obtained to ensure that the patient does not have GAS infection".
- The Genzyme OSOM® Strep A has been categorized as CLIA waived only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs. The application for the confirmation of presumptive Group A Streptococcal colonies recovered from culture is not waived.
- The use of swab specimens taken from sites other than throat or the use of other samples such as saliva, sputum or urine has not been established.

- This test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A *Streptococcus*.
- In the event that two swabs were submitted and the OSOM® Strep A test results were invalid from one swab, the test may be repeated using the second swab, rather than reporting the test with the TNP message. Appropriate culture plate(s) must be setup prior to using the second swab for antigen testing. The extraction step in the OSOM® Strep A test makes the swab nonviable for culture. All criteria for a valid test must be obtained with the second swab in order to report that test result.
- This is an FDA cleared assay.

14. LIMITATIONS OF METHOD

14.1 Precision

Not applicable

14.2 Interfering Substances

- Gel transport medium may interfere with test results.
- The following organisms were tested at levels of approximately $1x10^8$ organisms/test and found to be negative when tested with the OSOM® Strep A kit.

Streptococcus Group B	*Cornybacterium diphtheria*
Streptococcus Group C	*Serratia marcescens*
Streptococcus Group F	*Candida albicans*
Streptococcus Group G	*Klebsiella pneumoniae*
Streptococcus pneumoniae	*Pseudomonas aeruginosa*
Streptococcus sanguis	*Bordetella pertussis*
Streptococcus mutans	*Neisseria meningitides*
Haemophilus influenzae	*Neisseria gonorrhoeae*
Enterococcus faecalis	*Neisseria sicca*
Staphylococcus aureus	*Neisseria subflava*
Staphylococcus epidermidis	*Branhamella catarrhalis*

14.3 Clinical Sensitivity/Specificity/Predictive Values

- In a multi-center study, OSOM® with 639 specimens from patients with pharyngitis. 464 specimens were culture negative and 454 negative by the OSOM® test for a specificity of 97.8%. Of the 175 culture positives, 168 were also positive by the OSOM® test for a sensitivity of 96.0%. Overall agreement was 97.3%
- A negative result may be obtained if the specimen is inadequate or antigen concentration is below the sensitivity of the test. Therefore, all specimens yielding negative OSOM® Group A Strep results should undergo confirmatory testing using the culture method.

- The Genzyme OSOM® Strep A should be used only with throat swabs. The use of swab specimens taken from the other sites or the use of other samples such as saliva, sputum or urine has not been established. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained.

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.

Refer to your local and corporate safety manuals for detailed information on safety practices and procedures.

Report all accidents and injuries immediately to your supervisor or to the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

- Quest Diagnostics Incorporated Corporate Safety Manual.
- Quest Diagnostics Incorporated Critical and Priority Result Policy and Procedure SOP (QDMED704).
- Material Safety Data Sheets.
- Quest Diagnostics Incorporated *Directory of Services*, Specimen Collection section.
- Quest Diagnostics Incorporated Training Verification (QDNQA600) and Competency Assessment (QDNQA601) SOPs.
- Quest Diagnostics Incorporated Proficiency Test Handling and Result Submission SOP (QDNQA711).
- Quest Diagnostics Incorporated Records Management Program for Record Retention Requirements.
- *Streptococcus Group A Antigen with Reflex to Culture* (QDMI700)
- Local Quality Control policies and procedures
- Current package insert for OSOM® Strep A
- Strep Group A Quality Control Log (AG.F35)

17. REFERENCES

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8. OSOM® Strep A Package Insert, June, 2011 Revision 3096-0. Sekisui Diagnostics
9. Assay and BD swab in liquid Amies Evaluation data, Quest Diagnostics, Collegeville, PA.

18. DOCUMENT HISTORY

Version	Date	Section	Revision	Revised By	Approved By
1.0	5/2012		New SOP, supersedes WAH.M26.001, SGAH.M26.001, GEC.M07.001	R. Master	R. Schlesinger
1.0	5/25/12	Title pg	Update to local format	L. Barrett	R. Master
1.0	5/25/12	1	Added local test code	R. Master	R. Master
1.0	5/25/12	3.1	Add 'reject' to list of unacceptable	L. Barrett	R. Master
1.0	5/25/12	8.0	Add instruction for ordering	R. Master	R. Master
1.0	5/25/12	10.6	Add local LIS codes	R. Master	R. Master
1.0	5/25/12	11.2	Update heading to local terminology, add local policy, removed corporate policy	L. Barrett	R. Master
1.0	5/25/12	16	Add current package insert	L. Barrett	R. Master
1.0	5/25/12	19	Add QC log	L. Barrett	R. Master
1.0A	4/22/14	6.3	Changed QC frequency	R. Master	R. Master
1.0A	4/22/14	10.6	Added detail for LIS reporting	L. Barrett	R. Master
1.0A	4/22/14	11.2	Clarified not a Critical Value	R. Master	R. Master
1.0A	4/22/14	16	Log moved from section 19	L. Barrett	R. Master
1.0A	4/22/14	Footer	New local version numbering adopted per corporate policy change	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics

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

STREP Group A QUALITY CONTROL LOG

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 30 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.

Date	Patient Name / MR#	Patient Result	Kit	Internal Negative Control	Internal Positive Control	Internal Reagent Control	External Positive Control		External Negative Control		Tech
			Lot # / Expire	Clear (Yes or No)	Red (Yes or No)	Pink to Yellow (Yes or No)	Lot # / Expire	Result	Lot # / Expire	Result	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Technical SOP **Approved draft for training**

Title	**C. DIFF QUIK CHEK COMPLETE™**
Prepared by	Ron Master Date: 07/18/2010
Owner	Ron Master Date: 07/18/2010

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

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

Quest Diagnostics Nichols Institute
Site: SGAH & WAH
Title: C. DIFF QUIK CHEK COMPLETE

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
GDH and *C. difficile* toxin A&B	Manual, Rapid membrane EIA	QCDIF

Synonyms/Abbreviations
Antigen - GDH – glutamate dehydrogenase - *C. difficile* antigen, *C diff* antigen Toxin - *C. difficile* toxin A&B, *C diff* toxin

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2. ANALYTICAL PRINCIPLE

The *C. DIFF QUIK CHEK COMPLETE*™ test uses antibodies specific for glutamate dehydrogenase and toxins A and B of *C. difficile*. The device contains a *Reaction Window* with three vertical lines of immobilized antibodies. The antigen test line ("Ag") contains antibodies against *C. difficile* glutamate dehydrogenase. The control line ("C") is a dotted line that contains anti-horseradish peroxidase (HRP) antibodies. The toxins A and B test line ("Tox") contains antibodies against *C. difficile* toxins A and B. The *Conjugate* consists of antibodies to glutamate dehydrogenase and antibodies to toxins A and B coupled to horseradish peroxidase. To perform the test, the sample is added to a tube containing a mixture of *Diluent* and *Conjugate*. The diluted sample-conjugate mixture is added to the *Sample Well* and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, any glutamate dehydrogenase and toxins A and B in the sample bind to the antibody-peroxidase conjugates. The antigen-antibody-conjugate complexes migrate through a filter pad to a membrane where they are captured by the immobilized glutamate dehydrogenase-specific and toxins A and B-specific antibodies in the lines. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10 minute incubation period, the "Ag" reaction is examined visually for the appearance of a vertical blue line on the "Ag" side of the *Reaction Window*. A blue line indicates a positive test. If the "Ag" is positive, then the "Tox" reaction should be examined visually for the appearance of a blue line on the "Tox" side of the *Reaction Window*. A blue line indicates a positive test. A positive "C" reaction, indicated by a vertical dotted blue line under the "C" portion of the *Reaction Window*, confirms that the test is working properly and the results are valid.

3. SPECIMEN REQUIREMENTS

CAUTION: Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus may be present in clinical specimens. "Standard Precautions" and institutional guidelines should be followed in handling all items contaminated with blood and other body fluids.

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Standard collection and handling procedures used in-house for fecal specimens are appropriate.
Special Collection Procedures	None
Other	Submit specimen immediately to Laboratory or store refrigerated until sent.

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3.2 Specimen Type & Handling

Criteria	
Type -Preferred **-Other Acceptable**	Raw stool (no preservative) Fecal specimen in Cary Blair or C&S transport media
Collection Container	Clean airtight container
Volume - Optimum **- Minimum**	N/A 2 mm diameter sized portion for solid stool 50 µl for liquid or semi-solid stool
Transport Container and Temperature	Same as above. Transport at room temperature.
Stability & Storage Requirements	Room Temperature: Not Recommended Refrigerated: Acceptable: 2-8°C for up to 72 hours Frozen: -20°C or colder if sample cannot be tested within 72 hours.
Timing Considerations	Ideally samples must be tested within 24 hours, otherwise the storage requirements above must be observed.
Unacceptable Specimens & Actions to Take	Stool samples in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol preservatives. Reject sample and request an unpreserved sample from client.
Compromising Physical Characteristics	N/A
Other Considerations	Store specimens frozen (≤ □-10°C) if the test cannot be performed within 72 hours of collection, but note that freezing and thawing of the specimen may result in loss of activity due to degradation of the toxins. If using frozen specimens, thaw at room temperature. A single freeze thaw cycle should not affect results. Repeated freezing and thawing of samples should be avoided. Storing fecal specimens in the *Diluent* is NOT recommended.

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
Wampole *C. DIFF QUIK CHEK COMPLETE*™ Kit	Inverness Medical Catalog Number: 30525C 30550C

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4.2 Reagent Preparation 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.

Storage Instructions: This product is ready for use and no further preparation is necessary. Store product in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use.

Kit Components	Container	Storage/ Stability	Preparation
Membrane Devices	Each pouch contains 1 device	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Diluent	22 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Wash Buffer	12 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Substrate	3.5 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Conjugate	2.5 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Positive Control	1 mL per bottle	Store at 2-8°C. Stable until expiration date on vial label.	Ready for use.
Disposable plastic transfer pipettes	50 per kit	N/A	N/A

Warnings and Precautions:

1. Reagents from different kits should not be mixed or interchanged. Do not use a kit past the expiration date.
2. Bring all components to ROOM TEMPERATURE BEFORE USE.
3. Caps, tips and dropper assemblies are color-coded; do NOT mix or interchange.
4. Do not freeze the reagents. The kit should be stored between 2°C and 8°C.

5. The pouch containing the *Membrane Device* should be at room temperature before opening, and opened just before use. Keep the membrane devices dry before use.
6. Use fecal specimens within 72 hours of collection to obtain optimal results. Specimens that are frozen may lose activity due to freezing and thawing. If using frozen specimens, thaw at room temperature.
7. Do not use specimens that have been preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin or polyvinyl alcohol.
8. Specimens in transport media such as Cary Blair and C&S can be used as specified in the specimen preparation protocol.
9. Hold reagent bottles vertically to dispense reagents to ensure consistent drop size and correct volume.
10. Specimens and membrane devices should be handled and disposed of as potential biohazards after use. Wear disposable gloves when doing the test.
11. Membrane devices cannot be reused.
12. The test has been optimized for sensitivity and specificity. Alterations of the specified procedure and/or test conditions may affect the sensitivity and specificity of the test. Do not deviate from the specified procedure.
13. Microbial contamination of reagents may decrease the accuracy of the assay. Avoid microbial contamination of reagents by using sterile disposable pipettes if removing aliquots from reagent bottles.
14. Be attentive to the total assay time when testing more than one fecal specimen. Add *Diluent* first, and then add the *Conjugate* to each tube of *Diluent*. Then add specimen to the tube of *Diluent/Conjugate*. Thoroughly mix all of the diluted specimens, and transfer to the *Membrane Device*. The 15-minute incubation step begins after the last diluted sample-conjugate mixture has been transferred to the final *Membrane Device*.
15. If the *Substrate* reagent changes to a dark blue/violet color call technical services for replacement.

5. CALIBRATORS/STANDARDS

N/A

6. QUALITY CONTROL

6.1 Controls Used

Internal: A dotted blue line must be visible in the middle of the *Reaction Window*, below the "C" on every *Membrane Device* that is tested. The appearance of the blue control dots confirms that the sample and reagents were added correctly, that the reagents were active at the time of performing the assay, and that the sample migrated properly through the *Membrane Device*. A clear background in the result area is considered an internal negative control. If the test has been performed correctly and reagents are working properly, the background will be white to give a discernible result.

External: The reactivity of the *C. DIFF QUIK CHEK COMPLETE* ™ kit should be verified upon receipt using the *Positive Control* and negative control (*Diluent*). The *Positive Control* is supplied with the kit (gray-capped bottle). The *Positive Control* confirms the reactivity of the other reagents associated with the assay, and is not intended to ensure precision at the analytical assay cut-off. *Diluent* is used for the negative control.

6.2 Control Preparation and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) check for visible signs of degradation on of all items received.

Refer to section 4.2

6.3 Frequency

Internal controls are recorded for each patient test.

External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

6.4 Tolerance Limits

Control	Expected Result
Internal Positive Control	A blue dotted line is visible in the middle of the *Reaction Window*
Internal Negative Control	Clear background in the result area
External Positive Control	Blue lines on the "Ag" and Tox" sides of the *Reaction Window*
External Negative Control (Diluent)	A single blue dotted line is visible in the middle of the *Reaction Window*, below the "C" and no test lines are visible on the "Ag" side or the "Tox" side of the *Reaction Window*

- The following are guidelines for failed controls:

IF …	THEN…
Any control does not produce the expected result	The test is invalid. Do not report patient results. Repeat testing. Do not report patient results until acceptable QC results are obtained. If repeat testing does not produce acceptable QC, then notify supervisor immediately.

6.5 Review Patient Data

Review patient data for unusual patterns, trends or distributions in patient results, such as an unusually high percentage of abnormal result.

6.6 Documentation

The results of the controls are documented on the appropriate manual QC log sheet.

6.7 Quality Assurance Program

- Quality Control cross-checks must be done with each new lot/shipment of kit using both internal and external controls.
- The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

N/A

7.3 Supplies

Small test tubes (e.g., plastic tubes or glass tubes)
Applicator sticks
Timer
Vortex mixer
Disposable gloves for handling fecal samples
Pipettor and tips

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.

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	Sample Preparation
1.	Bring all reagents and the required number of devices to room temperature before use.
2.	Set up and label one small test tube for each specimen and external controls as necessary.
3.	Using the black graduated dropper assembly, add **750 µL** (2nd graduation from the tip) *Diluent* to each tube for fecal specimens and the external *Positive Control*. For specimens in transport media such as Cary Blair or C&S, add 650 µL of *Diluent* to the tube.
4.	Add **one drop** of *Conjugate* (red capped bottle) to each tube.
5.	Obtain one disposable plastic transfer pipette (supplied with the kit) for each sample – the pipettes have raised graduations at 25 µL, 400 µL and 500 µL.
6.	Mix all specimens thoroughly regardless of consistency - it is essential that the specimens be evenly suspended before transferring. **Liquid/Semi-solid specimens** – pipette 25 µL of specimen with a transfer pipette (graduated at 25 µL, 400 µL and 500 µL) and dispense into the *Diluent/Conjugate* mixture. Use the same transfer pipette to mix the diluted specimen. **Formed/Solid specimens** – Care must be taken to add the correct amount of formed feces to the sample mixture. Mix the specimen thoroughly using a wooden applicator stick and transfer a small portion (approximately 2 mm diameter, the equivalent of 25 µL) of the specimen into the *Diluent/Conjugate* mixture. Emulsify the specimen using the applicator stick. *NOTE: Transferring too little specimen, or failure to mix and completely suspend the specimen in the Diluent mixture, may result in a false-negative test result. The addition of too much fecal specimen may cause invalid results due to restricted sample flow.*
7.	**External Control Samples:** **External Positive Control** - add one drop of *Positive Control* (gray-capped bottle) to the appropriate test tube. **External Negative Control** - add 25 µL *Diluent* to the appropriate test tube.

8.2	Procedure
1.	Obtain one *Membrane Device* per specimen, and one device per optional external positive or negative control as necessary. The foil bags containing the devices should be brought to room temperature before opening. Label each device appropriately and orient it on a flat surface so the "C. DIFF COMPLETE" print is at the bottom of the device, and the small *Sample Well* is located in the top right corner of the device.
2.	Mix each tube of diluted specimen thoroughly. Proper mixing can be achieved by vortexing or by repeated aspirations with the transfer pipette. Once a patient sample or *Positive Control* has been diluted in the *Diluent/Conjugate* mixture, it may be incubated at room temperature for any period of time up to 24 hours prior to addition to the *Membrane Device*.

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8.2	Procedure
3.	Using a new transfer pipette, transfer **500 µL** of the diluted sample-conjugate mixture into the ***Sample Well*** (smaller hole in the top right corner of the device) of a *Membrane Device*, making certain to expel the liquid sample onto the wicking pad inside of the *Membrane Device*. When loading the sample into the sample well, make sure that the tip of the transfer pipette is angled towards the *Reaction Window* (larger hole in the middle of the device).
4.	Incubate the device at room temperature for **15 minutes** – the sample will wick through the device and a wet area will spread across the *Reaction Window*. **NOTE FOR SAMPLES THAT FAIL TO MIGRATE:** Occasionally, a diluted fecal specimen cannot be tested because it clogs the membrane and the Reaction Window does not wet properly. If the diluted fecal specimen fails to migrate properly within 5 minutes of adding the sample to the Sample Well (i.e. the membrane in the Reaction Window does not appear to be completely wet), then add 100 µL (4 drops) of Diluent to the Sample Well and wait an additional 5 minutes (for a total of 20 minutes).
5.	After the incubation, add **300 µL** of *Wash Buffer* to the ***Reaction Window*** using the graduated white dropper assembly (or equivalent). Allow the *Wash Buffer* to flow through the *Reaction Window* membrane and be absorbed completely.
6.	Add 2 drops of *Substrate* (white-capped bottle) to the ***Reaction Window***. Read and record results visually after **10 minutes**.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Results

1. Interpretation of the test is most reliable when the device is read immediately at the end of the 10 minute reaction period. Read the device at a normal working distance in a well-lit area. View with a line of vision directly over the device.
2. Observe device for the appearance of blue dots in the middle of the *Reaction Window* representing the internal positive control. The appearance of any control dot(s) represents a valid internal control. Observe device for the appearance of blue lines on the "Ag" and Tox" sides of the *Reaction Window* representing the test lines. The lines may appear faint to dark in intensity.
3. **Positive Antigen ("Ag") Result:** A positive antigen result may be interpreted at any time between the addition of *Substrate* and the 10-minute read time. For a positive antigen result, the blue "Ag" line and the dotted blue control line below "C" are visible (Figure 1a). The lines may appear faint to dark in intensity. An obvious partial line is interpreted as a positive result. Do not interpret membrane discoloration as a positive result. A positive result indicates the presence of *C. difficile.*

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4. **Positive Antigen and Toxin ("Tox") Result:** If the antigen result is positive (i.e., a blue "Ag" line and a dotted blue control below "C" are visible), proceed to the interpretation of the toxin result. A positive toxin result may be interpreted at any time between the addition of *Substrate* and the 10-minute read time. For a positive toxin result, a blue "Tox" line is visible (Figure 1b). The line may appear faint to dark in intensity. An obvious partial line is interpreted as a positive result. Do not interpret membrane discoloration as a positive result. A positive result indicates the presence of *C. difficile* toxin.
5. **Negative Result: A test cannot be interpreted as negative or invalid until 10 minutes following the addition of *Substrate***. A single blue dotted line is visible in the middle of the *Reaction Window*, below the "C" and no test lines are visible on the "Ag" side or the "Tox" side of the *Reaction Window* (Figure 1c). A negative result in the antigen portion indicates *C. difficile* antigen is either absent in the specimen or is below the detection limit of the test. A negative result in the toxin portion indicates *C. difficile* toxin is either absent in the specimen or is below the detection limit of the test.
6. **Invalid Result:** No lines are visible in the *Reaction Window* (Figure 1d). The test result is invalid if a blue dotted line is not present below the "C" at the completion of the reaction period (Figures 1e, 1f, 1g).
7. **Indeterminate Result**: A low percentage of specimens may test negative for antigen but positive for toxin. These samples should be considered indeterminate and retested using a fresh specimen (Figure 1h).

FIGURE 1: ***C. DIFF QUIK CHEK COMPLETE* ™ INTERPRETATION OF RESULTS**

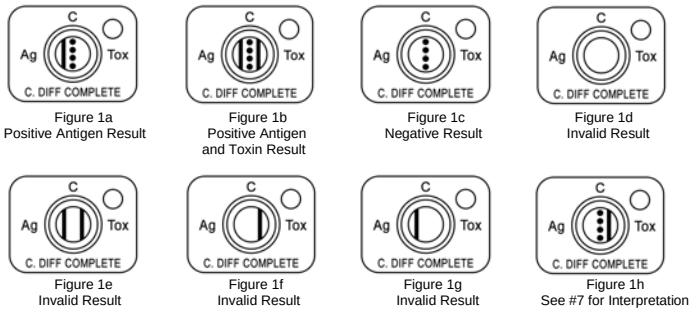

Figure 1a Positive Antigen Result | Figure 1b Positive Antigen and Toxin Result | Figure 1c Negative Result | Figure 1d Invalid Result

Figure 1e Invalid Result | Figure 1f Invalid Result | Figure 1g Invalid Result | Figure 1h See #7 for Interpretation

10.2 Rounding / Units of Measure / Clinically Reportable Range (CRR)

N/A

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10.4 Resulting

Use function **MEM** to enter results.

Enter Shift (1, 2, or 3)

Worksheet: Use WIM2 for WAH or SIM2 for SGAH.

Test: <Enter>

Enter "A" (Accept)

Enter Accession number

Press <Enter> until Result screen displayed

Enter Results as listed below:

Test	Result	Report as	LIS code
Clostridium difficile GDH antigen (test code CDAG)	Negative	Negative	NEG
Clostridium difficile toxins A/B (test code CTOXIN)	Negative	Negative	NEG
Clostridium difficile GDH antigen (test code CDAG)	Positive	Positive	POS
Clostridium difficile toxins A/B (test code CTOXIN)	Positive	Positive	POS

IF	THEN
Clostridium difficile GDH antigen = Negative and *Clostridium difficile* toxins A/B = Negative	Report results.
Clostridium difficile GDH antigen = Positive and *Clostridium difficile* toxins A/B = Positive	Report results.
Clostridium difficile GDH antigen = Positive and *Clostridium difficile* toxins A/B = Negative	Report results. *C. difficile* PCR is reflexed on same specimen, label prints (test code XCDQL), and send to Chantilly.
Clostridium difficile GDH antigen = Negative and *Clostridium difficile* toxins A/B = Positive	Results are inconclusive, do NOT report. Repeat test. If repeat results are the same, order *C. difficile* PCR (XCDQL)

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11. EXPECTED VALUES

11.1 Reference Ranges

Clostridium difficile toxins A/B – Negative
Clostridium difficile GDH antigen – Negative

11.2 Critical Values

Clostridium difficile toxins A/B and GDH antigen – Positive

11.3 Priority 3 Limit(s)

None established

12. CLINICAL SIGNIFICANCE

After treatment with antibiotics, many patients develop gastrointestinal problems ranging from mild diarrhea to severe pseudomembranous colitis. Many cases of the milder forms of gastrointestinal illness and most cases of pseudomembranous colitis are caused by toxigenic strains of *Clostridium difficile* (1). This organism is an opportunistic anaerobic bacterium that grows in the intestine once the normal flora has been altered by the antibiotic. Toxigenic strains of *C. difficile* carry the genes encoding the toxins while non-toxigenic strains do not carry the toxin genes. Disease onset is associated with the toxins that are produced by the toxigenic organism. The clinical symptoms associated with the disease are believed to be primarily due to toxin A, which is a tissue damaging enterotoxin (2,3). *C. difficile* also produces a second toxin, designated toxin B. Toxin B, which has been referred to as the cytotoxin of the organism, is the toxin detected by the tissue culture assay currently used by many laboratories. Toxigenic *C. difficile* strains produce both toxins, or only toxin B (4-7). The glutamate dehydrogenase of *C. difficile* is a good antigen marker for the organism in feces because it is produced in high amounts by all strains, toxigenic or non-toxigenic (8-10). The antigen can be detected in fecal specimens by using the C. DIFF QUIK CHEK COMPLETE™ test. A positive result in the test for the glutamate dehydrogenase of *C. difficile* confirms the presence of this organism in a fecal specimen; a negative result indicates the absence of the organism. A positive result in the test for toxins A and B confirms the presence of toxigenic *C. difficile*.

13. PROCEDURE NOTES

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

14. LIMITATIONS OF METHOD

1. The *C. DIFF QUIK CHEK COMPLETE* ™ test is used to detect *C. difficile* antigen and toxin(s) in fecal specimens. The test confirms the presence of toxin in feces and this information should be taken under consideration by the physician in light of the clinical history and physical examination of the patient. The *C. DIFF QUIK CHEK COMPLETE* ™ test will detect levels of toxin A at ≥0.63 ng/mL, toxin B at ≥0.16 ng/mL, and glutamate dehydrogenase at ≥0.8 ng/mL.
2. Fecal specimens are extremely complex. Optimal results with the *C. DIFF QUIK CHEK COMPLETE* ™ test are obtained with specimens that are less than 24 hours old. Most undiluted specimens can be stored between 2°C and 8°C for 72 hours before significant degradation of the toxin is noted. If specimens are not assayed within this time period, they may be frozen and thawed. However, repeated freezing and thawing may result in loss in the immunoreactivity of antigen and toxins A and B.
3. Some specimens may give weak reactions. This may be due to a number of factors such as the presence of low levels of antigen and/or toxin, the presence of binding substances, or inactivating enzymes in the feces. *Under these conditions, a fresh specimen should be tested.* Additional tests that may be used in conjunction with the *C. DIFF QUIK CHEK COMPLETE* ™ test include culture with toxigenic testing or tissue culture cytotoxicity assay for the detection of *C. difficile* or its toxin(s).
4. Fecal specimens preserved in 10% Formalin, merthiolate formalin, sodium acetate formalin, or polyvinyl alcohol cannot be used.
5. The *C. DIFF QUIK CHEK COMPLETE* ™ test is qualitative. The intensity of the color should not be interpreted quantitatively.
6. Some isolates of *C. sordellii* may react in the *C. DIFF QUIK CHEK COMPLETE* ™ test due to the production of immunologically related toxins (1).
7. Colonization rates of up to 50% have been reported in infants. A high rate has also been reported in cystic fibrosis patients (1,3).
8. The only non-*C. difficile* organism to react in the toxin portion of the *C. DIFF QUIK CHEK COMPLETE* ™ test was *Clostridium sordellii* VPI 9048. This strain produces toxins HT and LT, which are homologous to toxins A and B, respectively.

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

The following substances had no effect on test results when present in feces in the concentrations indicated: mucin (3.5% w/v), human blood (40% v/v), barium sulfate (5% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Pepto-Bismol® (5% v/v), steric/palmitic acid (40% w/v), Metronidazole (0.25% w/v), Vancomycin (0.25% w/v).

14.4 Clinical Sensitivity/Specificity/Predictive Values/Performance Characteristics

Refer to Wampole *C. DIFF QUIK CHEK COMPLETE* ™ package insert.

15. SAFETY

The employee has 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 Environmental Health and Safety (EHS) Manual to learn the 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 needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Current package insert for C. DIFF QUIK CHEK COMPLETE ™
C. DIFF QUIK CHEK COMPLETE Quality Control Log (AG.F69)

17. REFERENCES

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10. Lyerly, D. M., and T. D. Wilkins. 1986. Commercial latex test for *Clostridium difficile* Toxin A does not detect Toxin A. J. Clin. Microbiol. **23**: 622-623.
11. Product Information Wampole *C. DIFF QUIK CHEK COMPLETE* ™ package insert, RMS #91-525C-01, Issued: 03/2009.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	4/22/2014	6.3	Clarified QC frequency	R. Master	R. Master
000	4/22/2014	16	Log moved from section 19	L. Barrett	R. Master
000	4/22/2014	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics

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

C. DIFF QUIK CHEK COMPLETE QUALITY CONTROL LOG

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 30 days, whichever is more frequent.
2. **Internal controls** must be documented with each patient test.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Date	**Patient Name / MR#**	**Patient Result**		**Kit**	**Internal Controls**		**External Positive Controls**		**External Negative Control**	**Tech**
		Ag	**Tox**	**Lot # / Expire**	**Pos** Dotted Blue Line (Yes or No)	**Neg** Clear Background (Yes or No)	**Ag Result** (Pos)	**Toxin Result** (Pos)	**Diluent** (Neg)	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review:

Approved draft for training

Technical SOP

Title	**Rotavirus Antigen Detection**	
Prepared by	Ron Master	Date: 12/14/2009
Owner	Ron Master	Date: 12/14/2009

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

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

Quest Diagnostics Nichols Institute
Site: Shady Grove Adventist Hospital
Title: Rotavirus Antigen Detection

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1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Rotavirus antigen	Immunoassay	ROTA

Synonyms/Abbreviations
None

Department
Microbiology

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2. ANALYTICAL PRINCIPLE

Rotavirus is a major cause of acute gastroenteritis, especially in children 6 to 24 months in age. In addition, Rotavirus infections can produce severe illness as well as asymptomatic infection in adults. The incubation period of rotavirus infection is usually one to three days followed by gastroenteritis with an average duration of five to eight days. Virus titers in stool reach a maximum shortly after onset of illness then decline.

The ImmunoCard STAT Rotavirus assay detects the presence of rotavirus antigen in stool. Patient specimen is diluted 1:15 in sample diluent. The suspension is mixed and 150 ul is added to the sample port of the device. The sample mobilizes gold particles coated with monoclonal antibody to rotavirus and migrates along the membrane through **the Test (polyclonal anti-rotavirus antibody) and Control zones**. After ten minutes, the Test and Control zones are observed for the presence of red/purple lines across the membrane surface. If rotavirus is present in the sample, a complex is formed between the capture antibody and the monoclonal antibody-gold conjugate, which can be seen visually as a red/purple line in the Test zone. No red/purple line in the Test zone indicates a negative result. The Control line serves as a procedural control to assure that the sample has migrated the appropriate distance along the membrane.

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Raw stool in a clean dry container or on a culturette (obtained from a diaper).
Special Collection Procedures	Specimens should be collected after onset of symptoms.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	Raw stool (dry or in a culturette)	
-Other Acceptable	Swab	
Collection Container	Container or culturette	
Volume - Optimum	1 mL	
- Minimum	50 uL	
Transport Container and Temperature	Container or culturette at room temperature	
Stability & Storage Requirements	Room Temperature:	Test as soon as possible
	Refrigerated:	2 – 8 °C up to72 hours
	Frozen:	≤ -20° C up to 30 days

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Criteria	
Timing Considerations	N/A
Unacceptable Specimens & Actions to Take	The testing of meconium stools in this assay is not recommended, as their performance characteristics have not been evaluated. Reject sample and request recollection
Compromising Physical Characteristics	Specimens containing high levels of blood may fail to flow in the ImmunoCard STAT Rotavirus device, resulting in an invalid test result. Testing of an additional specimen is recommended under such circumstances.
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
ImmunoCard STAT	Meridian Diagnostics 750030

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.

Assay Kit	
Reagent a	ImmunoCard STAT test devices in individual foil pouches
Reagent b	Positive control (1.8ml)
Reagent c	Sample diluent (10.5ml)
Storage	2 – 8°C
Stability	Expiration date printed on kit label. Do not use reagents beyond expiration dates.
Preparation	All reagents come ready to use. Allow kit components to reach 21 - 25°C prior to use. Gently mix liquid reagents prior to use. Do not substitute reagents from other manufacturers or between different kit lot numbers

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5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

N/A

5.2 Calibrator Preparations and Storage

N/A

5.3 Calibration Procedure

N/A

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
External Positive Control	included in kit
External Negative Control	sample diluent

The ImmunoCard STAT Rotavirus test contains a built-in procedural control. The Control line serves as an internal positive control. A visually detectable red/purple Control line must be present. The presence of this Control line verifies reagent integrity and assay performance. The presence of a clear background in the Test and Control zone serves as an internal negative control.

6.2 Control Preparations and Storage

NOTE: Date and initial all controls upon opening. Each container should be labeled with (1) substance name, (2) lot number, (3) date of preparation, (4) expiration date, (5) initials of tech, and (6) any special storage instructions; check for visible signs of degradation.

See section 4.2.

6.3 Frequency

External positive and negative controls are tested with each new kit lot number or shipment or every 30 days, whichever is more frequent.

The internal procedural controls are recorded for each test.

Add three drops of positive control or, using a transfer pipette, add 150 ul sample diluent directly to sample port of appropriate device (do not dilute positive control).

6.4 Tolerance Limits

The external positive control should yield detectable red/purple test and control lines.

The external negative control should yield a visually detectable red/purple control line. No test line should be present.
Patient results are not to be reported if the controls do not perform as expected.

- Re-analyze in accordance with Laboratory Quality Control Program.
- Corrective action must follow the Laboratory Quality Control Program.

6.5 Review Patient Data

N/A

6.6 Documentation

Document quality control data immediately on appropriate log sheet.

6.7 Quality Assurance Program

The laboratory participates in CAP proficiency testing.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

N/A

7.2 Equipment

N/A

7.3 Supplies

Immunocard STAT device
Diluent
Transfer pipettes
12 X 75 test tubes
Applicator sticks
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.

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8.1	Specimen / Reagent Preparation
1.	Add 350 µl of sample diluent to one 12 X 75 mm test tube for each specimen to be tested.
2.	Mix stool thoroughly, regardless of consistency.

8.2	Test Run
8.2.1	**Liquid or Semi solid stool**
1.	Using a transfer pipette, draw stool to the 25 µl calibration point.
2.	Dispense the stool into the sample diluent in appropriate 12 X 75 mm tube.
3.	Using the same pipette, gently withdraw and expel the stool suspension several times.
4.	Vortex ten seconds.
5.	Leave transfer pipette in tube for further use. Proceed to the next step within 30 minutes.
6.	Do not pipette more than 25 µl of stool. Over-inoculation with stool may produce invalid results.
8.2.2	**Solid Stool**
1.	For solid stool: using a wooden applicator stick, transfer a 2 mm diameter portion of stool into the sample diluent in the appropriate 12 X 75 mm tube. For swabs: mix the swab into the diluent, ring out diluent from the swab.
2.	Emulsify the stool thoroughly using the applicator stick.
3.	Vortex ten seconds.
4.	Place transfer pipette in the tube. Proceed to the next step within 30 minutes.
8.2.3	
1.	Remove appropriate number of Immunocard STAT Rotavirus devices from their pouches.
2.	Label appropriately. Use one device per control or sample.
3.	Vortex each diluted specimen for ten seconds.
4.	Using the original specimen transfer pipette, draw diluted sample to the 150 µl calibration point and add to Sample port.
5.	Incubate ten minutes at 21 - 25° C. During the ten-minute incubation, diluted specimen must move past the Control zone.
6.	In a well-lit area, visually read Control and Test zones for the presence or absence of a red/purple line at the end of the incubation period.
7.	On occasion, a stool may have high levels of rotavirus antigen and will yield a visible test line and no visible control line. In such cases, the specimen may be diluted twofold or greater, beyond original 1:15 dilution and re-tested.

9. CALCULATIONS

N/A

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

10.1.1 Positive test result: visually detectable red/purple Test and Control lines. A positive result indicates the presence of rotavirus antigen.

10.1.2 Negative test result: visually detectable red/purple Control line. No red/purple Test line present. A negative result indicates that rotavirus antigen is absent or below the level of detection.

10.1.3 Invalid test result: no visually detectable red/purple Control line, with or without a visually detectable red/purple Test line.

10.2 Rounding

N/A

10.3 Units of Measure

N/A

10.4 Clinically Reportable Range (CRR)

N/A

10.5 Repeat Criteria and Resulting

IF the result is …	THEN…
Red/purple test and control lines	Positive
Red/purple control line. No red/purple test line present.	Negative
Red/purple test line. No red/purple control line present.	Invalid test. Perform an additional twofold dilution (1:30 final dilution) and repeat test.
No red/purple test or control lines	Invalid test. Run external controls and if acceptable, repeat test.

10.6 Reporting

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

Enter Shift: (1, 2, or 3)

Worksheet: Use SIM2

Test: <Enter>

Enter “A” (Accept)

Enter Accession number

Press <Enter> until Result screen is displayed

Enter Results as listed below:

IF the result is …	THEN report with LIS code
Positive	POS
Negative	NEG

11. EXPECTED VALUES

11.1 Reference Ranges

Negative

11.2 Critical Values

None established

12. CLINICAL SIGNIFICANCE

The ImmunoCard STAT Rotavirus Immunoassay is a rapid in vitro qualitative procedure for the detection of rotavirus antigen in human stool. The test can be used to aid in the diagnosis of rotavirus-associated gastroenteritis.

13. PROCEDURE NOTES

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

The Immunocard STAT Rotavirus test does not define the presence of rotavirus-associated gastroenteritis, but only demonstrates the presence of the antigen in stools. As with all *in vitro* diagnostic test procedures, test results should be interpreted by a physician in conjunction with other clinical information.

A positive result does not preclude the presence of other infective organisms.

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

N/A

14.2 Precision

N/A

14.3 Interfering Substances

The use of meconium stools in this assay is not recommended as their performance characteristics have not been evaluated.

14.4 Clinical Sensitivity/Specificity/Predictive Values

A negative test result does not exclude the possibility of Rotavirus infection as too small quantities of virus, obtaining sample too late in infection, or inadequate and improper sampling techniques may cause a false negative result.

Intestinal infection with bacterial pathogens may be present simultaneously with Rotavirus infection. Therefore, perform bacterial testing in parallel with the Rotavirus assay.

Results of this test should be interpreted in conjunction with information available from the clinical evaluation of the patient.

The ImmunoCard STAT Rotavirus test does not define the presence of rotavirus-associated gastroenteritis, but only demonstrates the presence of the antigen in stool.

The rate of positivity may vary depending on patient age, geographic location, season, method of specimen collection, handling, transport and general health environment of the patient population under study.

It has been reported that in neonates, when rotavirus was present, the disease was mild or totally asymptomatic. However, during cooler months, rotavirus may account for approximately 50% or more of the gastroenteritis found in hospitalized children.

In adults, the incidence of serious gastroenteritis caused by the virus is relatively low and when infected, adults tend to be asymptomatic. Studies from nursing homes and hospital geriatric wards show that this population is at an increased risk and susceptible to rotavirus associated disease.

15. SAFETY

The employee has 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 Environmental Health and Safety (EHS) Manual to learn the 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 needlesticks can result in serious health consequences. Attempt to find ways to eliminate your risk when working with sharp materials.

Report all accidents and injuries immediately to your supervisor or the business unit Environmental Health and Safety Manager or Specialist.

16. RELATED DOCUMENTS

Current package insert for Immunocard STAT Rotavirus
Rota Virus Quality Control Log (AG.F34)

17. REFERENCES

Immunocard STAT Rotavirus package insert, Meridian Diagnostics, 12/2001

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
			Supersedes SGAH.M008.003		
000	12/14/2010	6.3	Corrected QC frequency	R. Master	R. Master
		11.2	Title change to local terminology	L. Barrett	R. Master
		16	Moved Current PI to related docs	L. Barrett	R. Master
001	11/9/2012	6.1	Added description of internal control	R. Master	R. Master
002	4/22/2014	6.3	Changed external QC frequency	R. Master	R. Master
002		10.6	Added detail for LIS reporting	L. Barrett	R. Master
002		16	Log moved from section 19	L. Barrett	R. Master
002		Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13.	L. Barrett	R. Master

19. ADDENDA

None

Quest Diagnostics

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

ROTAVIRUS QUALITY CONTROL LOG

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 30 days, whichever is more frequent.
2. **Internal Controls** must be documented each time the test is performed.
3. If QC results are not acceptable, document corrective action. Do not accept patient results before reviewing QC results for proper reactions.

Temp. 21-25C	Date	Patient Name / MR#	Patient Result	Kit	Internal Negative Control	Internal Positive Control	External Positive Control		External Negative Control		Tech
				Lot # / Expire			Lot # / Expire	Result	Lot # / Expire	Result	

Weekly review:	Weekly review:	Weekly review:
Weekly review:	Weekly review:	Monthly review: