TRAINING UPDATE

Lab Location:	GEC, SGMC & WAH	**Date Distributed:**	7/21/2016
Department:	Core	**Due Date:**	8/31/2016
		Implementation:	**9/1/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

RSV Testing by Binax NOW® SGAH.M01 v1

RSV Quality Control Log AG.F33.4

Note: this has been converted to a system SOP

Description of change(s):

Section	Reason
Header	Add other sites
6.3	Changed ext. QC frequency to 31 days

QC frequency on log changed to 31 days

This revised SOP & FORM will be implemented on September 1, 2016

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

Technical SOP

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.

Form revised 2/2/07

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 Safety Data Sheet (SDS) 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 Safety Data Sheet (SDS) 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.

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.

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 31 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.

8.1	Specimen/Test Run
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.
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

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 Standard Report Messages

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
2	7/18/16	Header	Added other sites	L. Barrett	R. Master
2	7/18/16	6.3	Changed ext. QC frequency to 31 days	L. Barrett	R. Master

19. ADDENDA

None

RSV QUALITY CONTROL LOG

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

Next external QC is due = *Month* _____ *Circle day*

1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31

1. **External Positive and Negative Controls** are tested and documented with each new kit lot number or shipment or every 31 days, whichever is more frequent.
2. **Internal controls** must be documented each time the test is performed.
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: