LABORATORY NAME:	
LABORATORY ADDRESS:	
DATE OF THIS PACKET:	
INSERT REVISION:	IN430050 Rev. 08 2019/07

BinaxNOW™ RSV Card Laboratory Procedure

Re-order numbers: #430-100 BinaxNOW™ RSV Card 10 Test

#430-122 BinaxNOW™ RSV Card 22 Test

This procedure is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. **Any modifications to this document are the sole responsibility of the Facility.**

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA

Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

CLIA Complexity: Waived

ATTENTION: Do not use RSV test in patients 5 years or older.

1. INTENDED USE

The **BinaxNOW™** RSV Card is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (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 5. Negative test results should be confirmed by cell culture or DFA.

2. SUMMARY AND EXPLANATION OF THE TEST

RSV is a common cause of upper and lower respiratory tract infections and the major cause of bronchiolitis and pneumonia in infants and children. Infections and outbreaks due to RSV typically occur yearly in the fall, winter and spring. While RSV can cause significant respiratory illness in older children and adults, the disease tends to be milder in these populations than in infants and young children.

Rapid identification and diagnosis of RSV has become more important due to the availability of effective antimicrobial therapy. Rapid identification can lead to reduced hospital stays, reduction in antimicrobial use, and reduction in the cost of hospital care.[1]

The **BinaxNOW™** RSV Card provides a simple, rapid method for the diagnosis of RSV using nasal wash and nasopharyngeal swab specimens. The easy-to-use format and rapid results allow for its use in "STAT" testing where it can provide invaluable information to assist with treatment and hospitalization decisions.

3. TEST PRINCIPLE

The **BinaxNOW™** RSV Card is an immunochromatographic membrane assay used to detect RSV fusion protein antigen in nasal wash and nasopharyngeal swab specimens. 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 the test strip. This test strip is mounted on the right side of a cardboard, book shaped hinged test card.

Swab samples (controls and patients) require a preparation step, in which the sample is eluted off the swab into an appropriate solution. Nasal wash samples do not require any preparation.

To perform the test, the sample to be tested is added to the white pad at the top of the test strip, and the test card is closed. RSV antigen present in the sample reacts to bind anti-RSV conjugated antibody. The resulting antigen-conjugate complexes are captured by immobilized anti-RSV antibody, forming the Sample Line. Immobilized Control Line antibody captures a visualizing conjugate, forming a pink Control Line. The Control Line is blue in a card that has not been tested.

Test results are interpreted by the presence or absence of visually detectable pink-to-purple colored lines. A positive test result, read at 15 minutes, will include the detection of both a Sample Line and a Control Line. A negative test result, read at 15 minutes, will produce only a Control Line, indicating that RSV antigen was not detected in the sample. Failure of the Control Line to appear, or the Control Line remaining blue, indicates an invalid assay, whether the Sample Line is present or not.

4. SPECIMEN COLLECTION/TREATMENT

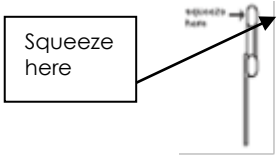
Use fresh NP swabs and nasal washes for best test performance.

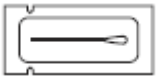
SPECIMEN:	Acceptable: NP Swabs (Nasopharyngeal Swabs) Nasal Washes
SPECIMEN COLLECTION:	**NP Swabs:** Use polyester, rayon, foam, cotton and flocked flexible shaft nasopharyngeal swabs to collect NP sample. Elute swab within one hour of collection in 0.5 – 3.0 ml of a suitable transport liquid. Test as soon as possible. **Nasal Washes:** Collect nasal washes in standard containers. Use procedures appropriate for the age of the patient. Test as soon as possible.
HANDLING/STORAGE/ TRANSPORT:	**NP Swabs:** Elute swab within one hour of collection in 0.5 - 3.0 ml of a suitable transport liquid. Test as soon as possible. Eluted swab samples can be held at 15-30˚C for up to 4 hours

	before testing. Eluted swabs can be held at 2-8˚C for up to 48 hours before testing. Allow samples to warm to room temperature before testing. Swirl gently to mix before testing. **<u>Nasal Washes:</u>** Washes can be held at 15-30˚C for up to 4 hours, or at 2-8˚C for up to 24 hours, before testing. Washes can be put in up to 3.0 ml of a suitable transport liquid before testing. Doing so will dilute wash samples. This dilution may result in test sensitivity that is lower than that shown in this insert. Allow samples to warm to room temperature before testing. Swirl gently to mix before testing. If needed, transport sample at 2-8˚C in a leak proof container.
TRANSPORT MEDIA:	The following transport media were tested and are acceptable for use in the **BinaxNOW™** RSV Card. Amies Media Brain Heart Infusion Broth Dulbecco Medium Hank's Balanced Salt Solution M4 Media M4-RT Media M5 Media Phosphate Buffer Solution Saline Stuart's Media Tryptose Phosphate Broth UTM-RT Media Veal Infusion Broth
HANDLING PRECAUTIONS	Patient samples, controls and test devices should be handled as though they could transmit disease. Observe established precautions against microbial hazards.

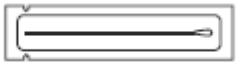
5. REAGENTS AND MATERIALS

Materials Provided

COMPONENT	CONTENT	QUANTITY
TEST CARDS 	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 card. The membrane of an untested card contains a blue line at the control line area.	10/22
TRANSFER PIPETTES 	Fixed volume (100 µl) transfer pipettes used to transfer sample to the test cards. Use only pipettes provided by or a calibrated pipette capable of delivering 100 µl sample volume.	10/22
POSITIVE CONTROL SWAB 	Inactivated RSV dried onto swab.	1

NEGATIVE CONTROL SWAB 	Inactivated *Streptococcus* Group A dried onto swab.	1
ELUTION SOLUTION VIALS FOR CONTROL SWABS/SWAB SPECIMENS 	Vials containing elution solution used to prepare the Control Swabs/Swab Specimens for testing. Do not use other elution solutions with the **BinaxNOW™** RSV Card Control Swabs.	10/22
NP SWABS 	Sterile swabs for use in the **BinaxNOW™** RSV Card.	10/22
PRODUCT INSTRUCTIONS		1

Nasopharyngeal (NP) swab specimen accessory pack (Available Separately)

NASOPHARYNGEAL SWABS 	Sterile swabs for use in the **BinaxNOW™** RSV Card.
ELUTION SOLUTION VIALS FOR SWAB SPECIMENS 	Vials containing elution solution used to prepare swab specimens for testing. Appropriate transport media or saline may be used in place of Elution Vials.

A. Materials Recommended But Not Provided

- Clock, timer, or stopwatch
- Nasal wash collection containers

6. STORAGE AND STABILITY

Store at 2-30˚C. The **BinaxNOW™** RSV Card kit and reagents are stable until the expiration date printed on the kit box.

7. QUALITY CONTROL

Daily Quality Control:

The **BinaxNOW™** RSV Card has built-in procedural controls. For daily quality control, suggests that you record these controls for each test run.

Procedural Controls:

A. An untested card has a blue line at the "Control" position. If the test has been done correctly and the reagents flow, this blue line will always turn pink in a tested card.

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 interfere with the reading of the test.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to guarantee that:

- test reagents are working; and
- the test is correctly performed.

BinaxNOW™ RSV Card kits contain Positive and Negative Control Swabs. These swabs will check for substantial reagent failure. The Positive Control will not ensure precision at the assay cut-off. Test these swabs once with each new shipment received. Other controls may be tested in order to conform with:

- local, state and/or federal regulations,
- accrediting groups, and/or,
- your lab's standard QC procedures.

Refer to 42 CFR 493.1256 for help on proper QC techniques (U.S. customers only). If the correct control results are not obtained, do not report patient results. Contact Technical Service during normal business hours.

8. PRECAUTIONS

1. For *in vitro* diagnostic use.
2. Leave test 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** (drop by drop) to the **MIDDLE** of this pad such that all of the sample volume (100 µl) absorbs into the pad. **DO NOT** add sample to the pink/purple 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 card. To ensure delivery of an adequate volume (100 µl), 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 card. 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.
8. When testing nasal wash samples, avoid viscous areas of the sample when drawing specimen into the transfer pipette. If the pipette becomes clogged, such that the lower shaft of the pipette is not full, expel the specimen back into container by squeezing the top bulb and redraw the specimen into the pipette. Use a new pipette if necessary.
9. Polyester, rayon, foam, cotton and flocked flexible shaft nasopharyngeal swabs, have been evaluated and found to be acceptable for use in the **BinaxNOW™** RSV Card. Do not use calcium alginate nasopharyngeal swabs in the **BinaxNOW™** RSV Card.
10. All transfer pipettes and elution solution vials are single use items – do not use with multiple specimens.
11. Elution solution contains Triton® X-100 and ProClin® 300. Warning. Causes serious eye irritation.
12. Safety Data Sheets for this product are available upon request.
13. Follow your national, regional, and local ordinances accordingly for waste disposal regulations.

9. SAMPLE AND CONTROL SWAB PREPARATION PROCEDURE

Nasal Washes:

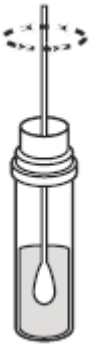
Nasal wash samples do not need preparation. Go to Test Procedure.

Nasopharyngeal Swabs:

Remove sample from swab in 0.5-3.0 ml of saline or media by rotating swab in the liquid. Go to Test Procedure. To use **BinaxNOW™** Elution Solution to elute swab, follow the Control Swab procedure below. Refer to Specimen Collection and Handling section (in the product instructions or Specimen Collection/Treatment section in this packet) for approved list of Transport Media.

Control Swabs:

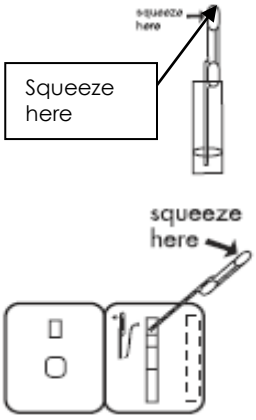
1. The test kit contains test vials pre-filled with elution solution. Twist off the test vial cap.
2. Put the swab to be tested into test vial. Rotate the swab vigorously (without making a lot of bubbles) three (3) times in the liquid.
3. Press the swab against the side of the vial and turn as you remove it from the vial. This removes sample from the swab.
4. Discard the swab.
5. Test the liquid sample (from the test vial) in the **BinaxNOW™** RSV Card as soon as possible. Go to Test Procedure.



10. TEST PROCEDURE

WARNING: INVALID RESULTS can occur when too little sample is added to the test. Be sure that the lower part of the transfer pipette is full and does not have any air spaces before you add the sample to the Sample Pad. If there are air spaces, put the sample back into the container by squeezing the top bulb. Redraw the sample from the bottom of the container into the pipette. Use a new pipette if needed.

1. Remove card from the pouch just prior to testing and lay flat on work bench.
2. Fill pipette by firmly squeezing the top bulb and then placing pipette tip into sample. Slowly 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 card to find the **WHITE** sample pad at the top of the test strip. **SLOWLY** (drop by drop) add entire contents of the pipette (100 µl) to the **MIDDLE** of this pad by squeezing the top bulb such that all of the sample volume absorbs into this pad. **DO NOT** add sample to the pink/purple colored pad.
4. Immediately peel off adhesive liner from the test card. Close and securely seal the card. Read result in window 15 minutes after closing the card.



Note: *Read test results under good lighting conditions. If necessary tilt the card to reduce glare on the result window.*

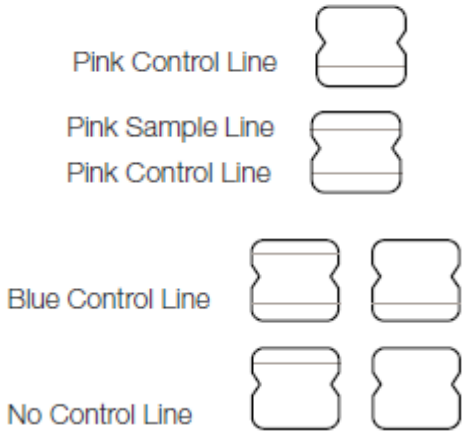
11. INTERPRETATION OF TEST RESULTS

Note: Do not read test results before or after 15 minutes as they may not be correct.

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.

For a **POSITIVE SAMPLE**, the BLUE Control Line turns a PINK TO PURPLE color. A second PINK TO PURPLE Sample Line appears above it. Any Sample Line, even when very faint, is positive.

A test is **INVALID** if the Control Line remains blue or is not present at all, whether a Sample line is present or not. Repeat an invalid test with a new test card. If the repeat test is also invalid, do not report test results. Call Technical Service during normal business hours.



12. REPORTING OF RESULTS

RESULT	SUGGESTED REPORT
POSITIVE	Positive for RSV antigen. A positive result may occur without the presence of live virus.
NEGATIVE	Negative for RSV antigen. Infection due to RSV cannot be ruled out. The antigen in the sample may be below the detection limit of the test. Negative test results should be confirmed by cell culture or DFA.

Notify Technical Service of any performance, perceived or validated, that does not meet test specifications described in the product insert (or this packet).

13. LIMITATIONS

1. A negative test result does not exclude infection with RSV nor is it intended to rule out other microbial-caused respiratory infections. Therefore, the results obtained with the **BinaxNOW™** RSV Card should be used in conjunction with clinical findings to make an accurate diagnosis.
2. The **BinaxNOW™** RSV Card 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.
3. Inadequate specimen collection or low levels of virus shedding may result in suboptimal performance and may yield false negative results.
4. **BinaxNOW™** RSV Card performance has not been evaluated in patients who have been treated with palivizumab. However, an analytical study has demonstrated that palivizumab interferes with the ability of the **BinaxNOW™** RSV Card to detect RSV.
5. The potential for interference from anti-microbials and interferon has not been established. Monoclonal antibodies may not detect all antigenic variants or new strains of RSV.

14. EXPECTED VALUES

The prevalence of RSV varies from year to year, with outbreaks typically occurring during the fall and winter months. The rate of positivity found in RSV testing is dependent on many factors including the method of specimen collection, the test method used, geographic location, and the disease prevalence in specific localities. In the 2002 clinical study, the average prevalence of RSV was 2% in wash samples and 4% in

nasopharyngeal swab samples. Prevalence of RSV in nasopharyngeal swab samples collected during the 2003 clinical study was 21%.

15. PERFORMANCE CHARACTERISTICS

ANALYTIC STUDIES

Analytical Reactivity:

There are 2 known subgroups of respiratory syncytial virus (RSV) and both contain the conserved fusion protein targeted by the **BinaxNOW™** RSV Card.[2] Six (6) subgroup A clinical isolates and five (5) subgroup B clinical isolates tested positive in the **BinaxNOW™** RSV Card at concentrations ranging from 1.56 x 10^{-1} $TCID_{50}$/ml to 5.00 x 10^{4} $TCID_{50}$/ml.

Note: The reported $TCID_{50}$/ml levels are dependent on a number of factors including the cell culture lines used, the number of passages performed and the efficiencies of the various isolates.

Analytical Specificity (Cross-Reactivity):

To determine the analytical specificity of the **BinaxNOW™** RSV Card, 48 commensal and pathogenic microorganisms (28 bacteria and 20 viruses) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations greater than 1 x 10^{5} $TCID_{50}$/ml (viruses) or greater than 1 x 10^{8} organisms/ml (bacteria). Metapneumovirus was tested at 2 x 10^{3} $TCID_{50}$/ml and did not cross-react.

BACTERIA	VIRUSES
Acinetobacter	Adenovirus 5*
Bordetella pertussis	Adenovirus 7*
Candida albicans	CMV*
Enterococcus faecalis	Coronavirus*
Escherichia coli	Coxsackie B4*
Gardnerella vaginalis	Influenza A 2 / Japan / 305 / 57
Haemophilus influenza	Influenza A / Hong Kong / 8 / 68
Klebsiella pneumonia	Influenza A / Aichi / 68
Lactobacillus casei	Influenza A / PR / 8 / 34
Legionella pneumophila	Influenza A / Victoria / 3 / 75
Listeria monocytogenes	Influenza A 1 / FM / 1 / 47
Moraxella catarrhalis	Influenza B Allen / 45
Neisseria gonorrhoeae	Influenza B Lee / 40
Neisseria meningitidis	Influenza B Mass / 3 / 66
Neisseria sicca	Influenza B Maryland / 1 / 59
Neisseria subflava	Influenza B Taiwan / 2 / 62
Proteus vulgaris	Metapneumovirus
Pseudomonas aeruginosa	Parainfluenza 1*
Serratia marcescens	Parainfluenza 2*
Staphylococcus aureus	Parainfluenza 3*
Staphylococcus aureus (Cowan protein A producing strain)	
Staphylococcus epidermidis	

Streptococcus, Group A
Streptococcus, Group B
Streptococcus, Group C
Streptococcus, Group F
Streptococcus mutans
Streptococcus pneumoniae

*These viral strains were obtained from American Type Culture Collection (ATCC) with titer information, and the titers were not verified by Abbott.

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated in the **BinaxNOW™** RSV Card at the concentrations listed and were found not to affect test performance.

SUBSTANCE	CONCENTRATION	SUBSTANCE	CONCENTRATION
Whole blood	2%	Diphenhydramine	5 mg/ml
3 OTC mouthwashes	25%	Guaiacol glycerol ether	20 mg/ml
3 OTC throat drops	25%	Oxymetazoline	10 mg/ml
3 OTC nasal sprays	25%	Phenylephrine	100 mg/ml
4-acetamidophenol	10 mg/ml	Phenylpropanolamine	20 mg/ml
Acetylsalicylic acid	20 mg/ml	Rebetol®	500 ng/ml
Albuterol	20 mg/ml	Relenza®	20 mg/ml
Chlorpheniramine	5 mg/ml	Rimantadine	500 ng/ml
Dextromethorphan	10 mg/ml	Tamiflu®	100 mg/ml

Clinical Studies:

Nasal Wash – Clinical Specificity (Prospective Study):

The performance of the **BinaxNOW™** RSV Card was compared to cell culture in a multi-center study conducted during the 2002 Flu season at physician offices and clinics located throughout the United States. Nasal wash specimens were collected from children and adults presenting with RSV-like symptoms for 3 days or less and evaluated in the test. The population tested was approximately 46% female and 54% male. Patients were not included in the study if they had received an influenza vaccine within 6 months of the enrollment period, or if they had taken either an influenza or RSV medication within 30 days of the enrollment period. There were no invalid tests reported.

One hundred ninety-one (191) nasal wash specimens were tested at 4 different test sites. **BinaxNOW™** RSV Card overall specificity was 98%, and overall test agreement was 98%. Ninety-five percent (95%) confidence intervals are listed below.

		WASH	
		VIRAL CULTURE	
		+	-
BINAXNOW™ RSV CARD	**+**	3	3
RESULT	**-**	1	184

			95% CI
SPECIFICITY	=	98% (184/187)	(95.4% - 99.4%)
OVERALL AGREEMENT	=	98% (187/191)	(94.7% - 99.1%)

The **BinaxNOW™** RSV Card performed similarly at the 4 test sites as shown in the table below.

	POSITIVE POINTS	**SPECIFICITY**		
	BinaxNOW™ RSV Card / Culture	**BinaxNOW™ RSV Card / Culture**	**%**	**95% CI**
SITE 1	1/1	91/94	97%	91.1 - 98.8
SITE 2	2/3	83/83	100%	95.7 - 100
SITE 3	0/0	6/6	100%	59.0 - 99.6
SITE 4	0/0	4/4	100%	47.8 - 99.5

Nasal Wash - Clinical Sensitivity and Specificity (Retrospective Study):

Since there were a low number of positive culture confirmed RSV infections generated during the prospective study, a retrospective study was conducted as follows. Nasal wash specimens from 47 viral culture positive RSV patients and 12 viral culture negative RSV patients were evaluated in the **BinaxNOW™** RSV Card. All of the samples were obtained from a large university medical center and had been collected from patients living in the northeastern region of the US. The population tested was approximately 49% male and 51% female.

BinaxNOW™ RSV Card sensitivity was 89%, while test specificity was 100%. Overall test agreement was 92%. Ninety-five percent (95%) confidence intervals are listed below.

		WASH	
		VIRAL CULTURE	
		+	-
BINAXNOW™ RSV CARD	**+**	42	0
RESULT	**-**	5	12

			95% CI
SENSITIVITY	=	89% (42/47)	(77.3% - 95.3%)
SPECIFICITY	=	100% (12/12)	(75.3% - 99.8%)
OVERALL AGREEMENT	=	92% (54/59)	(81.6% - 96.2%)

Nasopharyngeal Swab - Sensitivity and Specificity (Prospective Study):

The performance of the **BinaxNOW™** RSV Card on nasopharyngeal swab specimens was compared to cell culture/DFA in a multi-center US study conducted during the 2002 and 2003 flu seasons. Nasopharyngeal swab specimens were collected from children presenting with RSV or flu-like symptoms. All swab samples were placed in 0.5-3 ml of viral transport media prior to evaluation in the **BinaxNOW™** RSV Card. The population tested was 43% female and 57% male.

One hundred and seventy-nine (179) nasopharyngeal swab specimens were tested. There were no invalid tests reported. **BinaxNOW™** RSV Card sensitivity, specificity and overall agreement as compared to culture/DFA were 93%. Ninety-five percent (95%) confidence intervals are listed below.

		NASOPHARYNGEAL SWAB CULTURE/DFA	
		+	-
BINAXNOW™ RSV CARD	+	25	10
RESULT	-	2	142

			95% CI
Sensitivity	=	93% (25/27)	(76.5% - 97.7%)
Specificity	=	93% (142/152)	(88.3% - 96.4%)
Overall Agreement	=	93% (167/179)	(88.6% - 96.1%)

The **BinaxNOW™** RSV Card performed similarly at all test sites as shown in the tables below.

SENSITIVITY			
Site	**#**	**%**	**95% CI**
Site 1	14/15	93	69.8 - 98.4
Site 2	9/10	90	58.7 - 97.7
Site 3	0/0	NA	NA
Site 4	2/2	100	29.2 - 99.2

SPECIFICITY			
Site	**#**	**%**	**95% CI**
Site 1	69/74	93	85.1 - 97.0
Site 2	20/23	87	67.6 - 95.3
Site 3	16/18	89	66.9 - 96.6
Site 4	37/37	100	90.7 - 99.9

Reproducibility Study:

A blind study of the **BinaxNOW™** RSV Card was conducted at 3 separate sites using panels of blind coded specimens containing negative, low positive, and moderate positive samples. Participants tested each sample multiple times on 3 different days. One hundred percent (100%) of the 234 samples tested produced the expected result yielding a 95% confidence interval of 98.4 - 100%.

Consumer Precision Study:

Under CLIA, Abbott conducted Consumer Precision testing at three sites using proficiency panels consisting of 210 negative, limit of detection (LOD) positive and low positive samples.

Testing was performed with liquid samples only, not with swab samples. As indicated by the overlapping 95% confidence intervals in the tables below, no significant differences were observed between the lay user and expected results, demonstrating that users with no formal laboratory training can read the package insert and perform the test with a high level of precision.

RSV Sample Testing – Lay Users vs. Trained Laboratorians – Overall Results

PARTICIPANT TYPE	NEGATIVE- % NEGATIVE (95% CI)	LOD -% DETECTION (95% CI)	LOW POSITIVE – % DETECTION (95% CI)	% INVALID TESTS
Lay User	99% (67/68*) (92-100)	97% (64/66*) (90-99)	100% (67/67*) (95-100)	4.3% (9/210)
Trained Laboratorian	100% (60/60) (94-100)	100% (60/60) (94-100)	98% (59/60) (91-100)	0% (0/180)

*Invalid tests resulted in a reduced number of points graded on these sample types.

Note: Invalid test results can occur when an insufficient volume of sample is added to the test card due to misuse of the transfer pipette. Please see the Precautions Section (note #7) and the Test Procedure section (in the product instructions or this packet) for detailed instructions on the proper use of the transfer pipette.

RSV Sample Testing by Site – Lay Users and Trained Laboratorians

	SITE #	TOTAL # OF TESTS RUN	NEGATIVE-% NEGATIVE (95% CI)	LOD -% DETECTION (95% CI)	LOW POSITIVE – % DETECTION (95% CI)	% INVALID TESTS
Lay Users	1	75	100% (25/25) (87-100)	100% (24/24*) (86-100)	100% (25/25) (87-100)	1.3% (1/75)
	2	66	100% (21/21*) (85-100)	100% (22/22) (85-100)	100% (22/22) (85-100)	1.5% (1/66)
	3	69	95% (21/22*) (78-99)	90% (18/20*) (70-97)	100% (20/20*) (84-100)	10.1% (7/69)
Trained Laboratorian	1	180	100% (60/60) (94-100)	100% (60/60) (94-100)	98% (59/60) (91-100)	0% (0/180)

*Invalid tests resulted in a reduced number of points generated by these sites on these sample types.

16. REFERENCES

1. Williams, KM, Jackson MA, Hamilton M. Rapid Diagnostic Testing for URIs in Children: Impact on Physician Decision Making and Cost. Infect. Med. 19(3): 109-111, 2002.
2. Lopez, Juan A., R. Bustos, C. Orvell, M. Berois, J. Arbiza, B. Garcia-Barreno, J. Melero. Antigenic Structure of Human Respiratory Syncytial Virus Fusion Glycoprotein. Jr. of Virology, vol. 72, no. 8, August 1998, pp. 6922-6928.

Symbols

	℞ Only
Hazard Pictogram. See precautions.	Prescription Only

Ordering Information
Tel: 1 877 441 7440
Fax: 1 877 441 7441
Reorder numbers:
#430-100: BinaxNOW™ RSV Card 10 Test Complexity Waived
#430-122: BinaxNOW™ RSV Card 22 Test Complexity Waived
#400-065: BinaxNOW™ Nasopharyngeal Swab Specimen Accessory Pack
Technical Support
Advice Line
Further information can be obtained from your distributor, or by contacting Technical Support at 1 877 866 9340 **TS.SCR@abbott.com**

Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.abbott.com

Abbott

Test Procedure Approval and Review Sheet

PREPARED BY:	
DATE:	
SUPERVISOR REVIEW:	
DATE:	
LABORATORY DIRECTOR OR DESIGNEE APPROVAL:	
IMPLEMENTATION DATE:	
SUPERSEDES PROCEDURE DATED:	
DATE PROCEDURE RETIRED:	

LABORATORY DIRECTOR OR DESIGNEE	DATE REVIEWED	LABORATORY DIRECTOR OR DESIGNEE	DATE REVIEWED

BinaxNOW™ RSV Card Verification Form

ACCOUNT NAME: _____

ADDRESS: _____

_____

TELEPHONE: _____

BINAXNOW™
RSV CARD
LOT #/EXP: _____

DATE: _____

SUPERVISOR SIGNATURE: _____

Record the results from reference specimens below.

Record the Sample #, the **BinaxNOW™** RSV Card test results, Tester's Initials, and any comments. After the **BinaxNOW™** RSV Card test results have been recorded (positive or negative) then record the Expected Results (positive or negative).

SAMPLE #	EXPECTED RESULTS	**BINAXNOW™** RSV CARD RESULT	TESTER'S INITIALS	COMMENTS

BinaxNOW™ RSV Card Verification Form (Continued)

SAMPLE #	EXPECTED RESULTS	**BINAXNOW™** RSV CARD RESULT	TESTER'S INITIALS	COMMENTS

REVIEWED BY: _____ DATE: _____

LABORATORY DIRECTOR REVIEW AND APPROVAL FOR CLINICAL USE: _____

DATE: _____

BinaxNOW™ RSV Card External Quality Control

NAME OF FACILITY: _____

External QC testing is recommended:

- Run controls with each new shipment received.
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures.

DATE	**BINAXNOW™** RSV CARD KIT LOT/EXP	POSITIVE CTRL LOT/EXP	NEGATIVE CTRL LOT/EXP	POSITIVE RESULT	NEGATIVE RESULT	TESTER'S INITIALS	COMMENTS

REVIEWED BY: _____ DATE: _____

BinaxNOW™ RSV Card Internal Control and Patient Record

LOT NUMBER _____ **EXP. DATE** _____

Record the Date, Patient's Name, Patient Test Result, Internal Control Results and the Tester's Initials.

Positive Internal Control = The blue line at the "Control" position will turn pink, (pink-to-purple), if test and reagents are working correctly.

Negative Internal Control = The background color in the window should be light pink to white within 15 minutes and not interfere with the reading of the test.

DATE	PATIENT NAME	PATIENT ID NUMBER	PATIENT RESULTS	ARE THE INTERNAL CONTROL RESULTS INVALID OR VALID?		INTERNAL CONTROL RESULTS		COMMENTS	TESTER'S INITIALS
				INVALID	**VALID**	**+**	**-**		

REVIEWED BY: _____ DATE: _____

Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

QUALITY ASSESSMENT ACTIVITY	COMMENTS	DATE	INITIALS
Patient Test Management: Evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality Control: Assess control data, reference range verification, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency Testing: Review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of Test Results: Review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of Patient Test Information to Test Results: Evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with Patient's age, sex, diagnosis, and other test parameters.			
Personnel: Evaluate the effectiveness of policies and procedures for assuring employees competence of testing and reporting test results.			
Communications: Evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint Investigation: Evaluate documented complaints and corrective actions.			
Quality Assessment Reviews with Staff: Document discussion with Staff regarding identified problems and corrective actions during the QA review.			

Corrective Action Form

Problem/Error	Corrective Action

TECHNOLOGIST: _____ DATE: _____

SUPERVISOR: _____ DATE: _____

LABORATORY DIRECTOR: _____ DATE: _____

Temperature Log

EQUIPMENT: _____

NAME OF FACILITY: _____

To be recorded at the beginning of each workday. TEMPERATURE RANGE: _____

DATE	˚C	INITIALS	ADJUSTMENTS	DATE	˚C	INITIALS	ADJUSTMENTS

Tips for Successful Proficiency Testing (PT) Performance

- Strictly follow the PT provider's storage or handling requirement ***before testing PT specimens***.
- Analyze PT specimens ***within the time frame*** provided by the PT provider.
- Contact the PT provider ***promptly*** when specimens are received damaged. You may be able to receive a replacement immediately.
- Avoid clerical error when filling out PT answer sheets. Be sure to ***enter the correct result next to the correct analyte*** on the answer form.
- Remember to identify the instrument or method you are using to perform your PT so you are ***graded among your peer group***.
- Make copies of all answer forms ***before submitting them*** to your PT provider.
- Please contact Technical Support at 877-441-7440 or ts.scr@abbott.com for further information on proficiency providers.

Certification of Training

This is to verify that personnel responsible for running the **BinaxNOW™** RSV Card at _____ have been thoroughly in-serviced on the test and the test procedure. This has included:

- **Review of the package insert**
- **Demonstration of the product assay**
- **Successful performance of the BinaxNOW™ RSV Card and interpretation of results**

Names of the personnel who have been trained with the **BinaxNOW™** RSV Card and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature of Laboratory Director(s) responsible for personnel and testing:

_____ _____

SIGNATURE DATE

_____ _____

SIGNATURE DATE

_____ _____

TRAINER DATE

Testing Personnel Training Assessment

Test Method: BinaxNOW™ RSV Card

PROCEDURE	SATISFACTORY	UNSATISFACTORY	NOT APPLICABLE	COMMENTS / CORRECTIVE ACTIONS
Observation of Test Performance:				
Patient Sample Preparation (if applicable)				
Specimen Handling/Processing				
Testing				
Recording/Reporting Results				
Assessment of Test Performance Using Known Samples				
Review of Records:				
Patient/Quality Control Log Sheet Records				
Proficiency Testing Records				
Assessment of Problem Solving Skills				

(Attach all supporting documents)

EVALUATOR:_____ **DATE:**_____

EMPLOYEE:_____

BinaxNOW™ RSV Card Quiz

NAME:_____

DATE: _____

Circle T (True) or F (False) for each Question:

1.	The **BinaxNOW™** RSV Card kit needs to be refrigerated at 2° to 8°C.	T	F
2.	The **BinaxNOW™** RSV Card test device should not be removed from the foil pouch until just before use.	T	F
3.	Throat swabs are an acceptable sample type for testing on the **BinaxNOW™** RSV test.	T	F
4.	Nasal Wash samples may be stored at room temperature for 24 hours.	T	F
5.	Transport media may be used with the **BinaxNOW™** RSV Card test.	T	F
6.	The sample should be added quickly to the top of the white sample pad.	T	F
7.	Test results should be read at 15 minutes.	T	F
8.	Fresh NP swabs and nasal wash samples are the optimal sample types for the **BinaxNOW™** RSV test.	T	F
9.	If the Control Line remains BLUE in color, the test results are valid.	T	F
10.	The appearance of a pink-to-purple Control Line and a pink-to-purple Sample Line is a positive result.	T	F

BinaxNOW™ RSV Card Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	F	The **BinaxNOW™** RSV Card kit may be stored at 2-30ºC. The kit and reagents are stable until the expiration date printed on the kit box.
2.	T	The **BinaxNOW™** RSV Card should be left sealed in its foil pouch until just before use.
3.	F	Nasal Wash and Nasopharyngeal swabs are the accepted sample types for the waived **BinaxNOW™** RSV Card kit.
4.	F	Nasal wash samples may be held at room temperature (15-30ºC) for up to 4 hours and refrigerated (2-8ºC) up to 24 hours.
5.	T	Transport media may be used. Transport media that were tested and are acceptable for use in the **BinaxNOW™** RSV Card can be found in the Specimen Collection and Handling section in the Product Instructions or in the Specimen Collection/Treatment section in this packet.
6.	F	The sample should be added **SLOWLY** (drop by drop) to the **MIDDLE** of the White Sample Pad such that all of the sample volume absorbs into the pad.
7.	T	**BinaxNOW™** RSV Card test results should be read at 15 minutes after closing the card. Results read before or after 15 minutes may be inaccurate.
8.	T	The optimal sample types for the **BinaxNOW™** RSV Card test are fresh NP swabs and nasal washes.
9.	F	The Control Line must change from a blue color to a pink-to-purple color in order for the test result to be valid.
10.	T	A positive **BinaxNOW™** RSV Card test will have a pink-to-purple control line and a second pink-to-purple sample line above it.

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