



### Alere BinaxNOW RSV Antigen Kit

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Date: 07/22/2019

Document Control Number: MB.40.020.00

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Reviewed:		Date:	
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Retired:

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#### Kettering Health Network (KHN) Organization-Wide Policy

KHN adopts this policy for Kettering Medical Center, Sycamore Medical Center, Grandview Hospital and Medical Center/Southview Hospital, Greene Memorial Hospital, Inc., Soin Medical Center, Fort Hamilton Hospital, Troy Hospital, Kettering Physician Network, all hospital off-sites, and KHN Support Services.

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### I. PRINCIPLE

Respiratory Syncytial Virus (RSV) is a common cause of upper and lower respiratory tract infections and the major cause of bronchiolitis and pneumonia in infants and children, usually in the fall, winter, or spring. Rapid identification and diagnosis of RSV has become more important due to the availability of effective antimicrobial therapy. While RSV can cause significant respiratory illness in older children and adults, the disease tends to be milder in these populations making rapid identification unnecessary.

The Alere 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.

### II. SPECIMEN COLLECTION, TRANSPORT, AND HANDLING

#### A. Specimens

1. Nasopharyngeal swab
2. Nasal wash

#### B. Specimen Collection

##### 1. Nasopharyngeal swab

- a. Use polyester, rayon, foam, cotton, or flocked flexible shaft nasopharyngeal swabs to collect an 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.
  - 1) Eluted swab samples can be held at 15-30°C for up to 4 hours before testing.
  - 2) Eluted swabs can be held at 2 – 8°C for up to 48 hours before testing.

##### 2. Nasal wash

- a. Collect nasal washes in standard containers. Use procedure appropriate for the age of the patient. Washes may 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 a test sensitivity that is lower than that shown in the insert. Test as soon as possible.
  - 1) Washes can be held at 15 – 30°C for up to 4 hours before testing.
  - 2) Washes can be held at 2-8°C for up to 24 hours before testing.

**Allow samples to warm to room temperature before testing. Swirl gently to mix before testing.**

#### C. Specimen Handling

##### 1. Nasopharyngeal Swabs:

- a. To elute sample from swab swirl in Alere BinaxNOW® Elution Solution:
  - 1) Twist off the test vial cap.
  - 2) Put the swab to be tested into test vial.
  - 3) Rotate the swab vigorously (without making a lot of bubbles) three (3) times in the liquid.

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- 4) Press the swab against the side of the vial and turn as you remove it from the vial. This removes sample from the swab.
  - 5) Discard the swab.
  - 6) Test the liquid sample (from the test vial) in the Alere BinaxNOW® RSV Card as soon as possible. Go to section VI for the test procedure.
2. **Nasal Washes:**
- a. Nasal wash samples do not need preparation. Go to section VI for the test procedure.

#### D. Rejection Criteria

1. **Patient is  $\geq 5$  years old**

### III. MATERIALS

- A. BinaxNOW RSV Antigen Test Cards
- B. Transfer pipettes
- C. Elution Solution Vials for Swab Specimens
  1. Vials containing elution solution used to prepare the Control Swabs/Swab Specimens for testing. **DO NOT** use other elution solutions with the Alere BinaxNOW RSV Card Control Swabs.
- D. Nasopharyngeal (NP) swabs
- E. Nasal wash collection containers
- F. Positive Control Swab: Inactivated RSV dried onto swab.
- G. Negative Control Swab: Inactivated Streptococcus Group A dried onto swab.
- H. Clock, timer or stopwatch

### IV. STORAGE AND STABILITY

- A. Store kit at room temperature (2-30°C). The Alere BinaxNOW RSV Card kit and reagents are stable until the expiration date printed on the kit box.

### V. QUALITY CONTROL

- A. The Alere BinaxNOW RSV Antigen card contains both internal and external quality controls.
  1. **Internal Controls:** The internal quality controls are built-in to each test card and are performed with each test.
    - a. **Positive Control:** 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. **Negative Control:** The clearing of the background color in the window provides a negative background control. The background color in the window should be light pink to white within 15 minutes and should not interfere with the reading of the test.
  2. **External Controls:** The external quality control swabs are provided in the kit and must be run with each new lot or new shipment.
    - a. The Alere BinaxNOW RSV Card kits contain Positive and Negative Control Swabs.
      - 1) These swabs check for substantial reagent failure, as well as check that the test was performed properly.
      - 2) Do not use the kit if the positive and negative control swabs do not give expected reactions and contact the supervisor for further instructions.
    - b. Prepare the control swabs in the same manner as a nasopharyngeal swab, outlined in Section II-C.

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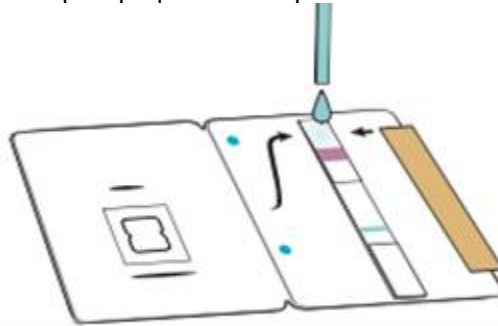
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### VI. PROCEDURE

- A. Remove card from the pouch just prior to testing and lay flat on work bench
- B. 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.**
- C. 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  $\mu$ l) to the **MIDDLE** of this pad by squeezing the top bulb so that all the sample volume absorbs into this pad.
  1. **DO NOT** add sample to the pink/purple colored pad.



- D. Immediately peel off adhesive liner from the test card. Close and securely seal the card.
- E. Read result in window 15 minutes after closing the card.

### VII. INTERPRETATION

- A. 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.
- B. For a **POSITIVE SAMPLE**, the **BLUE Control Line** turns a **PINK TO PURPLE** color. A second **PINK TO PURPLE Sample Line** appears above it.
  1. **Any Sample Line, even when very faint, is positive.**
- C. A test is **INVALID** if the **Control Line** remains blue or is not present at all, whether a **Sample line** is present or not.
  1. Repeat an invalid test with a new test card.
    - a. If the repeat test is also invalid, do not report test results.
    - b. Call Technical Service during normal business hours.

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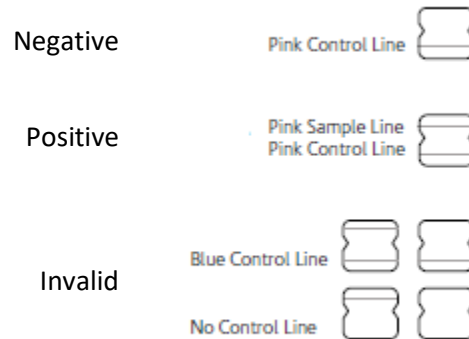
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### VIII. REPORTING RESULTS

#### A. Resulting in Epic Beaker

1. Select result entry and enter the specimen number.
  - a. Verify patient information matches patient information on the test card.
2. Click on "Edit"
3. Enter the result of positive or negative in the value box for the RSV Direct Antigen Test.
4. Enter the internal QC result as "pass" or "fail".
  - a. Note: Patient results should not be reported if the QC fails. The test should be repeated.
5. Final verify the results.

### IX. CRITICAL DETERMINANTS

- A. INVALID RESULTS can occur when too little sample is added to the test.
- B. Do not read test results before or after 15 minutes as they may not be correct.
- C. Read test results under good lighting conditions. If necessary, tilt the card to reduce glare on the result window.
- D. A negative test result does not exclude infection with RSV nor is it intended to rule out other microbial-caused respiratory infections.
- E. DO NOT mix reagent lots from different kits.

### X. REFERENCES

- A. Jorgensen, J. H., Pfaller, M. A., Carroll, K. C., Landry, M. L., Funke, G., Richter, S. S., et al. (2015). *Manual of Clinical Microbiology 11th Edition American Society for Microbiology*. Washington: ASM Press.
- B. Weber, A. L. (2016). *Clinical Microbiology Procedures Handbook 4th Edition American Society for Microbiology*. Washington: ASM Press.
- C. Alere BinaxNOW RSV Card Product Instructions. Product Insert.

### XI. FORMS ASSOCIATED WITH PROCEDURE

- A. MB.30.080.FA BinaxNOW RSV Quality Control

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