ALERE BINAX NOW® RSV TEST
(for Patient under the Age of 5)

PURPOSE:
This test is intended for in vitro diagnostic use to aid in the diagnosis of respiratory syncytial virus (RSV) infections in neonatal and pediatric patients under the age of 5. It is recommended that negative test results be followed up with confirmatory testing.

PRINCIPLE:
The Alere Binax NOW® RSV Test is a rapid immunochromatographic assay for the qualitative detection of respiratory syncytial virus (RSV) fusion protein antigen in nasal wash and nasopharyngeal swab specimens taken from symptomatic patients. The test is performed by applying the sample to the white pad at the top of the test strip. 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 device 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 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.

SCOPE
This test is performed in both inpatient and ambulatory settings. Do not use RSV test in patients 5 years or older.

PERSONNEL:
Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants, Physicians, Respiratory Tech. In the ambulatory setting, this includes the aforementioned personnel as well as Medical Assistants,
Licensed Vocational Nurses and other licensed Technologists. Personnel who have difficulties with color discrimination must demonstrate ability to read the test.

**EQUIPMENT & REAGENTS:**
Test Kit Components:
- Test Devices (42)
- Transfer Pipettes (42)
- Positive Control Swab (1)
- Negative Control Swab (1)
- Elution Solution vials (2)

Other Testing Equipment:
- Gloves
- Clock/Timer
- Nasal Wash Collection Container or Nasopharyngeal Swabs
- Saline

Storage and Handling
- Store kits at room temperature (59-86 F, 15-30 C).
- The test kit and reagents are stable until the expiration dates marked on their outer packaging and containers.
- Do not mix components from different kit lots.

**SPECIMEN REQUIREMENTS:**
Use fresh nasopharyngeal swab or nasal wash specimens for optimal test performance.

If testing is not performed immediately by the person collecting the specimen, then the sample must be labeled in the presence of the patient, using two forms of patient identification.

Nasopharyngeal Swabs:
Flocked, polyester, rayon, foam or cotton nasopharyngeal swabs, all with flexible shafts, may be used to collect the specimen. Add swab specimens to 0.5-3.0 ml of saline immediately after collection, rolling swab in the solution to elute sample.

Nasal Washes:
Collect nasal wash samples in standard collection cups. Use procedures appropriate for the age of the patient. Nasal washes do not need additional preparation.

**QUALITY CONTROL:**
Standard precautions must be practiced when performing testing.

**Daily Quality Control**
BINAX RSV provides built-in procedural controls with each test run. These built-in procedural controls must be documented on the log and in electronic medical record for each patient test.
1) 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.

2) 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.

If the blue Control Line does not change to pink, the test is invalid. Do not report results and repeat the test. Call the Point of Care Coordinator (353-1630) for assistance if procedural controls continue to fail.

External Quality Control
Each new kit must be tested for quality control using the Positive and Negative Control swabs.
1. Twist the vial cap off the pre-filled test vial.
2. Place the swab to be tested (positive or negative) into the test vial. Rotate the swab vigorously three 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 in the appropriate Biohazard container.
5. Test the liquid sample with a test device from the new kit (see Procedure below).
6. Record results on QC log.
7. Initial date and write “QC performed” on the box.
8. If either positive or negative test swab does not perform as expected, do not use kit for patient testing. Call Point of Care Coordinator (353-1630) or Binax Technical Support (800-323-3199) for aid in evaluating the problem.

PROCEDURE/PATIENT TESTING
Standard precautions must be practiced when performing patient testing or QC.

1. Using two patient identifiers, verify patient identification and explain the procedure to the patient and/or family.
2. Obtain sample.
3. Remove the test device from the pouch just prior to testing, and lay flat on workbench.
4. Fill pipette by firmly squeezing the top bulb and placing pipette tip into the liquid sample. Release bulb while tip is still in sample. This will pull liquid into the pipette.
5. SLOWLY add entire contents of pipette to the MIDDLE of the white sample pad by squeezing the top bulb.
   a. Caution: Invalid results can occur when too little sample is added to the sample pad. Ensure that lower part of transfer pipette is full and does not contain air bubbles.
6. Immediately peel off brown adhesive liner from the test device. Close and securely seal the device.
7. Read result in the window 15 minutes after closing the device.
   a. Caution: Results read before or after 15 minutes may not be correct.
8. Verify control line has changed from blue to pink/purple. If Control Line does not perform as expected do not report result. Repeat test and call Point of Care Coordinator (353-1630) or Binax Technical Support (800-323-3199) for aid in evaluating the problem.
RESULTS AND REPORTING

Positive Result
A positive test result occurs when the blue Control Line turns to a pink/purple color and a second pink/purple Sample Line appears above the Control Line.

Negative Result
A negative test result occurs when the blue Control Line turns to a pink/purple color in the lower half of the window and a second line does not appear.

Invalid Result
An invalid test occurs if the Control Line remains blue, or is not visible at all. Repeat the test with a new test device. If repeat test is not valid, do not report test results.

<table>
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<tr>
<th>CONTROL LINE</th>
<th>SAMPLE LINE (TEST RESULT)</th>
<th>INTERPRETATION</th>
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<tr>
<td>PINK</td>
<td>PINK</td>
<td>POSITIVE</td>
</tr>
<tr>
<td>PINK</td>
<td>NO COLOR</td>
<td>NEGATIVE</td>
</tr>
<tr>
<td>BLUE OR NO COLOR</td>
<td>PINK</td>
<td>DO NOT REPORT, REPEAT TEST</td>
</tr>
<tr>
<td>BLUE OR NO COLOR</td>
<td>NO COLOR</td>
<td>DO NOT REPORT, REPEAT TEST</td>
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Document both the patient result and the built-in procedural controls for each test. Record only valid results and report results to the provider.

Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

PROCEDURE NOTES:
Leave test device sealed in its foil pouch until just before use.

Use only Binax fixed volume pipettes (100ul) or calibrated pipette (100ul) to transfer specimen to test device.

To ensure optimum performance, add the sample slowly to the middle of the pad, such that all of the sample volume (100ul) absorbs into the pad.

INVALID RESULTS can occur when insufficient volume of specimen is added to the test device. To ensure adequate volume (100ul), make sure the lower shaft of the transfer pipette is full and does not contain air bubbles. If air spaces are present, expel specimen back into the container and redraw the specimen into the pipette. Use a new pipette if necessary.

When testing nasal wash samples, avoid viscous areas of the sample when drawing specimen into the transfer pipette. If air spaces are present, expel the specimen back into the container and re-draw the specimen. Use a new pipette if necessary.

You may use polyester, rayon, foam or cotton nasopharyngeal swabs to obtain specimens. **Do NOT use calcium alginate swabs.**

LIMITATIONS:
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 Alere BinaxNOW RSV Card should be used in conjunction with clinical findings to make an accurate diagnosis.

The Alere Binax NOW RSV test detects 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.

Inadequate specimen collection or low levels of virus shedding may result in sub-optimal performance and may yield false negative results.

Alere Binax RSV Card 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 Alere BinaxNOW RSV Test to detect RSV.

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.

REFERENCES:


BINAX NOW® RSV Test Package Insert Rev.12, 05/2012

Inverness Medical Professional Diagnostics Technical Bulletin, Release Date: 02 April 2009
**Signature Manifest**

**Document Number:** SOP-0097
**Revision:** 2
**Title:** Binax NOW RSV Test

All dates and times are in Pacific Standard Time.

### Binax NOW RSV procedure for review

#### SR Sup Review

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#### Med Dir Apprvl

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