**PURPOSE:** 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. Infections typically occur in the fall and winter months. RSV can also cause significant illness in older children and adults.

The Binax NOW RSV test is an immunochromatographic membrane assay used to detect RSV fusion protein antigen in nasopharyngeal specimens. RSV antigen in the specimen 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. Tests are interpreted by the presence or absence of pink-to-purple lines. A positive test shows a Sample Line and a Control Line. A negative test shows only a Control Line.

**SAMPLE INFORMATION:**

|  |  |
| --- | --- |
| **Type** | * Nasopharyngeal aspirate or swab submitted in Universal Transport Media (UTM). * Nasal swabs are also acceptable. |
| **Stability** | * Specimens can be stored at 2-8°C for up to 24 hours before testing. * Allow specimens to warm to room temperature before testing. |
| **Storage Requirements** | Refrigerated |
| **Criteria for rejection and follow up action** | 1. Unlabeled or mislabeled specimen 2. Specimen not properly collected |

**REAGENTS and/or MEDIA:**

|  |  |
| --- | --- |
| **Type** | BinaxNOW RSV Card |
| **Source** | Alere |
| **Volume** | 1 test device |
| **Stability** | Stable until date of expiration indicated on the package. |
| **Storage Requirements** | Store at room temperature. |
| **Criteria for rejection and follow up action** | Do not use if:   * Kit is past its expiry date. * Do not mix components from different kits. |

**SUPPLIES:**

* Small pipettes provided in kit
* Timer

**SPECIAL SAFETY PRECAUTIONS:**

Containment Level 2 facilities, equipment, and operational practices for work involving infectious or potential infectious materials or cultures.

* Lab gown must be worn when performing activities with potential pathogens.
* Gloves must be worn when direct skin contact with infected materials is unavoidable.
* Eye protection must be used when there is a known or potential risk of exposure of splashes.
* All procedures that may produce aerosols, or involve high concentrations or large volumes should be conducted in a biological safety cabinet (BSC).
* The use of needles, syringes and other sharp objects should be strictly limited.

All patient specimens are assumed to be potentially infectious. Universal precautions must be followed. Since viable micro-organisms are used, all cultures must be handled with appropriate precautions. All equipment in contact with cultures should be decontaminated by appropriate methods.

**QUALITY CONTROL:**

1. Internal Quality Control -

* An untested device has a blue line at the “Control” position. If the test flows and the reagents work, this blue line will turn pink.
* The clearing of background colour from the result window is a negative background control. The background colour in the window should be light pink to white within 15 minutes. Background colour should not hinder reading of the test.

1. External Quality Control -

Quality Control is set up with each new kit using the positive and negative control swabs included in the kit.

* A TQC order is automatically generated when a new kit is received in TQC to record QC results.
* If results are not acceptable, do not report patient results. Repeat QC testing.
* If repeat testing is acceptable, repeat patient testing and report results.
* If repeat testing is not acceptable:

1. Discard or return kit to manufacturer as directed.
2. Repeat QC testing with new kit.

|  |  |
| --- | --- |
| **Step** | **Action** |
| **Performing Binax NOW RSV quality control** | |
| **1** | Positive and negative control swabs are provided in the kit. These swabs monitor for reagent failure and for the correct performance of the test. Test the control swabs when opening a new test kit. |
| **2** | The test kit contains test vials pre-filled with elution solution. Label one of the vials “positive” and the other vial “negative”. Twist off the test vial cap. |
| **3** | Place the Positive Control swab into the test vial labelled “positive”. Place the Negative Control swab into the test vial labelled “negative”. Rotate the swab 3 times in the liquid. |
| **4** | Press swab against the side of the vial and turn as you remove it from the vial.  Discard the swab. |
| **5** | Test the liquid from the test vial in the Binax NOW test as soon as possible.  Go to step #2 in procedure if quality control testing is acceptable. |

**PROCEDURE INSTRUCTIONS:**

|  |  |
| --- | --- |
| **Step** | **Action** |
| **Performing Binax NOW RSV testing** | |
| **1** | **\*\*Perform all testing in the Biosafety Cabinet\*\*** |
| **2** | Allow sample to warm to room temperature before testing. |
| **3** | Mix specimen thoroughly by vortexing for 15 seconds. |
| **4** | Remove test device from foil pouch and label with LIS label. |
| **5** | Withdraw 100 µL of the well mixed specimen. Using the pipette provided in the kit, fill by firmly squeezing the top bulb and placing tip into the specimen. Release the bulb and ensure that there are no air spaces in the lower part of the pipette. |
| **6** | See arrow on test device to find **WHITE** sample pad. **SLOWLY** (drop by drop) add the specimen to the **MIDDLE** of this pad such that all of the sample volume absorbs into this pad. **DO NOT** add sample to the pink/purple colored pad. |
| **7** | Immediately peel off brown adhesive liner from the test device. Close and seal device. |
| **8** | Read results in window 15 minutes after closing the device. |
| **9** | Refer to interpretation of results below. |
| **10** | Positive results need to be sent to the Chief Medical Officer of Health and Infection Control. In order entry, copy report to Chief Medical Officer of Health (HPU1) and Infection Control (SOHS). |
| **11** | Send negative and positive specimens to the PLPH for confirmation by viral culture. Place in specimen receiving refrigerator on the “TDG area” shelf to be task listed by the MLA. |

**INTERPRETATION OF RESULTS:**

|  |  |
| --- | --- |
| **IF** | **THEN** |
| Pink-to-purple Control Line in the lower half of the window, no other line appears | **NEGATIVE** for RSV antigen |
| Pink-to-purple Control Line, and a pink-to-purple line in upper half of window | **POSITIVE** for RSV antigen |
| Control Line remains blue or is not present. Repeat with a new test device. | **INVALID** whether a sample line(s) is present or not:   * Repeat testing with a new test device. * Call Alere Technical Service if problem persists. |

**REPORTING RESULTS:**

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| --- | --- |
| **IF** | **THEN** |
| **Negative** for RSV antigen: | * **Report:** * NEGATIVE for RSV antigen by immunochromatographic assay * Sent to PLPH for confirmation by viral culture * A **VIRC** is automatically ordered after resulting of RSV |
| **POSITIVE** for RSV antigen: | * Report: * POSITIVE for RSV antigen by immunochromatographic assay * Sent to PLPH for confirmation by viral culture * A **VIRC** is automatically ordered after resulting of RSV * Phone results to ordering ward * Copy results to HPU1 * Copy results to SOHS if inpatient |
| **INVALID** results obtained | * **Report:** * INVALID testing results obtained by immunochromatographic assay * Sent to PLPH for viral culture * A **VIRC** is automatically ordered after resulting of RSV |

**PROCEDURE NOTES:**

* Contents of the pipette (the specimen) must be added **slowly** to the test device. Adding the specimen too fast will cause it to flow over the conjugate pad instead of through it. A positive specimen would then give a false negative result.
* Send negative and positive specimens to the PLPH for confirmation by viral culture.
* Any Sample Line, even when very faint, is positive.
* Leave test device sealed in its foil pouch until just before use.
* Solutions used to make the control swabs are inactivated using standard methods. However, patient samples, controls and test devices should be handled as though they could transmit disease.
* When testing nasal wash/aspirate 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.
* Calcium alginate swabs are not recommended for use in this test.
* RSV disease occurs with regularity in persons older than 5 years of age and can cause serious disease in the elderly.
* Palivizumab interferes with the ability of the Alere Binax NOW RSV card to detect RSV.

**LIMITATIONS:**

1. Invalid results can occur when an insufficient volume of specimen is added to the test device. Ensure that 100uL of specimen is added to the White Sample Pad.
2. Test detects viable and non-viable RSV.
3. Test performance depends on antigen load in the specimen and may not correlate with cell culture.
4. Inadequate specimen collection or low levels of virus shedding may result in a false negative result.
5. Results should be used in conjunction with other clinical information available to the physician.
6. A negative test result does not eliminate the possibility of an infection with RSV.
7. Visibly bloody specimens may not be appropriate for testing.

**REFERENCES:**

* Binax NOW RSV Test Kit package insert, 2017/03

**REVISION HISTORY:**

|  |  |  |  |
| --- | --- | --- | --- |
| **REVISION** | **DATE** | **Description of Change** | **REQUESTED BY** |
| 1.0 |  | Initial Release | L. Steven |
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