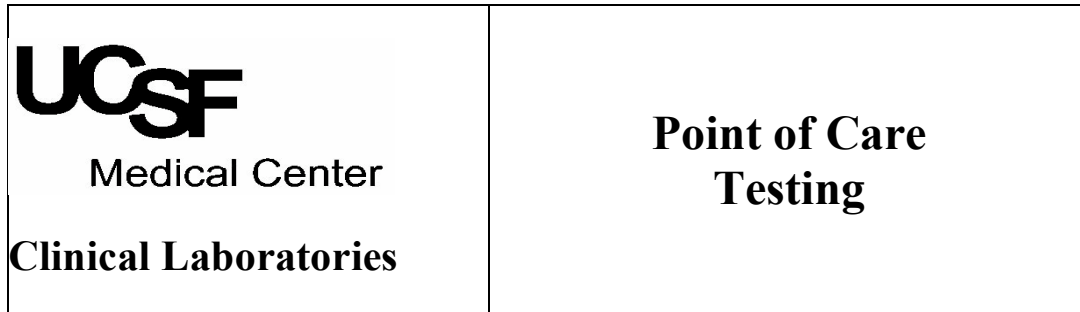


Director Approval _____ Date _____



BINAX NOW® RSV TEST

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 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.

PERSONNEL:

Intended for use by clinical personnel who have been trained and demonstrated competency in this procedure.

In the hospital setting, this includes:

- Registered Nurses,
- Nurse Practitioners,
- Physician Assistants, and
- Physicians.

In the ambulatory setting, this includes

- Hospital Assistants,
- Licensed Vocational Nurses,
- Registered Nurses,
- Nurse Practitioners,
- Physician Assistants, and
- Physicians.

Individuals who are color blind must demonstrate their ability to read the test results.

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:

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 procedural controls with each test run. These procedural controls must be documented on the Daily QC log, for the first patient tested each day of patient testing.

- 1) The blue Control line is an internal control. The Test strip must absorb the proper amount of sample and the Test strip must be working properly for the blue Control line to change to pink. For the Test strip to be working properly capillary flow must occur.
- 2) In the test window, the background clears to a light pink/white color and is considered an internal negative procedural 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.

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.

CONTROL LINE	SAMPLE LINE (TEST RESULT)	INTERPRETATION
PINK	PINK	POSITIVE
PINK	NO COLOR	NEGATIVE
BLUE OR NO COLOR	PINK	DO NOT REPORT, REPEAT TEST
BLUE OR NO COLOR	NO COLOR	DO NOT REPORT, REPEAT TEST

Record only valid results in the patient's medical record and report results to the provider.

PROCEDURE NOTES:

Leave test device sealed in it's 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.

The Binax 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.

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 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:

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Lopez, Jaun A., R. Bustos, C. Orvell, M. Berios, J. Arbiza, B. Garcia-Barreno, J. Melero. Antigenic Structure of Human Respiratory Syncytial Virus Fusion Glycoprotein. *Jr. of Virology*, vol.72, no.8, August 1988, pp. 6922-6928.

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