**DOCUMENT CONTROL**

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**Alere BinaxNOW® *Legionella* Urinary Antigen Test**

**Applicable Standards Version History**

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| **Standard** | **Organization** |  | **Version** | **Effective Date** | **Deactivation Date** |
|  |  | 1.0.0 | 04/01/2018 |  |
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| **Related Policies and/or Documents** |
| *Legionella Urinary Antigen Test Log* |
| *IQCP Alere BinaxNOW® Legionella Urinary Antigen Test* |
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**Alere BinaxNOW® *Legionella* Urinary Antigen Test**

**PURPOSE**

The Alere BinaxNOW® *Legionella* Urinary Antigen Card is an *In vitro* method for the rapid qualitative detection of *Legionella pneumophilia* serogroup 1 antigen in patient urine specimens. It is intended to aid in the presumptive diagnosis of *Legionella* infection in conjunction with other methods.

**PRINCIPLE**

*Legionella pheumophilia* causes 80-90% of reported cases of *Legionella* infection. Serogroup 1 accounts for greater than 70% of all legionellosis. Other laboratory methods for detection of *Legionella* require obtaining an adequate respiratory specimen, however one of the signs of legionellosis is the lack of productive sputum - making testing difficult. The Alere BinaxNOW® *Legionella* Urinary Antigen Test (L-UAT) allows for rapid detection of *Legionella pneumophilia* Serogroup 1 (LPS1) in an easily obtained urine specimen.

Patient urine is introduced to the test system via a test-specific swab and Reagent A is added. LPS1 antigen present in the specimen binds to anti-LPS1 antibody conjugated with visualizing particles. The resulting complex is captured by anti-LPS1 antibody immobilized along the test strip forming the Sample Line. Immobilized anti-species antibody captures anti-species conjugates to form the Control Line.

**REAGENTS AND MATERIALS**

1. Test Cards**:** A membrane coated with rabbit antibody specific for LPS1 antigen and with control line antibody is combined with rabbit anti-LPS1 antigen and anti-species conjugates in a hinged test card.
   1. Test Cards are sealed in a protective pouch. **DO NOT** use a card if the pouch is damaged or unintentionally opened.
   2. **DO NOT** touch the reaction area of the Test Card.
2. Reagent A: Citrate/Phosphate with Tween®20 and Azide.
3. Alere Swabs**:** Designed for use with the L-UAT. **DO NOT** use other swabs.
4. Positive Control Swab**:** Heat inactivated *L. pneumophilia* dried onto swab.
5. Negative Control Swab**:** *L. pneumophilia* negative swab.
6. Timer: A device capable of measuring and notifying user when 15 minutes has elapsed.
7. Urine specimen container: Any sterile-container intended for urinary specimen collection.

**STORAGE AND STABILITY**

Store kit refrigerated or at room temperature (36-86°F/2-30°C). The L-UAT card and reagents are stable until the expiration dates marked on their outer packaging and containers. **DO NOT** use any kit component past its labeled expiration date. Allow test kit components to equilibrate to room temperature prior to analysis.

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| **WARNING:** Inaccurate results may be obtained if refrigerated test components are not allowed to warm to room temperature. |

**QUALITY CONTROL**

1. Internal Control:
   1. The L-UAT device has built-in procedural controls.
   2. Positive Control: If proper capillary flow along the test device has occurred a pink-to-purple line will appear at the "Control" marker within the test period.
   3. Negative Control: The clearing of background color from the result window is a negative 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.
   4. For routine quality control, record these controls for each test performed. Record results in the L-UAT Log and in the LIS,

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| **WARNING:** Do not report specimen values if QC is not within expected range. Troubleshoot appropriately per protocol and rerun specimen. Only report results when acceptable QC is met per Laboratory protocol. |

1. External Control:
   1. The L-UAT kits contain Positive and Negative Control Swabs. These swabs monitor the entire testing process.
   2. Perform Positive and Negative external control in the following circumstances:
      1. Each new test kit.
      2. Each new untrained operator prior to performing tests on patient specimens.
      3. If the test kit is exposed to temperatures outside 2-30°C.
      4. If the testing area temperature falls outside 15-30°C.
   3. Record control results in the L-UAT Log, and if applicable, the LIS.

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| **WARNING:** Do not report specimen values if QC is not within expected range. Troubleshoot appropriately per protocol and rerun specimen. Only report results when acceptable QC is met per Laboratory protocol. |

1. Individualized Quality Control Plan:
   1. See IQCP for *Alere BinaxNOW® Legionella Urinary Antigen Test*

**SPECIMEN COLLECTION AND HANDLING**

1. Specimen Collection:
   1. Urine specimens should be collected in sterile-containers intended for urine specimen collection.
2. Specimen Handling and Storage:
   1. At room temperature (15-30°C), specimens may be tested up to 24 hours post collection.
   2. Refrigerated specimens (2-8°C) may be tested up to 14 days post collection.
   3. Boric acid is an acceptable specimen preservative.
   4. Allow specimens to equilibrate to room temperature prior to analysis.

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| **WARNING:** Inaccurate results may be obtained if refrigerated specimens are not allowed to warm to room temperature. |

**SPECIMEN REJECTION**

Specimens are ineligible for testing and are to be rejected if they meet any of the criteria described below:

1. Specimen has been stored at room temperature longer than 24 hours or refrigerated longer than 14 days post collection.
2. Specimen is not labeled with two unique patient identifiers (e.g. Full name, date of birth, medical record number, etc...)
3. Specimen volume is minimal and does not allow for the Alere Swab head to be fully submerged.
   1. Specimen may be transferred from the original collection container into a clean tube that increases the specimen depth, allowing the swab head to be submerged.

**TEST PROCEDURE**

1. Quality Control Swabs:
   1. Remove Test Card from its pouch immediately prior to use. Lay card flat on a stable surface.
   2. Remove Control Swab from its pouch.
   3. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole.
   4. Firmly push upwards so that the swab tip is fully visible in the **TOP** hole.
   5. **DO NOT** remove swab.
   6. Hold Reagent A vial vertically, 1/2-1 inch above the card.
   7. Slowly add **SIX** free falling drops of Reagent A to the **BOTTOM** hole.
   8. Promptly remove the adhesive liner from the right edge of the Test Card. Close and seal the card.
   9. **DO NOT** disturb Test Card or Control Swab.
   10. Read result window 15 minutes after closing the card - consult "Result Interpretation" section for directions. A positive result may be read anytime during the testing period, however a negative result cannot be identified until the 15 minute test period has elapsed.

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| 1. Patient Urine Specimens:    1. Remove Test Card from its pouch immediately prior to use. Lay card flat on a stable surface.    2. Gently mix urine specimen by swirling.    3. Dip an Alere swab into the urine specimen to be tested. Ensure swab head is fully submerged.  |  | | --- | | **NOTE:** The loaded swab should be saturated with urine, but not dripping. If swab drips upon removal from specimen lightly touch the swab head to the side of the specimen container to aid in discharge of excess urine. |  * 1. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole.   2. Firmly push upwards so that the swab tip is fully visible in the **TOP** hole.   3. **DO NOT** remove swab.   4. Hold Reagent A vial vertically, 1/2-1 inch above the card.   5. Slowly add **TWO** free falling drops of Reagent A to the **BOTTOM** hole.   6. Promptly remove the adhesive liner from the right edge of the Test Card. Close and seal the card.   7. **DO NOT** disturb Test Card or swab.      1. EXCEPTION: Alere swab shafts have been scored and may be snapped off **AFTER** closing the Test Card. Avoid dislodging the swab head from the well when doing so.      2. Read result window 15 minutes after closing the card - consult "Result Interpretation" section for directions. A positive result may be read anytime during the testing period, however a negative result cannot be identified until the 15 minute test period has elapse | a. b. |
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**RESULT INTERPRETATION**

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| 1. For a **NEGATIVE SAMPLE**, a single pink-to-purple colored Control Line will appear in the top half of the window. 2. For a **POSITIVE SAMPLE**, two pink-to-purple lines will appear in the window. One Control Line will be shown in the top half of the window and one Sample Line will be shown in the bottom half.  |  | | --- | | **NOTE:** Any visible pink-to-purple in the Control or Sample Lines is enough to consider the line the present. |  1. A test is **INVALID** if the Control Line is not present at all. Repeat **Invalid** tests with a new test device. Call Alere™ Technical Services if the problem persists    1. An **Invalid** result may occur when an insufficeint volume of Reagent A is add to the Test Card. Insure adequate volume delivery by holding the vial vertically with the tip 1/2-1 inch above the **BOTTOM** hole and add drops slowly. |  |
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**REPORTING OF RESULTS**

After the 15 minute testing period, interpret and record specimen results and internal QC in the L-UAT Log and the LIS.

1. **POSITIVE:** Presumptive positive for *L. pneumophilia* Serogroup 1 antigen in urine, suggesting current or past infection.
2. **NEGATIVE**: Presumptive negative for *L. pneumophilia* Serogroup 1 antigen in urine, suggesting no recent or current infection. Antigen may not be present in urine in early infection or the level of antigen present may be below the detection limit of the test. Infection with other serogroups and *Legionella* species may be present but are not detected by test method.

**LIMITATIONS**

1. The L-UAT has been validated using urine specimens only. The test cannot be used on environmental specimens (e.g. potable water).
2. The test will not detect infections cause be other *L. pneumophilia* serogroups or species.
3. A **Negative** result does not exclude infection with LPS1 as infection may be too early for LPS1 antigen to be present in urine or antigen concentration may be below the detectable limit of the test.
   1. Antigen may not be present in urine until after 3 days of onset of symptoms.
4. A **Positive** result can occur due to current or past infection and is not definitive for current infection.
   1. Antigen may be found in urine up to 1 year after infection.
5. Laboratory results should be used in conjunction with clinical findings to make an accurate diagnosis.
6. The L-UAT performance has not been evaluated on diuretic urine.
7. The L-UAT is intended for hospitalized patients only, No evaluation of an outpatient population has been performed.

**METHOD PERFORMANCE SPECIFICATIONS**

1. Do not use kit past its expiration date.
2. Do not mix components from different kits.
3. The L-UAT has been tested to have a sensitivity of 95%.
4. The L-UAT has been tested to have a specificity of 95%.
5. No discrete sources of cross-reactivity have been identified with the L-UAT.

**REFERENCES**

Alere BinaxNOW® *Legionella* Urinary Antigen Card Product Insert. IN852050 Rev 9 02/2017

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