Alere™

Alere BinaxNOW®
Legionella Urinary Antigen Card

Materials Provided

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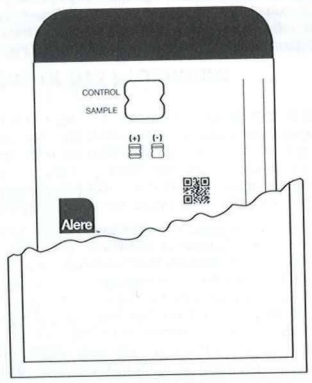

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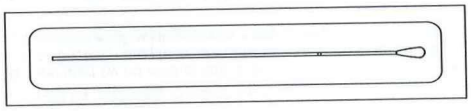

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Intended Use

The Alere BinaxNOW® *Legionella* Urinary Antigen Card (Alere BinaxNOW® *Legionella)* is an *in vitro* rapid immunochromatographic assay for the qualitative detection of *Legionella pneumophila* serogroup 1 antigen (*L. pneumophila* serogroup 1 antigen) in urine specimens from patients with symptoms of pneumonia. It is intended to aid in the presumptive diagnosis of *Legionella* infection (Legionnaires' Disease) caused by *L. pneumophila* serogroup 1 in conjunction with culture and other methods. Alere BinaxNOW® *Legionella* Urinary Antigen card can be read visually or used in conjunction with the Alere™ Reader.

Summary and Explanation of the Test

Legionnaires' Disease, named after the outbreak in 1976 at the American Legion convention in Philadelphia, is caused by *Legionella pneumophila* and is characterized as an acute febrile respiratory illness ranging in severity from mild illness to fatal pneumonia.[1] The disease occurs in both epidemic and endemic forms and sporadic cases are not easily differentiated from other respiratory infections by clinical symptoms. An estimated 25,000[2] to 100,000[3] cases of *Legionella* infection occur in the United States annually. The resulting mortality rate, ranging from 25% to 40%[2], can be lowered if the disease is diagnosed rapidly and appropriate antimicrobial therapy is instituted early. Known risk factors include immunosuppression, cigarette smoking, alcohol consumption and concomitant pulmonary disease.[2] The young and the elderly are particularly susceptible.[4-6]

Legionella pneumophila is responsible for 80-90% of reported cases of *Legionella* infection with serogroup 1 accounting for greater than 70% of all legionellosis.[2,7,8] Current methods for the laboratory detection of pneumonia caused by *Legionella pneumophila* require a respiratory specimen (e.g. expectorated sputum, bronchial washing, transtracheal aspirate, lung biopsy) or paired sera (acute and convalescent) for an accurate diagnosis. These techniques include *Legionella* culture, direct fluorescent antibody (DFA), DNA probe, and indirect fluorescent antibody (IFA). All of these rely on either obtaining an adequate respiratory specimen for sufficient sensitivity, or collecting sera at a two to six week interval. Unfortunately, one of the presenting signs of patients with Legionnaires' Disease is the relative lack of productive sputum.[8,9] In many patients, this necessitates the use of an invasive procedure to obtain a respiratory specimen. Diagnosis by serological techniques is usually retrospective in nature, and even then, patient compliance in obtaining the necessary specimen is poor.

Alere BinaxNOW® *Legionella* allows for early diagnosis of *Legionella pneumophila* serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires' Disease.[10-14] *Legionella pneumophila* serogroup 1 antigen has been detected in urine as early as three days after the onset of symptoms.[15] The test is rapid, giving a result within 15 minutes, and utilizes a urine specimen which is convenient for collection, transport, and subsequent detection of early, as well as later, stages of disease.[15]

Principles of the Procedure

Alere BinaxNOW® *Legionella* is an immunochromatographic membrane assay to detect *Legionella pneumophila* serogroup 1 soluble antigen in human urine. Rabbit anti-*Legionella pneumophila* serogroup 1 antibody, the patient line, is adsorbed onto nitrocellulose membrane. Control Line antibody, is adsorbed onto the same membrane as a second stripe. Both rabbit anti-*Legionella pneumophila* serogroup 1 antibodies and anti-species 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 and a well to hold the swab specimen are mounted on opposite sides of a hinged, book-shaped test card.

To perform the test, a swab is dipped into the urine specimen, removed, and then inserted into the test card. Reagent A is added from a dropper bottle. The card is then closed, bringing the specimen into contact with the test strip. *L. pneumophila* serogroup 1 urinary antigen captured by immobilized anti-*L. pneumophila* serogroup 1 antibody reacts to bind conjugated antibody. Immobilized control antibody captures anti-species conjugate, forming the control line. A positive test result is read visually in 15 minutes or less. A negative Alere BinaxNOW® *Legionella* result, read in 15 minutes, indicates that *L. pneumophila* serogroup 1 antigen was not detected in the urine specimen.

The test is interpreted by the presence or absence of pink-to-purple colored lines. A positive result will include the detection of both a patient and a control line, while a negative assay will produce only the control line. Failure of the control line to appear, whether the patient line is present or not, indicates an invalid assay.

Reagents and Materials

Refer to illustrations on pull-out flap.

Materials Provided

1. **Test Cards:** A membrane coated with rabbit antibody specific for *Legionella pneumophila* serogroup 1 antigen and with control antibody is combined with rabbit anti-*Legionella pneumophila* serogroup 1 antigen and anti-species conjugates in a hinged test card.
2. **Reagent A:** Citrate / Phosphate with Tween® 20 and Azide.
3. **Swabs**: Designed for use with Alere BinaxNOW® *Legionella*. **Do not use other swabs.**
4. **Positive Control Swab:** Heat inactivated *L. pneumophila* dried onto swab.
5. **Negative Control Swab:** *L. pneumophila* negative swab.

Materials Recommended But Not Provided

Clock, timer or stopwatch; standard urine collection containers; Alere™ Reader.

Accessory Item

Alere BinaxNOW® *Legionella* Urinary Antigen Control Swab Pack containing 5 positive and 5 negative control swabs.

Precautions

1. **INVALID RESULTS**, indicated by no control line, can occur when an insufficient volume of Reagent A is added to the test card. To insure delivery of an adequate volume, hold vial vertically, ½ - 1 inch above the swab well, and add drops slowly.
2. For *In Vitro* Diagnostic Use.
3. If the kit is stored in a refrigerator, allow all kit components to equilibrate to room temperature (15-30°C) before use.
4. The test card is sealed in a protective foil pouch. Do not use if pouch is damaged or open. Remove test card from pouch just prior to use. Do not touch the reaction area of the test card.
5. Do not use kit past its expiration date.

6. Do not mix components from different kit lots.
7. Swabs in the kit are approved for use with Alere BinaxNOW® *Legionella*. **Do not use other swabs.**
8. Solutions used to make the control swabs are inactivated using standard methods. However, patient specimens, controls, and test cards should be handled as though they could transmit disease. Observe established precautions against microbial hazards.
9. Refer to the Alere™ Reader User Manual, INLFR000, for operating instructions.

Storage and Stability

Store kit at 36-86°F (2-30°C). The Alere BinaxNOW® *Legionella* card and reagents are stable until the expiration dates marked on their outer packaging and containers. Do not use the kit beyond its labeled expiration date.

Quality Control

Daily Quality Control:

Alere BinaxNOW® *Legionella* contains built-in control features. The manufacturer's recommendation for daily quality control is to document these controls for each specimen run.

Positive Procedural Control

The pink-to-purple line at the "Control" position can be considered an internal positive procedural control. If capillary flow has occurred, this line will always appear.

Negative Procedural Control

The clearing of background color in the result 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 result.

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that:

- test reagents are working; and
- the test is correctly performed.

Alere BinaxNOW® *Legionella* kits contain Positive and Negative Control Swabs. These swabs will monitor the entire assay. Test these swabs with each new shipment received. Other controls may be tested in order to conform with:

- local, state and/or federal regulations;
- accrediting groups, and/or;
- your lab's standard Quality Control procedures.

Refer to 42 CFR 493.1256 for guidance on proper QC practices (U.S. customers only).

To use liquid controls, simply process as you would a patient specimen.

If the correct control results are not obtained, do not report patient results. Contact Technical Service during normal business hours.

Specimen Collection

Urine specimens should be collected in standard containers. The specimens can be stored at room temperature (59-86°F, 15-30°C) if assayed within 24 hours of collection. Alternatively, specimens may be stored at 2-8°C for up to 14 days or at -10°C to -20°C for longer periods before testing. Boric acid may be used as a preservative.

When necessary, urine specimens should be shipped in leakproof containers at 2-8°C or frozen.

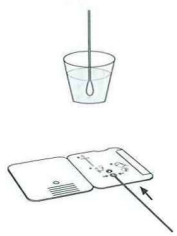
Allow all specimens to equilibrate to room temperature before testing on Alere BinaxNOW® *Legionella*.

Test Procedure Using Visual Interpretation

Procedure for Patient Specimens (and Liquid Urine Controls):

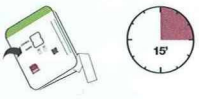
***Note**: Use 2 drops of Reagent A when testing liquid specimens.*
Do not remove card from pouch until the specimen has reached room temperature.

1. Allow reagents and cards to equilibrate to room temperature (15-30°C) before testing. Bring patient urine and/or liquid urine control(s) to room temperature (59-86°F, 15-30°C). Remove card from its pouch **just before use** and lay flat.
2. Dip an Alere™ swab into the urine specimen to be tested, completely covering the swab head. If the swab drips, touch swab to side of urine container to remove excess liquid.
3. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole (swab well). Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB.**



4. Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **two (2)** free falling drops of **Reagent A** to the **BOTTOM** hole.

5. Immediately peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Read result in window 15 minutes after closing the card. Results read beyond 15 minutes may be inaccurate. However, some positive patients may produce a visible specimen line in less than 15 minutes.



***Note**: For convenience, the swab shaft has been scored and may be snapped off **after** closing the card. Avoid dislodging the swab from the well when doing so.*

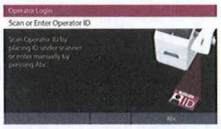
Test Procedure using the Alere™ Reader

Procedure for Patient Specimens (and Liquid Urine Controls):

***Note**: Use 2 drops of Reagent A when testing liquid specimens.*
Do not remove card from pouch until the specimen has reached room temperature.

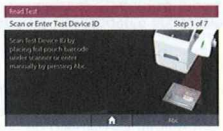
1. Allow reagents and cards to equilibrate to room temperature (15-30°C) before testing. Bring patient specimen(s) and/or liquid control(s) to room temperature (59-86°F, 15-30°C. Remove card from its pouch **just before use** and lay flat.
2. Turn on the Alere™ Reader by pressing the power button. Wait for approximately 10 seconds for the instrument start up sequence. For full instructions on using the Alere™ Reader please refer to Manual and Quick Start Guide. ***Note**: Ensure the correct tray for use with the Alere™ BinaxNOW Legionella test is in place in the drawer of the Reader.*

3. Enter Operator ID by placing Operator ID barcode under scanner or entering manually with the keyboard. Enter Operator Password and confirm by pressing 'OK'.

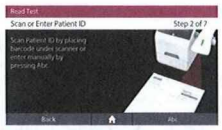


4. Select 'Read Test' on the Alere™ Reader menu. Pressing 'Read Test' on the display will start the reading process.

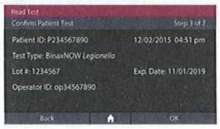
5. Remove card from the foil pouch just prior to testing and lay flat on work bench. Enter Test Device ID by scanning the barcode on the foil pouch, or manually enter the numerical number written below the barcode using the electronic keyboard by pressing Abc.



6. Enter Patient ID by scanning Patient ID barcode under scanner or entering manually with the keyboard.

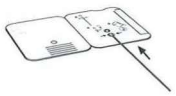


7. Confirm the data entry of User ID, Patient ID and Test Device ID on the screen and press 'OK' to confirm.



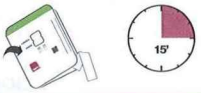
8. Dip an Alere™ swab into the specimen to be tested, completely covering the swab head. If the swab drips, touch the swab to the side of the collection container to remove excess liquid.

9. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole (swab well). Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB**.



10. Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **two (2)** free falling drops of **Reagent A** to the **BOTTOM** hole.

11. Immediately peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Gently snap off swab shaft which is purposely scored. Avoid dislodging the swab from the well when doing so.



12. At 15 minutes open the Reader drawer, insert test device into product specific tray insert and close drawer. A result will be displayed in approximately 15 seconds. **DO NOT OPEN THE DRAWER** until Test Results appear on the screen. ***Note**: Do not read Test Results before or after 15 minutes as they may not be correct.*

13. To print test result press 'Print'.

14. Open drawer, discard test device and close drawer. **DO NOT REINSERT TEST DEVICE ONCE A RESULT HAS BEEN OBTAINED.**

Procedure for Alere BinaxNOW® Swab Controls:

Procedure Using Visual Interpretation

Remove card from the pouch **just before use**. Lay card flat and run test as follows:

1. Allow reagents and cards to equilibrate to room temperature (15-30°C) before testing. There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole. Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB**.
2. Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **six (6)** free falling drops of **Reagent A** to the **BOTTOM** hole.
3. Immediately peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Gently snap off swab shaft which is purposely scored. Avoid dislodging the swab from the well when doing so. Read result in window 15 minutes after closing the card. Results read beyond 15 minutes may be inaccurate. However, the positive control swab specimen line may be visible in less than 15 minutes. ***Note**: For convenience, the swab shaft has been scored and may be snapped off **after** closing the card. Avoid dislodging the swab from the well when doing so.*

Procedure Using the Alere™ Reader

1. Allow reagents and cards to equilibrate to room temperature (15-30°C) before testing.
2. Turn on the Alere™ Reader by pressing the power button. Wait for approximately 10 seconds for the instrument start up sequence. For full instructions on using the Alere™ Reader please refer to Manual and Quick Start Guide.
3. Enter Operator ID by placing Operator ID barcode under scanner or entering manually with the keyboard. Enter Operator Password and confirm by pressing 'OK'.
4. Select 'Read QC Test' on the Alere™ Reader menu. Pressing 'Read QC Test' on the display will start the reading process.
5. Remove card from the pouch just prior to testing and lay flat on work bench. Enter Test Device ID by scanning the barcode on the foil pouch or manually enter the numerical number written below the barcode using the electronic keyboard by pressing Abc
6. Select whether a positive or negative control is to be tested and press "OK" to continue.
7. Confirm the data entry of User ID, Test type, Control type and Test Device ID on the screen and press 'OK' to confirm.
8. Lay card flat and run test as follows:
   a) There are two holes on the inner right panel of the card. Insert swab into the **BOTTOM** hole. Firmly push upwards so that the swab tip is fully visible in the top hole. **DO NOT REMOVE SWAB.**
   b) Hold Reagent A vial vertically, ½ to 1 inch above the card. Slowly add **six (6)** free falling drops of **Reagent A** to the **BOTTOM** hole.
   c) Immediately peel off adhesive liner from the right edge of the test card. Close and securely seal the card. Gently snap off swab shaft which is purposely scored. Avoid dislodging the swab from the well when doing so.
9. At 15 minutes open the Reader drawer, insert test device and close drawer. A result will be displayed in approximately 15 seconds. DO NOT OPEN THE DRAWER until QC Test Results appear on the screen. ***Note**: Do not read Test QC Results before or after 15 minutes as they may not be correct.*
10. To print test result press 'Print'.
11. Open drawer, discard test device and close drawer. **DO NOT REINSERT TEST DEVICE ONCE A RESULT HAS BEEN OBTAINED.**

Visual Result Interpretation

A **negative specimen** will give a single pink-to-purple colored Control Line in the top half of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test was done correctly, but no *L. pneumophila* serogroup 1 antigen was detected.

A **positive specimen** will give two pink-to-purple colored lines. This means that antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. **Any visible line is positive.**

If no lines are seen, or if just the Sample Line is seen, the assay is **invalid**. Invalid tests should be repeated. If the problem persists, contact Alere™ Technical Service.

Alere™ Reader Results Interpretation:

Results will be automatically displayed on the Alere™ Reader screen within 15 seconds of closing the test drawer. Results will be interpreted as positive or negative for *Legionella* antigen in addition to the procedural control line status.

Legionella antigen positive result

Legionella antigen negative result

Invalid test result

Reporting of Results

Result	Recommended Report
Positive	Presumptive positive for *L. pneumophila* serogroup 1 antigen in urine, suggesting current or past infection.
Negative	Presumptive negative for *L. pneumophila* serogroup 1 antigen in urine, suggesting no recent or current infection. Infection due to *Legionella* cannot be ruled out since other serogroups and species may cause disease, antigen may not be present in urine in early infection, and the level of antigen present in the urine may be below the detection limit of the test.

Limitations

Alere BinaxNOW® *Legionella* has been validated using urine specimens only. Other specimens (e.g., plasma, serum or other body fluids) that may contain *Legionella* antigen have not been evaluated. The test cannot be used on environmental specimens (i.e. potable water).

This test will not detect infections caused by other *L. pneumophila* serogroups and by other *Legionella* species. A negative antigen result does not exclude infection with *L. pneumophila* serogroup 1. Culture is recommended for suspected pneumonia to detect causative agents other than *L. pneumophila* serogroup 1 and to recover *L. pneumophila* serogroup 1 when antigen is not detected in urine.

The diagnosis of Legionnaires' disease cannot be based on clinical or radiological evidence alone. There is no single satisfactory laboratory test for Legionnaires' disease. Therefore, culture results, serology and antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.

Excretion of *Legionella* antigen in urine may vary depending on the individual patient. Antigen excretion may begin as early as 3 days after onset of symptoms and persist for up to 1 year afterwards.[15] A positive Alere BinaxNOW® *Legionella* result can occur due to current or past infection and therefore is not definitive for infection without other supporting evidence.

Performance of Alere BinaxNOW® *Legionella* on diuretic urine has not been evaluated.

Alere BinaxNOW® *Legionella* has been evaluated on hospitalized patients only. An outpatient population has not been tested.

Performance Data

Clinical Sensitivity and Specificity (Retrospective Study):

Alere BinaxNOW® *Legionella* was used to evaluate 300 frozen archived patient urine specimens at a large University. One hundred (100) of these patients were positive for *Legionella pneumophila* serogroup 1 infection as determined by culture, DFA, RIA and/or IFA (4X titer).

Overall agreement of Alere BinaxNOW® *Legionella* with laboratory diagnosis was 95%. Sensitivity and specificity were each 95%. Ninety five percent (95%) confidence intervals are listed below:

		Laboratory Diagnosis	
		+	–
Alere BinaxNOW® Result	+	95	10
	–	5	190

Sensitivity = 95% (88.7% - 98.4%)
Specificity = 95% (91.0% - 97.6%)
Accuracy = 95% (91.9% - 97.2%)

Clinical Specificity (Prospective Study):

In a multi-site study, 93 fresh urine specimens collected from hospitalized patients with lower respiratory symptoms or sepsis were tested in Alere BinaxNOW® *Legionella*. One hundred percent (100%) of these presumed negative patients produced negative Alere BinaxNOW® *Legionella* results, indicating that Alere BinaxNOW® *Legionella* is highly specific in the population for which it is intended.

Cross-Reactivity:

Of the 200 negative urine specimens tested, 85 were from patients with bacteremic pneumonia (other than *Legionella* spp.), 84 with urinary tract infections, 14 with mycobacterial infections, 5 with empyema, 11 with other pulmonary conditions, and 1 with pneumonia caused by a transtracheal aspirate.

One hundred ninety (190) of these patient specimens produced negative results in Alere BinaxNOW® *Legionella* yielding a specificity of 95%.

Reproducibility Study:

A blind study of Alere BinaxNOW® *Legionella* was conducted at 3 separate sites using a panel of coded specimens. The proficiency panels contained negative, low positive, moderate positive, and high positive specimens. Specimens both with and without boric acid were tested. Each specimen was tested multiple times at each site on 3 different days. Six hundred twenty-nine (629) of the 630 total specimens tested produced the expected result.

Ordering and Contact Information

Reorder numbers:

#852-012: Alere BinaxNOW® *Legionella* Urinary Antigen Card (12 test kit)
#852-100: Alere BinaxNOW® *Legionella* Urinary Antigen Card (22 test kit)
#852-010: Alere BinaxNOW® *Legionella* Urinary Antigen Control Swab Pack
#LFR-000: Alere™ Reader

OUS +1-321-441-7200

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Alere™ Technical Support on:

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References

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www.alere.com

CE

Positive

Negative

INV Invalid

IN852100 Rev. 2 2017/02