

BinaxNOW® Legionella Test

One of the most widely recognised rapid urine tests in the world due to sensitivity, specificity and ease of use

Urinary antigen tests recommended by Infectious Diseases Society of America¹⁰

Performance as good as traditional methods*

Methodology	Component Detected	Sample Type	Sensitivity	Specificity	Turnaround Time
Culture	Organism	Sputum	Gold Standard [†]		4-10 days
BinaxNOW® Legionella	Antigen	Urine	95%	95%	15 minutes
DFA	Organism	Sputum	25% – 70%	>95%	40-60 minutes
Serology/IFA	Antibody	Serum	40% – 60%	>95%	60-90 minutes

*Sensitivity and specificity data for methodologies listed were obtained through comparison to clinical diagnosis including culture.

[†]A College of American Pathologists survey of labs showed that only 32% successfully identified a pure culture of L. pneumophila.

References:

1. Marston BJ, Lipman HB, Breiman RF. Surveillance for Legionnaires' Disease: risk factors for morbidity and mortality. *Arch Intern Med* 1994;154:2417-2422.
2. Horwitz MA, Marston BJ, Broome CV, et al. Prospects for vaccine development. Presented at the 4th International Symposium on Legionella, 1992. In: Barbaree JM, Breiman RF, DuFour AP, eds. *Legionella: Current Status and Emerging Perspectives*. Washington, D.C. American Society for Microbiology, 1993.
3. Fraser DW, Tsai TR, Orenstein W, et al. Legionnaires' disease: description of an epidemic of pneumonia. *N Engl J Med* 1977;297:1189-1197.
4. Yu VL, Greenberg RN, Zadekis N, et al. Levofloxacin efficacy in the treatment of community-acquired legionellosis. *Chest* 2004;125:2135-2139.
5. Stout JE, Yu VL. Hospital-acquired Legionnaires' disease: new developments. *Curr Opin Infect Dis* 2003;16:337-341.
6. Stout JE, Yu VL. Legionellosis. *New Engl J Med* 1997;337:682-697.
7. Edelstein PH. Legionnaires' Disease. *Clin Infect Dis* 1993;16:741-749.
8. Reingold AL, Thomason BM, Brake BJ, et al. Legionella pneumonia in the United States: the distribution of serogroups and species causing human illness. *J Infect Dis* 1984;149:819.
9. Kohler RB, Winn, Jr, WC, Wheat LJ. Onset and duration of urinary antigen excretion in Legionnaires' disease. *J Clin Microbiol* 1984;20:605-607.
10. Mandell LA, Bartlett JG, Dowell SF, et al. Update of practice guidelines for the management of community-acquired pneumonia in immunocompetent adults. *Clin Infect Dis* 2003;37:1405-1433.

Ordering Information:

- 852-012 BinaxNOW® Legionella Urinary Antigen Test (12 test kit)
- 852-000 BinaxNOW® Legionella Urinary Antigen Test (22 test kit)
- 852-010 BinaxNOW® Legionella Urinary Antigen Control Swabs (5 each positive and negative swabs)

Other BinaxNOW Tests:

- BinaxNOW® Influenza A & B
- BinaxNOW® RSV
- BinaxNOW® Strep A
- BinaxNOW® S. pneumoniae
- BinaxNOW® Malaria
- BinaxNOW® Filariasis (not available in US or EU)

Distributed by:

Unipath Limited, Bedford MK44 3UP, United Kingdom
Tel: +44 (0)1234 835000 Fax: +44 (0)1234 835009



Binax, Inc. 10 Southgate Road, Scarborough, Maine 04074



BinaxNOW®

Legionella

It may masquerade as other pneumonias...

...but its true identity must be detected fast

When the result is critical...

...so is the test

www.binax.com



Legionella

Legionnaires' Disease is more prevalent than you might think

BinaxNOW® Legionella Test

A rapid immunochromatographic (ICT) assay for detection of *Legionella pneumophila* serogroup 1 antigen in urine



Legionella – a leading cause of both community-acquired and nosocomial bacterial pneumonia

- 25,000¹ to 100,000² cases of Legionnaires' Disease occur in the US each year
- Legionnaires' Disease can present ranging from mild respiratory illness to fatal pneumonia³
- Differentiation of Legionnaires' Disease from other respiratory infections based on clinical symptoms is difficult – only 3% of sporadic cases are correctly diagnosed⁴
- Infection is not restricted to elderly, smokers and those with pulmonary conditions – new risk groups have been identified^{4,5}
 - Immunocompromised pediatric patients
 - Younger people without known risk factors
- Rapid diagnosis and appropriate antimicrobial therapy can lower the significant mortality rate – 25% to 40%¹ – associated with this disease

Current laboratory methods of diagnosis are inconvenient and slow in providing results

- Culture, DFA, IFA and DNA probe require a respiratory specimen
 - Expecterated sputum
 - Bronchial washing
 - Transtracheal aspirate
 - Lung biopsy
 - Paired sera (acute and convalescent)
- Patients with Legionnaires' Disease characteristically have a lack of productive sputum^{6,7}
- Can necessitate an invasive procedure to obtain respiratory specimen
- Patient compliance can be poor

Legionella pneumophila causes 80% to 90% of all cases, and serogroup 1 accounts for over 70% of all infection^{1,6,8}

Rapid

- Results seen in 15 minutes
- Enables immediate, targeted therapy with a pathogen-specific antimicrobial
- Early treatment can improve patient outcomes and decrease mortality

Easy to use

- Simple, time-saving procedure
- Non-invasive urine specimen
- Self-contained, swab-based device – no tubes or pipettes

Easy to interpret

- Objective, qualitative results
- No subjective assessment required

Accurate

- High specificity and sensitivity
- Detects early, as well as later, stages of disease⁹
- Previous antibiotic therapy has minimal affect on performance
- Both built-in and external positive and negative controls ensure test viability

