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BINAXNOW™

Legionella urinary antigen card

All adult patients with severe CAP should be investigated with blood and sputum samples for culture and UAT for *Legionella pneumophila* and *Streptococcus pneumoniae* to help guide treatment decisions.[1]

THE BINAXNOW™ *LEGIONELLA* TEST DELIVERS ACCURATE, TIMELY RESULTS

- Highly sensitive and specific.
- Detects *Legionella pneumophila* serogroup 1 antigen.
- Results in 15 minutes.
- No sample prep and no multiple pipetting, mixing or vortexting steps.
- Enables timely and accurate guidance of appropriate therapy.

TEST PERFORMANCE [11, 12]

UAT METHOD	SAMPLE	SAMPLE PREP	TEST PERFORMANCE	TEST TIME	SAMPLE STORAGE
BinaxNOW *Legionella*	Urine	None	95% Sensitivity 95% Specificity	15 minutes	Room temp up to 24 hours
Meridian TRU *Legionella*	Urine	Multiple pipetting and mixing (or vortexing) steps	95% Positive agreement 100% Negative agreement (to BinaxNOW®)	20 minutes	2-8°C at all times

INDEPENDENT STUDY DATA

In an independent study at the national *Legionella* testing center in France, the BinaxNOW™ *Legionella* test showed a 13% greater sensitivity as compared to the Meridian TRU LEGIONELLA® assay, and represents the only head to head comparison study of the two methods conducted by an independent laboratory.[13]

UAT METHOD	SENSITIVITY	SPECIFICITY
BinaxNOW *Legionella*	100%	100%
Meridian TRU *Legionella*	86.8%	98.9%

IDSA = Infectious Diseases Society of America
ATS = American Thoracic Society

LEGIONELLA IS A SERIOUS THREAT

- *Legionella* is a leading cause of waterborne disease outbreaks.[4]
- Every case is a reportable event to state health departments and is tracked by the CDC.
- Incidence has increased over 5-fold from 2000 to 2017.[5,6]

LEGIONELLA EXPOSURE FREQUENTLY OCCURS IN HEALTHCARE FACILITIES

- 76% of locations reporting *Legionella* confirmed a healthcare facility as the source.[2]
- 2/3 of outbreaks occur in hospitals, healthcare facilities, and nursing homes.[4]

LEGIONELLOSIS OFTEN REQUIRES HOSPITALIZATION, WITH HIGH COSTS AND HIGH MORTALITY

- Up to 98% of patients require hospitalization, and up to 44% require care in the ICU.[2]
- The average hospital stay is 10.2 days.[8]
- Costs nearly $43,000 per case.[9]
- 25% of patients will die if acquired in a healthcare facility.[2]
- Settlements and jury awards range from $255,000 to $5.2 million.[10]

AN ACCURATE DIAGNOSIS ENABLES APPROPRIATE ANTIBIOTIC THERAPY

- Facilitates targeted treatment and antibiotic stewardship.[1]
- Consistent with recommended guidelines for pathogen directed therapy.[1]

TARGETED TREATMENT IMPROVES OUTCOMES IN CAP

Clinical trials show targeted treatment helps reduce symptoms, length of stay, and infection rates.

- Fever duration was shortened by 2.5 days.[14]
- Time to patient clinical stability was improved by 2 days.[14]
- Length of stay was reduced by 2.1 days, a 35% reduction.[3]
- Incidence of *C.difficile* was lowered by up to 60%.[15]

MISSED *LEGIONELLA* INCREASES EXPOSURE TO SIGNIFICANT RISKS

- Mortality.[2]
- Extended hospital stays.[8]
- Outbreak of healthcare-acquired infection.[2]
- Inappropriate antibiotic use.[1]
- Antibiotic resistance.[1]
- *C. difficile* infections.[15]

Projected Impact of Reduced Test Accuracy

For every 800 patients tested for *Legionella* with a 5.4% prevalence rate[16], a test with a 5% lower sensitivity (90% vs. 95%) may:

Increase false negatives by 50% (2 patients)

Delay time toappropriate treatment

Add a total of 4.2 days for hospital stay

Increase total cost of care by nearly $20,000

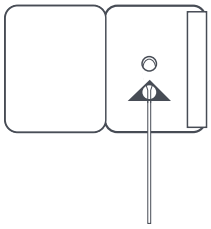
Calculations based on 2.1 additional hospital stay days per patient[3], at $4,200 cost per day[8,9]. Time and costs relate to hospital stay only, and do not include projections associated with other risks in the presence of false negatives.

Urinary Antigen Testing (UAT) for Community Acquired Pneumonia (CAP) is recommended by the IDSA and ATS[1]

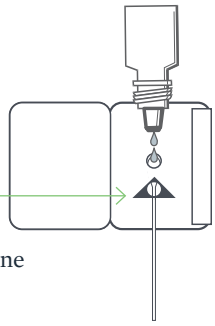
For a deadly disease that carries significant patient and healthcare system risks, accurate *Legionella* testing is critically important for appropriate treatment decisions and improved outcomes.[1,2,3]

PROCEDURE — EASY TO USE AND EASY TO READ

1 Dip swab into urine specimen. Then place swab into device.

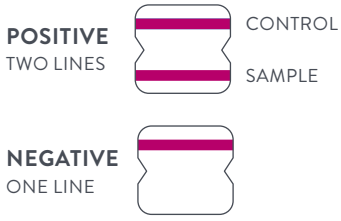


2 Add reagent then close the device and break swab at perforated line.



3 Wait 15 minutes.

4 Results can be read visually.



For complete instructions for use, see the package insert.

ORDERING INFORMATION

PRODUCT NAME	PRODUCT CODE
BinaxNOW™ *Legionella* urinary antigen card	
22 Test Kit	852-000
Control swab pack— 5 positive and 5 negative	852-010
BinaxNOW™ *Streptococcus pneumoniae* antigen card	
22 Test Kit	710-000
Control swab pack— 5 positive and 5 negative	710-010

The BinaxNOW™ *S. pneumoniae* Antigen Card is available as a complementary test to BinaxNOW™ *Legionella* Urinary Antigen Card for ease of compliance with IDSA/ATS CAP guidelines.

When avoidance of patient and healthcare system risks warrant proven performance and utility, use the BinaxNOW™ *Legionella* test.

- Test performance compared to cell-culture has been determined in clinical trials.[11,12]
- Clinical impact has been assessed in a randomized, controlled clinical trial.[3]
- Urine samples can be stored at room temperature for up to 24 hours.[11]
- No sample preparation, vortexing, or pipetting is required.[11]
- No urine concentration or heating necessary to increase sensitivity.[11]
- Results available in 15 minutes.[11]

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15. Wenisch JM, et al. Decreasing *Clostridium difficile* Infections by an Antimicrobial Stewardship Program That Reduces Moxifloxacin Use. Antimicrob. Agents Chemother. 2014 Sep; 58(9): 5079–5083.
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FOR MORE INFORMATION, CONTACT YOUR LOCAL ABBOTT REPRESENTATIVE.

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