

COUNTY OF SAN LUIS OBISPO PUBLIC HEALTH LABORATORY

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LABORATORY TEST FACT SHEET

TEST: LEGIONELLA URINARY ANTIGEN

ORDER CODE: 2400

TEST DESCRIPTION

The *Legionella* Urinary Antigen test (BinaxNOW *Legionella*) is a rapid immunochromatographic assay for the qualitative detection of *Legionella 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 when combined with culture and other methods.

Legionella pneumophila is responsible for 80–90% of reported *Legionella* cases, with serogroup 1 accounting for more than 70% of all legionellosis. Current methods in the laboratory detection of pneumonia caused by *Legionella pneumophila* often include collection of a respiratory specimen (e.g., expectorated sputum, bronchial wash). These methods rely on obtaining a sufficient respiratory specimen for optimal sensitivity. Unfortunately, one of the presenting signs of patients with Legionnaires' Disease is the relative lack of productive sputum, often necessitating the use of an invasive procedure to obtain a respiratory specimen. The *Legionella* Urinary Antigen test allows for early diagnosis of *Legionella pneumophila* serogroup 1 infection through detection of a specific antigen present in the urine of patients with Legionnaires' Disease. *Legionella pneumophila* serogroup 1 antigen has been detected in urine as early as three days after symptom onset.

SENSITIVITY AND SPECIFICITY

Based on both retrospective and prospective studies, the sensitivity for the *Legionella* Urinary Antigen test was determined to be 95%. Specificity was found to range from 95% to 100%.

LIMITATIONS

- Results are for presumptive diagnosis only.
- The test only detects infections caused by *L. pneumophila* serogroup 1.
- Culture is recommended for suspected pneumonia to recover *L. pneumophila* serogroup 1 when antigen is not detected in urine.
- Culture results, serology, and antigen detection methods should be used in combination with clinical findings to make an accurate diagnosis.
- A positive result can occur due to current or past infection.
- This test has been evaluated on hospitalized patients only. An outpatient population has not been tested.

SPECIMENS ACCEPTED FOR TESTING

1. Urine specimen from a hospitalized patient collected in a sterile container or a collection container with boric acid as a preservative, having a volume ≥ 5 mL.

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STORAGE AND TRANSPORT TEMPERATURE

Store and transport urine refrigerated within 14 days. Alternately, a urine specimen may be stored at room temperature if it can reach the lab within 24 hours. Freeze at -10 °C or lower if the specimen is to be stored for longer periods.

CPT code: 87426

ICD-10 code for Legionella pneumonia: A48. 1