

PRODUCT LAUNCH

PROFLOW™

LEGIONELLA URINARY ANTIGEN

Rapid, Simple, Inexpensive.

An exciting addition to the Proflow™ range to aid laboratory diagnosis of *Legionella pneumophila*.

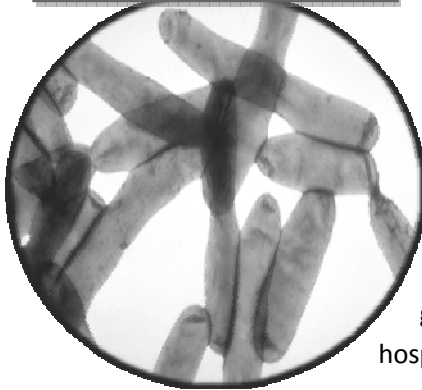
Direct from urine! No sample preparation!

www.pro-lab.com

Pro-Lab Diagnostics is pleased to introduce...

A new lateral flow test for the detection of Legionella Urinary Antigen direct from urine samples without the need for sample dilution, providing results in 15 minutes!

Legionella pneumophila



Legionnaires' disease is a serious form of pneumonia that carries a mortality rate in the order of 10-15% in otherwise healthy individuals. Symptoms include a flu-like illness, followed by a dry cough and can frequently progress to pneumonia. Approximately 30% of people infected may also present with diarrhoea and vomiting and around 50% may show signs of mental confusion.

Legionnaires' disease may present in a number of ways; as an outbreak of two or more cases following a limited temporal and spatial exposure to a single source, as a series of independent cases in an area in which it is highly endemic or as sporadic cases without any obvious temporal or geographical grouping. Outbreaks have occurred repeatedly in buildings such as hotels and hospitals.

The Proflow™ LUA lateral flow test 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.

PRINCIPLE OF THE ASSAY

The Proflow™ Legionella Urinary Antigen test is a single use rapid membrane immunoassay for the qualitative detection of *L. pneumophila* serogroup 1 soluble antigen in human urine.

The Proflow™ LUA test consists of anti-*L. pneumophila* serogroup 1 antibody coated onto the test line region of the nitrocellulose zone of the test strip. Anti-*L. pneumophila* serogroup 1 antibodies are conjugated to visualizing particles that are dried onto an inert absorbent support.

During testing the sample is allowed to react with the conjugate on the test strip. The mixture then migrates along the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. Antibodies on the control line capture conjugate within the sample forming the control line.

A positive test result is read visually in 15 minutes or less depending on the concentration of antigen present in the urine specimen. A negative test result, read at 15 minutes, indicates that *L. pneumophila* serogroup 1 antigen was not detected in the urine sample.

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

ASSAY PROTOCOL

1. Bring patient urine and/or liquid urine control(s) to room temperature (15-30°C).
2. Remove the test from its pack just before use. Place the test on a clean flat surface.
3. Label each test with appropriate patient information.
4. Use a separate pastette and test strip for each sample or control.
5. Dispense 100 µL of the sample (urine), into the circular window marked with an arrow.
6. Read the result at 15 minutes. Do not read the results after 15 minutes as they may be inaccurate.



PERFORMANCE CHARACTERISTICS

The Proflow™ LUA test was used to evaluate 63 frozen archived patient urine specimens and 9 fresh specimens from a French hospital. Five of these patients were positive for Legionella pneumophila serogroup 1 infection as determined by a leading lateral flow test.

Overall agreement of the Proflow™ LUA test was >99%.
Sensitivity and specificity were both >99%.

INDEPENDENT EVALUATION

An evaluation was performed at an independent reference center comparing the performance of the Proflow™ LUA test to culture, serology, NAAT, two leading ELISA tests and a leading lateral flow test. 250 samples were tested with 48 known positive and 202 known negative samples. Results* are presented in the following table:

		Expected Result		
		Positive	Negative	Total
Proflow™ LUA	Positive	48	1	49
	Negative	0	201	201
	Total	48	202	250

Sensitivity	100%
Specificity	99.5%
Positive Predictive Value	98%
Negative Predictive Value	100%

*Data held by Pro-Lab Diagnostics

INTERPRETATION OF RESULTS



A coloured line in the test line (T) as well as the control line (C) indicates a positive result.

Any visible test line is considered a positive result.

No coloured line in the test line (T) indicates a negative result.

To serve as a procedural control, a coloured line should always appear in the control line (C).

If this line is not present the test is considered invalid and should be repeated with a new test.

ORDERING INFORMATION

PL.3007
PL.C1781

Proflow™ Legionella Urinary Antigen Test Kit
Proflow™ Station

x10 Tests
x1 Unit

Kit contains the required pastettes and positive and negative controls.

Take a look at the Proflow™ booklet for the complete range of lateral flow tests available!

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