INTENDED USE
The Proflow™ Legionella Urinary Antigen (LUA) test is a single use rapid membrane immunoassay for the qualitative detection of Legionella pneumophila serogroup 1 antigen in urine samples. This test is intended as an aid in the diagnosis of Legionnaires’ disease caused by L. pneumophila serogroup 1 in conjunction with culture and other methods. For In Vitro Diagnostic Use.

SUMMARY AND EXPLANATION
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 frequently progress to pneumonia. Approximately 30% of people infected may also present with diaphoresis and vomiting and around 50% may show signs of mental confusion. The incubation period is normally 2-10 days. Typically, the onset of illness occurs 3-4 days after exposure. Legionnaires’ disease may present as an outbreak of two or more cases following a limited temporal and spatial exposure to a single source. It may also occur 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 test allows for early diagnosis of L. pneumophila serogroup 1 infection through detection of a specific soluble antigen present in the urine of patients with Legionnaires’ disease. L. pneumophila serogroup 1 antigen has been detected in urine as early as three days after the onset of symptoms. The test is rapid, giving a result within 15 minutes, and utilizes a urine sample which is convenient for collection, transport and subsequent detection of early and later stages of disease.

PRINCIPLE OF THE TEST
The Proflow™ LUA test is a single use rapid membrane immunoassay for the qualitative detection of L. pneumophila serogroup 1 soluble antigen in human urine.

Specific antibodies to L. pneumophila serogroup 1 soluble antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip.

In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate.

A pink/red line should always appear in the control line to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.

The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 15 minutes or less depending on the concentration of antigen present.

A positive result will show a pink/red test line and a pink/red control line, indicating that L. pneumophila serogroup 1 antigen is present in the sample. A negative test result, read at 15 minutes, will show only a pink/red control line, indicating that L. pneumophila serogroup 1 antigen was not detectable in the sample.

MATERIALS PROVIDED
- PL3701 Proflow™ Legionella Urinary Antigen Test Devices: 10 devices
- PL3703 Proflow™ Legionella Urinary Antigen Positive Control Swab
- PL3704 Proflow™ Legionella Urinary Antigen Negative Control Swab
- PL3705 Proflow™ Legionella Urinary Antigen Positive Control Reagent
- PL3706 Proflow™ Legionella Urinary Antigen Negative Control Reagent
- Proflow™ pastettes: 10
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Urine sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE
Store all components at 2-30°C. Do not freeze or overheat.

PROCEDURE
1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Read the result at 15 minutes. Do not read the results after 15 minutes as they may be inaccurate.

INTERPRETATION OF RESULTS
Positive
Two pink/red lines of any intensity appear in the test window; at the test line and control line position. This indicates a positive result for L. pneumophila serogroup 1 antigen.

Negative
A single pink/red line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a negative result for L. pneumophila serogroup 1 antigen.

Invalid
No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition occurs, the test should be repeated with a new test strip.
**LIMITATIONS OF THE PROCEDURE**

1. The Proflow™ LUA test has been validated using urine samples only. Other samples (e.g. plasma, serum or other body fluids) that may contain Legionella antigen have not been evaluated. The test cannot be used on environmental samples (e.g. potable water).

2. This test will not detect infections caused by other *L. pneumophila* serogroups or 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.

3. 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.

4. 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. A positive *L. pneumophila* test result can occur due to current or past infection and therefore is not definitive for infection without other supporting evidence.

5. Performance of the Proflow™ LUA test on diuretic urine has not been evaluated. The Proflow™ LUA test has been evaluated on hospitalised patients only. An outpatient population has not been tested.

6. The test must be carried out within 2 hours of opening the sealed bag.

**PERFORMANCE CHARACTERISTICS**

The Proflow™ LUA test was used to evaluate 64 frozen archived patient urine samples and 9 fresh samples from a French hospital. Five of these patients were positive for *L. 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 centre 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:

<table>
<thead>
<tr>
<th>Expected Result</th>
<th>Proflow™ LUA</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>48</td>
<td>1</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>201</td>
</tr>
<tr>
<td>Total</td>
<td>49</td>
<td>202</td>
</tr>
</tbody>
</table>

*Data held by Pro-Lab Diagnostics

**REFERENCES**


