Proflow™ Legionella Urinary Antigen

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3007 **10 Tests**

INTENDED USE

The Proflow™ Legionella Urinary Antigen test is a single use rapid membrane immunoassay for the qualitative detection of Legionella serogroup 1 antigen in urine samples. This test is intended as an aid in the diagnosis of Legionella infection (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 diarrhoea 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 3-6 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™ Legionella Urinary Antigen 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 utilises 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™ 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.

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

- PL.3701 Proflow™ Legionella Test Devices: 10 devices
- PL.3703 Proflow™ Legionella Positive Control Swab
- PL.3704 Proflow™ Legionella pneumophila Positive Control Reagent
- PL.3705 Proflow™ Legionella Negative Control Swab
- PL.3706 Proflow™ Legionella Negative Control Reagent
- Plastic Pipette: 10
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

- Urine samples should be collected in standard containers.
- Boric acid may be used as a preservative.
- If assayed within 24 hours of collection, the samples can be stored at room temperature (15-30°C).
- If assayed 1-14 days after collection, the samples should be stored at 2-8°C.
- If assayed more than 14 days after collection, samples should be stored at -10 to -20°C.
- Urine samples should be shipped in leak-proof containers at 2-8°C or frozen.
- Allow all samples to equilibrate to room temperature before testing.

TEST PROCEDURE

Use a separate sample collection vial and test for each sample or control. Allow the tests, samples and buffer to reach room temperature prior to testing.

1. Remove the test from its pack just before use. Place the test on a clean flat surface.
2. Label each test with appropriate patient information.
3. Dispense 3 drops (100 uL) of the sample (urine), into the circular window marked with an arrow.
4. Read the result at 15 minutes. Do not read the results after 15 minutes as they may be inaccurate.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected. Positive and negative control swabs are provided in the kit.

The control line (C) is a procedural control. When a red/pink line appears at the control line position this indicates the test has been performed correctly; proper flow occurred and the test reagents functioned correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

Clearing of background colour in the result window provides a negative background control. The background colour in the window should be light pink to white within 15 minutes and should not interfere with the reading of the test result.

Procedure for Control Swabs

1. Add 15 drops (500 uL) of Positive Control Reagent to a test tube.
2. Remove the Positive Control Swab from the pouch and put the swab into the test tube with reagent, mix for 1 minute and extract as much liquid possible from the swab, squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
3. Remove the test from its pack just before use. Place the test on a clean flat surface.
4. Dispense 3 drops (100 µL) from the test tube into the circular window marked with an arrow.
5. Read the result at 15 minutes. Do not read the results after 15 minutes as they may be inaccurate.

Repeat the procedure for the Negative Control Swab using the Negative Control Reagent.

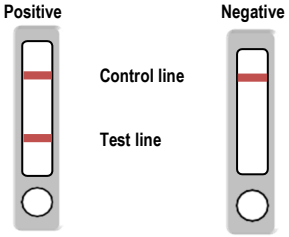
INTERPRETATION OF RESULTS

Positive

Two red lines of any intensity appear in the test window: one at the test line position, and one at the control line position. This indicates a positive result for *L. pneumophila* serogroup 1 antigen.

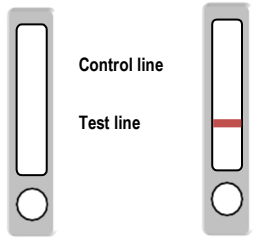
Negative

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 below occurs, the test should be repeated with a new test strip.



UK: Tel +44 (0)151 353 1613
3 Bassendale Road, Bromborough, Wirral, CH62 3QL
www.pro-lab.co.uk

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LIMITATIONS OF THE PROCEDURE

- The Proflow™ Legionella Urinary Antigen 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).
- 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.
- 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.
- 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.
- Performance of the Proflow™ Legionella Urinary Antigen test on diuretic urine has not been evaluated. The Proflow™ Legionella Urinary Antigen test has been evaluated on hospitalised patients only. An outpatient population has not been tested.
- The test must be carried out within 2 hours of opening the sealed bag.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

Legionnaires' disease occurs in both epidemic and endemic forms, and sporadic cases are not easily differentiated from other respiratory infections by clinical symptoms. An estimated 25,000 to 100,000 cases of Legionella infection occur in the US annually. The resulting mortality rate, ranging from 25% to 40%, can be decreased with rapid diagnosis and early appropriate antimicrobial therapy.

SENSITIVITY AND SPECIFICITY

The Proflow™ Legionella Urinary Antigen test was compared to a leading commercial immunoassay. Results were as follows:

Sensitivity: >99%
Specificity: >99%.

CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Legionella Urinary Antigen test. There is no cross reactivity with other pathogens occasionally present in urine:

- *Streptococcus pneumonia*

REFERENCES

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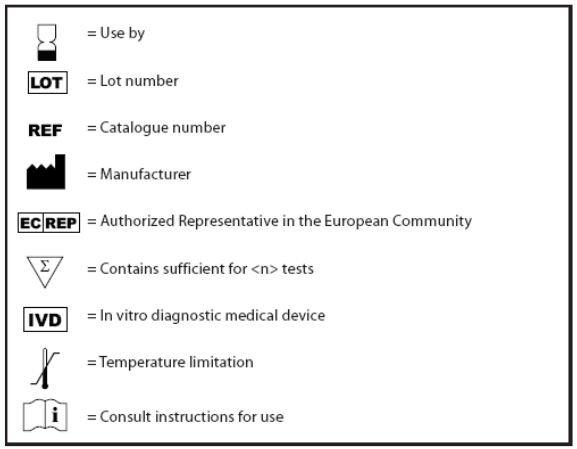

EC REP Advena Ltd. Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta.