Limit of detection

Laboratory analysis has demonstrated that tests are positive for clean water samples containing 1000 CFU/Litre Legionella pneumophila serogroup 1. The limit of detection (LOD) of the test is equivalent to 1000 CFU/L when a 100 ml sample is filtered. If smaller or larger volumes are processed, the detection limit will be altered accordingly.

Suspended solid content in water samples affects filtration and test performance, including analytical sensitivity. Actual results will vary. Water samples with high levels of suspended solids may block filtration entirely. L. pneumophila serogroup 1 bacteria recovery from water samples can range from <10 to 100%, depending on water sample composition. This is similar to filtration concentration techniques used in other microbiological analysis methods.

Test operating limits

The test has been evaluated for operation on samples between 10–45°C (50–113°F). The test has been validated for samples that filter in less than 10 minutes. Samples requiring greater than 10 minutes to filter may give erroneous results. Samples requiring long periods to filter may be indicative of poor system maintenance.

A wide range of non-oxidizing biocides and biodispersants have been checked for cross reaction and interference with the test.

The test should not be used on systems treated with biguanide or tetrakis hydroxymethyl phosphonium sulfate (THPS) based biocides.

Specificity

The test has been shown to be non-reactive with the following bacteria (at $1x10^8$ organisms per sample):

- Acinetobacter calcoaceticus
- Aeromonas hydrophila subsp. Hydrophila
- Bacillus subtilis
- Burkholderia cepacia
- Citrobacter freundii
- Citrobacter koseri
- Enterobacter cloacae
- Escherichia coli
- Klebsiella oxytoca
- Pseudomonas aeruginosa
- Pseudomonas fluorescens
- Pseudomonas putida
- Pseudomonas stutzeri
- Ralstonia pickettii
- Raoultella terrigena
- Streptococcus pyogenes
- Yersinia ruckeri

Organism	≥cfu/mL
L.p Sg-2,3,8,11,13,14	1.00E+08
L.p. Sg-4,5,6,7,9,10,15	1.00E+07
L.p. Sg-12	8.00E+06
S.aureus	2.00E+08

The Lovibond® Legionella Test™ has been shown to produce weak positive results with other legionella pneumophila serogroups at the cfu/mL stated in the above table.

Storage

The test is intended for storage at room temperature 18–22°C (64.4–71.6°F). Do not freeze. When stored correctly, the test will continue to operate within design specification, until the specified expiration date.

Do not use the test or the recovery buffer syringe after the date specified on the packaging of the test. Do not use any test where the foil packaging is perforated.

Disposal

The test, filter, syringe and caps cannot be reused or recycled. The packaging materials and this instruction leaflet can be recycled.

Lovibond® Water Testing

Tintometer® Group

Lovibond®

Single Syringe Legionella Test™ EU Kit

Instructions

This kit is designed to test for Legionella in risk areas identified by ECDC* such as:

- Domestic and industrial hot and cold water systems.
- Cooling towers.
- Decorative fountains, hot tubs and pools.
- Sinks and showers.
- Misters, sprinklers, air washers, humidifiers and others.

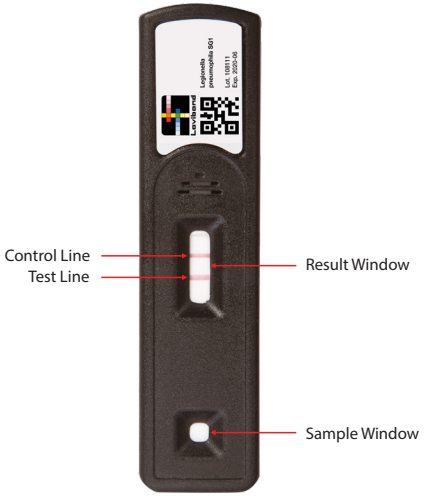
**The European Centre for Disease Prevention and Control*

Single Syringe Legionella Field Test™ EU Kit product code 56B006105

Overview

This test is used to detect the presence of Legionella pneumophila serogroup 1 bacteria in water samples from a wide range of sources. The test operates via a Lateral Flow Immunochromatographic Assay (LFICA). Each kit contains the following:

- 1 x individual foil wrapped LFICA test.
- 1 x hollow fibre filter.
- 1 x syringe containing recovery buffer.
- 1 x 250 ml beaker.
- 1 x 60 ml syringe.
- 1 x EU score card to determine action level: score of 1 or greater is = ≥ 1000 CFU/L and score of 6 or greater = ≥10,000 CFU/L.

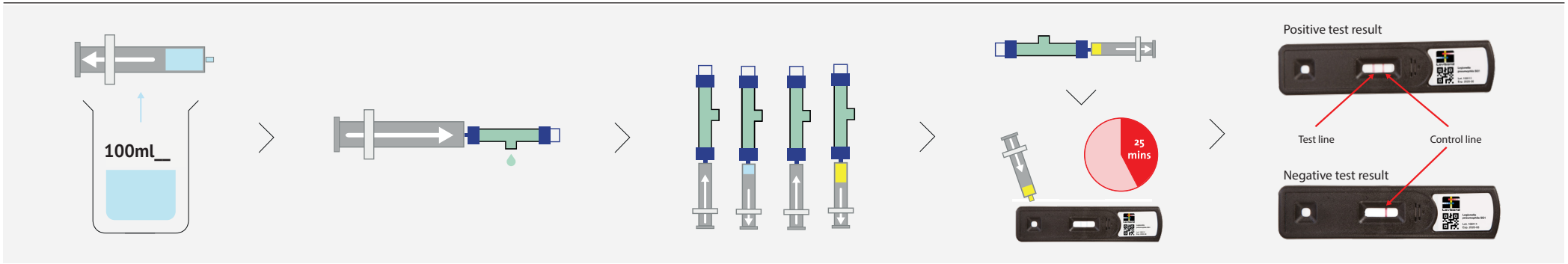


The product is intended for use as part of an overall water treatment, management and risk reduction approach and, as all testing methods including lab culture testing, should NOT be used as the sole method for assessing risks associated with Legionella bacteria.

This test is intended for the analysis of water samples only. It is NOT intended for the diagnostic testing, in a clinical or medical situation, of Legionnaires' Disease in humans.

www.lovibond.com

Test procedure



For optimum results the test should be performed at room temperature. The foil wrapping should NOT be opened until immediately prior to running the test. If the foil is opened and the test is NOT performed within 60 minutes discard the test.

Step 1. Take a sample

Collect a water sample of at least 100 ml in a clean container.

From the kit, take the 60 ml syringe and draw up 50–60 ml of the sample. Remove the Hollow Fibre Filter from the packaging and tighten the end cap. Next fix the filter onto the luer lock end of the filled 60 ml syringe. Now filter the sample over a sink or other waste water outlet. Repeat this process until all the 100 ml sample has been filtered. This should take no longer than 10 minutes.

Avoid generating aerosols when collecting or handling samples.

Step 2. Recover the bacteria

Disconnect the filter from the 60 ml syringe and discard the syringe. Hold the filter vertically with the cap at the top and the open end pointing towards the floor. Remove the cap and screw it onto the open (opposite) end of the filter (where you just fitted the 60 ml syringe). Now take the small blue capped syringe of recovery buffer, remove the blue cap and attach the syringe to the now open end of the filter with a twist and turn movement.

a) Pull the small syringe plunger back to the 1.0ml mark to re-suspend the recovery buffer, then push the syringe all the way to the 0 ml mark.

b) Repeat this process a further 2 times (total of 3).

c) Draw the syringe back to collect **0.1** ml of sample then disconnect from the hollow fibre filter. Avoid creating air bubbles in the syringe. Push and pull the syringe plunger again if necessary to remove any air bubbles.

d) The syringe now contains any recovered bacteria ready for testing.

Incorrect use of the syringe can cause flooding of the test (too much sample added) or failure to run (insufficient sample added). Please ensure that correct amount of sample has been collected.

Step 3. Add sample to test strip

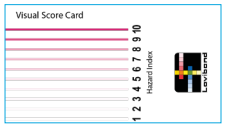
Remove the test strip from its foil wrapping, and place it on a flat surface. If the foil is opened and the test is NOT performed within 60 minutes discard the test.

Place the recovery buffer syringe over the small sample window at one end of the test strip. Depress the plunger to dispense the **0.1 ml** of recovery buffer, containing any bacteria, onto the test strip.

RECORD THE TIME. Allow the test to develop at room temperature for 25 minutes. Leave the test strip sitting on a flat surface during development.

Step 4. Interpreting the results

Leave the test strip sitting on a flat surface during incubation. After 25 minutes, examine the test strip in good lighting. The EU Visual Score Card can be used to read the test accurately. If the test is not read within 35 minutes of adding the water sample, it should be discarded and a new test should be run.



- Score of 1 or greater (on Score card or App Hazard Index) = ≥1000 CFU/L
- Score of 6 or greater = ≥10,000 CFU/L

The test should show one of the following results in the large result window on the test strip:

- Two RED lines across the result window. The red line closest to the sample window may be very faint (pale pink). Any distinct line, no matter how faint should be considered to be a POSITIVE result.

OR

- One RED line across the result window at the end furthest from the sample window. This is a NEGATIVE result.

Positive Results
If a positive result is observed, consult your risk management plan or seek advice from a water management specialist immediately.

Negative Results
A negative result indicates that Legionella pneumophila serogroup 1 was not detected and the concentration was below the detection limit of the test.

Invalid Tests
In the unlikely event that a test does not show any red lines, or if it only shows a line at the end closest to the sample window, or if the line furthest from the sample window is very faint, then the test result is invalid. Repeat the test.

Performance Factors
A positive test result indicates that Legionella pneumophila serogroup 1 was present in the sample above the detection limit. The test does not differentiate between viable and non-viable organisms. The test will detect dangerous viable but non-culturable bacteria, which cannot be detected by traditional laboratory techniques. A positive result does not necessarily mean that viable bacteria are present.

A negative result does not mean that the system is completely free from risks associated with Legionella bacteria.

The test detects Legionella pneumophila serogroup 1. The test does not detect the presence of other Legionella species or serogroups.