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Legionella Field Test Kit – Single Test

A rapid test intended for the qualitative detection of *Legionella pneumophila* serogroup 1

Overview

This test kit is used to detect the presence of *Legionella pneumophila* serogroup 1 bacteria in hot and cold water systems, cooling water and whirlpool spas. The test operates via a Lateral Flow Immuno-chromatagraphic Assay (LFICA).

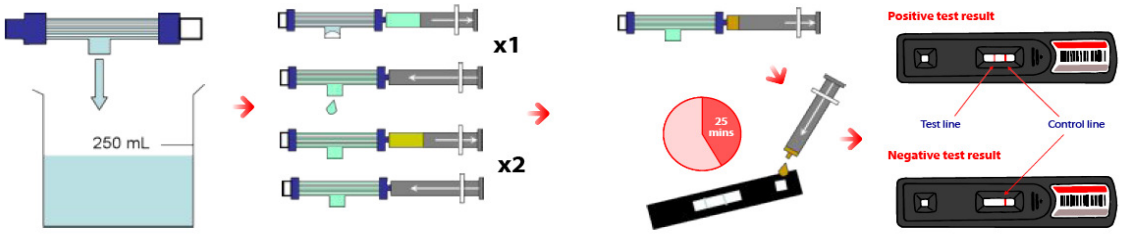
Each kit contains the following:

- 1 Individual foil wrapped test
- 1 Hollow fibre filter
- 1 Syringe with recovery buffer
- 1 Sample collection bottle
- 1 60ml Syringe (Luer Lock)

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 for the detecting of legionnaires disease in humans.
The product is intended for use as part of the overall water treatment management and risk reduction approach and should not be used as the sole method for assessing risks associated with *Legionella* bacteria.

Test Procedure

Please follow these easy to use instructions:



Step 1 – Take a sample

Before taking a sample, flush the sample tap for at least 15 seconds. Using the sample container collect at least 250ml of water.
From the kit, take the 60ml syringe and draw up 50-60ml of the sample. Remove the Hollow Fibre Filter from the packaging and fix onto the luerlock end of the syringe. Now filter the sample over a sink or other waste water outlet. Repeat this process until all the original 250ml sample has been filtered. This should take no longer than a maximum of 10 minutes.

Step 2 – Resuspend the bacteria

Disconnect the filter from the syringe. Discard the large syringe. The hollow fibre filter has a white cap on the opposite end to the end used for attaching the syringe. Remove this cap and swap ends, so the cap is now screwed into place where you fitted the sampling syringe.
Now take the small syringe of recovery buffer, remove the red cap and attach it to the open end of the hollow fibre filter with a twist and turn movement.
a) Pull the syringe back to the 0.5ml mark to re-suspend the recovery buffer, then push the syringe all the way to the 0ml mark.
b) Repeat this process a further 2 times.
c) Draw the syringe back to collect 0.1ml of sample then disconnect from the Hollow Fibre Filter
d) The syringe now contains the recovered bacteria ready for testing

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Step 3 – Add sample to test strip
Remove the test from its foil wrapping, and place on a flat surface. 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 (1 Hour), discard the test.
Before use, the test should have two pale blue lines across the results window. If these are not present notify your supplier to replace the test.
Place the syringe over the **small** sample window at one end of the test strip, and depress the plunger to dispenser the 0.1ml of recovered bacteria onto the test strip.
Allow the test to incubate at room temperature for 25 minutes. RECORD THE TIME to start the 25 minute incubation.

Step 4 – Interpreting the results
Leave the test strip sitting on a flat surface during incubation. For optimum results the test should be performed at room temperature. **After 25 minutes**, examine the test strip in good lighting. If the test is not read within 45 minutes of adding the sample, it should be discarded and a new test run.

The test should show one of the following results in the large result window on the test strip:
One RED line across the result window at the end furthest from
the sample window. This is a **NEGATIVE** result.

OR

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 included. This is a **POSITIVE** result.

OR

If the 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 and notify your supplier to troubleshoot the test.

Interpreting the results additional information:

Positive Results
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 (living) and non-viable (dead) organisms. The test will detect viable but non-culturable bacteria which are not detectable by traditional laboratory techniques. A positive result does not necessarily mean that viable bacteria are present. When a positive result is observed, seek advice from your risk management plan, or water specialist.

Negative Results
A negative result indicates that *Legionella pneumophila* serogroup 1 was not detected or the concentration was below the detection limit of the test.
A negative result does not necessarily mean that bacteria are absent.
A negative result does not mean that the system is completely free from risks associated with *Legionella* bacteria. The test only detects *Legionella pneumophila* serogroup 1. The test does not detect the presence of other *Legionella* species or serogroups.

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Limit of detection

Laboratory analysis has demonstrated that 98 to 100 percent (91% CI) of tests are positive for clean water samples containing 100 CFU/Litre *Legionella pneumophila* serogroup 1. The theoretical mathematical limit of detection of the test is equivalent to 100 CFU/L when a 250mL sample is filtered. If smaller volumes are processed the detection limit will be altered accordingly, i.e:

$$\text{Mathematical limit of detection} = \frac{\textbf{100 (CFU)}}{\textbf{sample volume}}$$

Suspended solid content in water samples impacts 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 between 10-40 ºC (50-104 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
Legionella pneumophila serogroups 2–15
Pseudomonas aeruginosa
Pseudomonas fluorescens
Pseudomonas putida
Pseudomonas stutzeri
Ralstonia pickettii
Raoultella terrigena
Streptococcus pyrogenes
Yersinia ruckeri
Staphylococcus aureus and *Legionella pneumophila* serogroups 4 and 7 in samples at concentrations higher than $1x10^8$ organisms per sample may interfere with test results in negative samples. These concentrations are higher than would be expected to be present in normal water samples.

Disposal and Storage

The test, filter, syringe and caps cannot be reused or recycled. The packaging materials and this instruction leaflet can be recycled.
The test is intended for storage at room temperature. Do not freeze. When stored correctly, the test will continue to operate within design specification, until the specified expiration date.

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Do not use the test after the date specified on the packaging. Do not use any test where the foil packaging is damaged.

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