

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 (LOD) of the test is equivalent to 100 CFU/L when a 250 ml sample is filtered. If smaller 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 between 10–40°C (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 1x10⁸ 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 1x10⁸ organisms per sample may produce weak positive results. These concentrations are higher than would be expected to be present in normal water samples.

Storage

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.

Do not use the test after the date specified on the packaging. 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.

Disclaimer

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hydrosense®

the world's fastest legionella test

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System Legionella Field Test™ Kit

Instructions

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

For testing water samples obtained from plumbing connections provided in installations including:

- Domestic, hospitality, residential and commercial water systems and showers.
- Industrial water systems, such as cooling.

The kit includes supplies for 5 tests.



System Legionella Field Test™ Kit, product code 100182

Overview

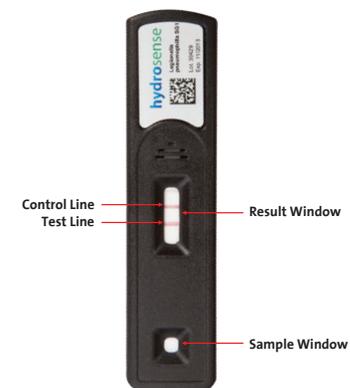
This test kit is used to detect the presence of *Legionella pneumophila* serogroup 1 bacteria in water systems, with samples obtained through standard pipework fittings. The test operates via a Lateral Flow Immunochromatographic Assay (LFICA).

Each kit contains the following:

- 5 individual foil wrapped tests.
- 5 hollow fibre filters.
- 5 syringes with recovery buffer.
- 1 filtrate collection bottle.
- 1 pipework adaptor with ½" and ¾" female threaded connectors. Note that this can also connect to a shower head thread.

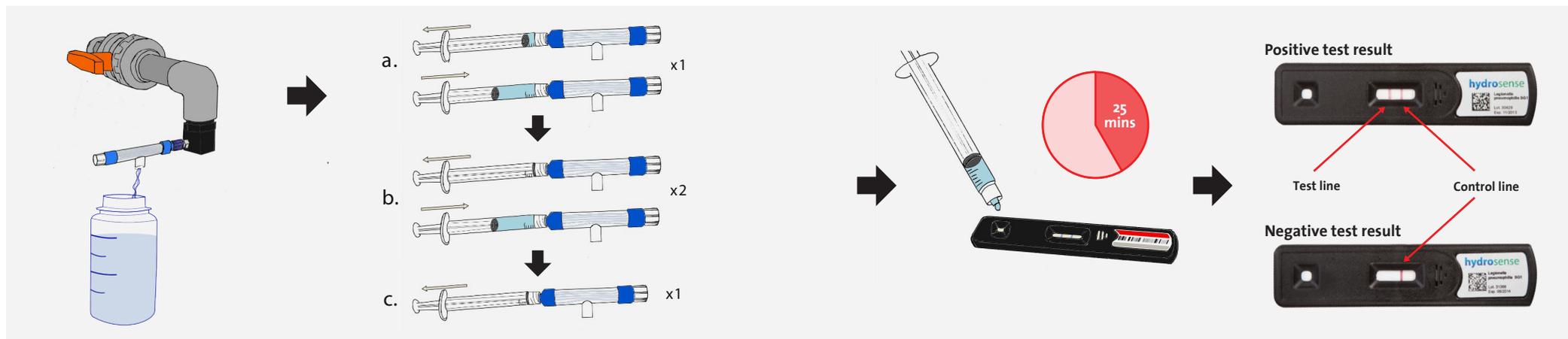
The product is intended for use as part of an overall water treatment, management and risk reduction approach and should NOT be used as the sole method for assessing risks associated with *Legionella* bacteria.

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.



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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.

Step 1. Fit the pipework adaptor

Attach a pipework adaptor to an appropriate connector from which to obtain a representative sample. Hydrosense recommends that a separate pipework adaptor (Hydrosense part 100171) be fitted and retained at each sample point to avoid cross contamination. The sample line pressure should not exceed 6 bar (87 psi).

Step 2. Take a sample

Before taking the sample, flush the sample port for 15 seconds.

Attach the filter to the pipework adaptor; push the open end of the filter into the plastic luer fitting and twist the locking ring to secure. Hold the filtrate collection bottle under the clear outlet port of the filter. Open the system valve to allow the filtration to start, filter at least 250 ml of water into the bottle and close off the valve.

If the sample takes longer than 10 minutes to filter then stop the filtration process and measure the amount of liquid in the collection bottle before proceeding to step 3. The detection limit will be

affected: see 'Limit of Detection' below.

Step 3. Recover any bacteria

Disconnect the filter from the pipework adaptor by twisting the lock ring and pulling the filter from the fitting. Remove the screw cap from the filter and replace it on the opposite end of the filter.

Now take the small syringe of recovery buffer, remove the red cap and attach it to the open end of the filter with a twist and turn.

- Pull the syringe back to the 0.5 ml mark, then push the syringe all the way to the 0 ml mark.
- Repeat this process a further 2 times.
- Draw the syringe back to collect 0.1 ml of sample then disconnect from the filter
- The syringe now contains any recovered bacteria ready for testing

Step 4. 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 incubate at room temperature for 25 minutes. Leave the test strip sitting on a flat surface during incubation.

Step 5. Interpreting the results

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 another test run.

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 included. This is 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 specialist immediately.

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.

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.

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.

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. You can visit www.hydrosense.biz, contact your supplier or email info@hydrosense.biz to troubleshoot the test.