

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 biocidal dispersants 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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Legionella Field Test Swab Kit

Instructions

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

For testing:

- Cooling towers.
- Hot and cold domestic water systems.
- Whirlpool spas.



Swab Test Kit product code 100144

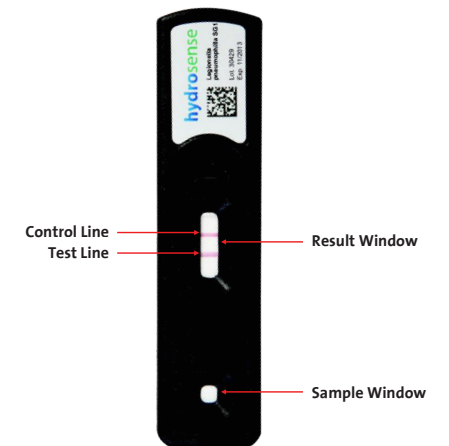
Overview

This test kit is used to detect the presence of *Legionella pneumophila* serogroup 1 bacteria in cooling water systems, domestic hot/cold water, and whirlpool spas. The test operates via a Lateral Flow Immunochromatographic Assay (LFICA). Each kit contains the supplies required to perform five tests. Each kit contains the following:

- 5 individual foil wrapped tests, each with exact volume pipette.
- 1 bottle of recovery buffer (65 ml).
- 5 swabs.
- 5 re-suspension tubes.
- Instructions for use.

This test is intended for analysis of biofilm samples only. This product is NOT intended for clinical or medical diagnostic use.

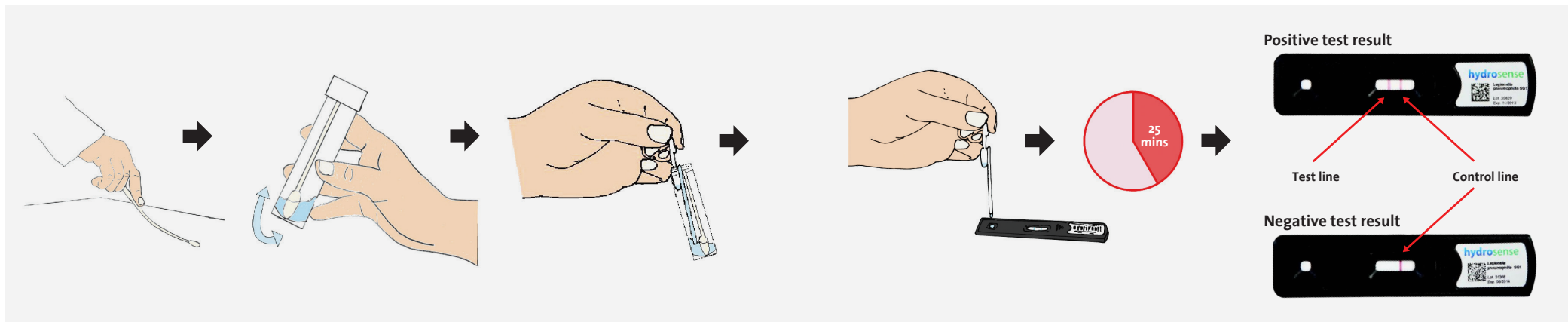
The product is intended for use as part of an overall water treatment, management and risk reduction approach and should NOT be used as the sole method for assessing risks associated with *Legionella* bacteria.



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Swb-I-13-01

Test procedure



Collect biofilm sample

Identify the water system to be sampled and an appropriate location from which to obtain a biofilm sample. Large systems may need to be sampled and tested at multiple locations. The recommended minimum area to swab is 10cm². If the surface to be sampled is dry then pre-moisten the swab in recovery buffer, using the re-suspension tube. Wipe the swab across the area to be tested.



Avoid generating aerosols when collecting or handling samples.

Transfer the swab containing sample to the re-suspension tube and snap off the handle.

Resuspend the bacteria

Add 2 ml of recovery solution (part no. 100119) to the re-suspension tube containing the swab sample and screw on the lid.

Shake the tube for at least 20 seconds or until the swab has released the biofilm sample into the recovery buffer.

Add sample to test strip

Remove the test from its foil wrapping, and place the test 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, discard the test.

Before use, the test should have two pale blue lines across the result window. If these are not present, notify your supplier to replace the test. Take the pipette from the foil wrapping.

Place open end of the pipette into the solution in the re-suspension tube, then squeeze and release the top bulb.

This should draw the sample all the way up the long tube and may place a small amount of sample in the bottom bulb.

Avoid getting air bubbles in the tube. The pipette filling process may be repeated if necessary to remove air bubbles.

Place the pipette over the **small** sample window at one end of the strip, and then squeeze the top pipette bulb again. This will dispense the correct amount of water sample onto the test strip. Record the time.

Wait, then read the test strip

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 60 minutes of adding the water sample, it should be discarded and a new test should be run. The test should show one of the following results in the larger 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

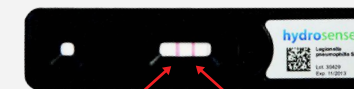
If the test does not show any red lines; or if it only shows a line at the end closest to the sample window; or if the line furthest from the sample window is very faint, then the **test result is invalid**. Repeat the test and notify your supplier to trouble shoot the test.

Interpreting the results

Positive Results

A positive test result indicates that *Legionella*

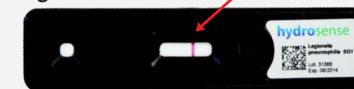
Positive test result



Test line

Control line

Negative test result



pneumophila serogroup 1 bacteria were 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 treatment specialist.

Negative Results

A negative result indicates that *Legionella pneumophila* serogroup 1 bacteria were not detected or the number of bacteria 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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