

FIRST – ONLY – RAPID TESTING KIT FOR LEGIONELLA

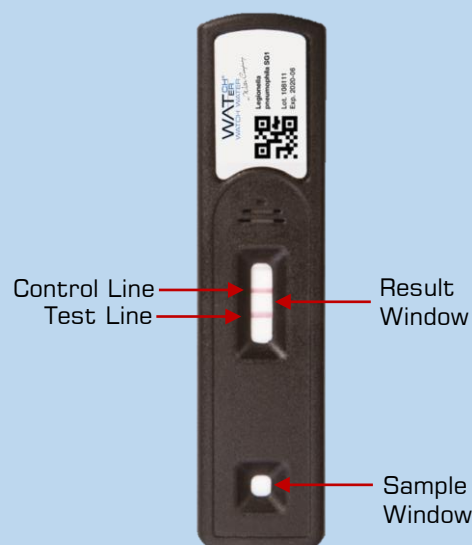
RED-OXY TREATMENT
 FILTRATION
 ADSORPTION
 FILTERS ORB
 INSTANT PRODUCTS
 TEST KITS

LEGIOTEST[®] INSTRUCTIONS & PROCEDURE

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

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

*Center for Disease Control and Prevention



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.

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.

LIMIT OF DETECTION

Laboratory analysis has demonstrated that tests are positive for clean water samples containing 100 CFU/Litre Legionella pneumophila serogroup 1. The 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.

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INSTRUCTIONS

TEST OPERATING LIMITS

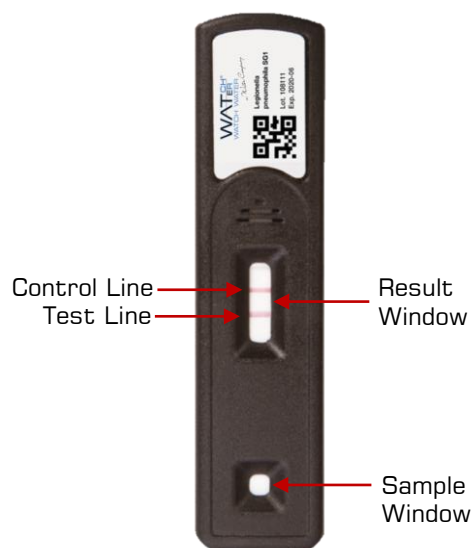
The test has been evaluated for operation on samples between 10–45°C (50–113°F). The test has been validated for samples that filter in less than 10 minutes. Samples requiring greater than 10 minutes to filter may give erroneous results. Samples requiring long periods to filter may be indicative of poor 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 1x10⁸ organisms per sample):

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



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.

DISPOSAL

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

DISCLAIMER

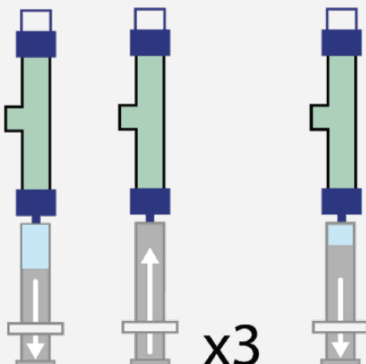
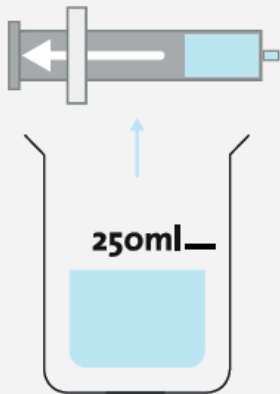
Watch Water makes no warranties or representations regarding performance of the products, or that the products are merchantable or fit for a particular purpose. **Watch Water** expressly disclaims all other warranties and representations, express or implied, or which arise by operation of law or otherwise

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 LegioTest Legionella pneumophila Sg-1 test has been shown to produce weak positive results with other Legionella pneumophila serogroups and S.aureus at the cfu/ml stated in the above table.

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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. 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 250 ml in the cup provided.

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 250 ml sample has been filtered. If the sample takes longer than 10 minutes to filter then stop the filtration and measure the amount of liquid in the cup before continuing. The detection limit will be altered.



Avoid generating aerosols when collecting or handling samples.

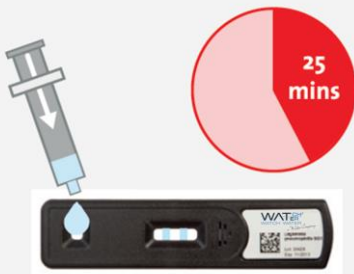
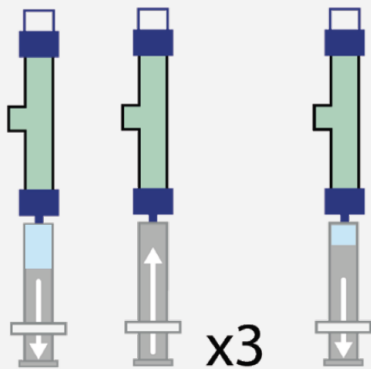
STEP 2. RECOVER THE BACTERIA

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 red capped syringe of recovery buffer, remove the red cap and attach the syringe to the now open end of the filter with a twist and turn movement. Rotate the filter and the syringe so the syringe is at the bottom.

- Pull the small syringe plunger back to the 0.5 ml mark to re-suspend the recovery buffer, then push the syringe all the way to the 0 ml mark.
- Repeat step (a) a further 2 times (total of 3).
- Draw the syringe back to the 0.5 ml mark to collect the sample then slowly push the syringe plunger in to the 0.1 ml mark. Avoid creating air bubbles in the collected 0.1 ml sample. If necessary, push and pull the syringe plunger again to remove any air bubbles. Disconnect the syringe from the hollow fibre filter.
- The syringe now contains 0.1 ml of a concentrated sample which is ready for testing.

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TEST PROCEDURE



Positive test result



Test Line

Control Line



Negative test result

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 (0.1ml) 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.

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

After 25 minutes, examine the test strip in good lighting. If the test is not read within 30 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 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

A positive test result indicates that *Legionella pneumophila* serogroup 1 was present in the sample above the detection limit. If a positive result is observed, consult your risk management plan or seek advice from a water management specialist immediately.

Negative Results

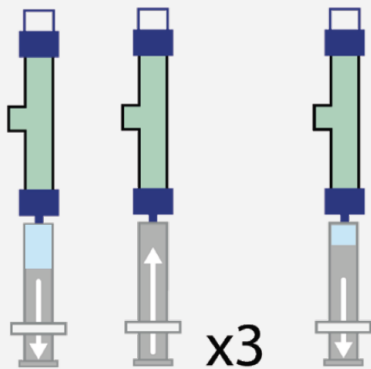
A negative result indicates that *Legionella pneumophila* serogroup 1 was not detected and the concentration was below the detection limit of the test.

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TEST PROCEDURE



Positive test result



Test Line

Control Line



Negative test result

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

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. You can visit www.legio-oxy.com, contact your supplier or email info@watchwater.de to troubleshoot the test.



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