The DrySpot Legionella Latex Test is a latex agglutination test for the identification of Legionella species isolated either from patients with suspected legionellosis or from environmental sources. The DrySpot Legionella Latex Test allows separate patients with suspected legionellosis or from environmental sources. The DrySpot Legionella Latex Test is a latex agglutination test for the identification of Legionella species isolated either from patients with suspected legionellosis or from environmental sources. The DrySpot Legionella Latex Test allows separate patients with suspected legionellosis or from environmental sources.

2. PRINCIPLE OF THE TEST

Legionella pneumophila has been shown to be a major cause of both pneumonia and an acute self-limiting febrile disease called Pontiac Fever. L. pneumophila strains and other Legionella species are isolated predominantly from patients with pneumonia and from the environment (mainly water).

L. pneumophila is the most common cause of Legionnaires’ disease. At present, 14 different serotypes are known of which serogroup 1 accounts for 90% of cases.

3. COMPONENTS OF THE KITS

3.1. LEGIONELLA SPECIES TEST KIT

Positive Control Strips (10 Sticks – pink spots). Pink-dyed inactivated polyvalent antigenic extract of L. pneumophila 1 strains dried onto strips.


DrySpot Legionella Buffer

Mixing Paddles

Plastic Pouch Clip for storage of opened pouches

Instructions For Use

4. MATERIALS REQUIRED BUT NOT PROVIDED:

Sterile microbiological loop.

Suitable laboratory disinfectant e.g. sodium hypochlorite solution >1.3% w/v.

5. PRECAUTIONS

This product is for in vitro diagnostic use only.

Specimen materials may contain pathogenic organisms, handle with appropriate precautions.

The Buffer (DR230M) contains a mild corrosive agent. Avoid direct contact with wearing suitable protective equipment. If the material comes into contact with the skin, mucous membranes or eyes immediately wash the areas by rinsing with plenty of water.

6. STORAGE AND OPENING

This kit must be stored between 2°C and 25°C. If stored in a cold environment, allow pouches to reach room temperature before opening to prevent condensation of moisture on the cards. The DrySpot reagents will deteriorate and may give false results if they are allowed to absorb moisture.

Open the pouches by cutting with scissors just below the seal.

Once opened, the remove the number of cards required for immediate testing (testing within the next 10 minutes) and seal the pouch immediately by clamping the open end of the bag between the two halves of the plastic clip provided.

If fewer tests are required cut the reaction cards along the indicated lines and return the unused portions to the pouch. Do not return unused portions because they will cause contamination of remaining cards in the pouch.

The Control Strips are also provided in a moisture-impermeable pouch. Ensure that the same techniques are used to avoid moisture damage.

Under these conditions the reagents will retain their activity until the expiry date shown on the kit box.

7. CONTROL PROCEDURES

The dried Control Strips provided should be used in the following way to check the correct working of the latex reagent each day before routine tests are performed.

Add a drop of DrySpot Legionella Buffer (DR230M) to the small ring (at the bottom of each oval) in both the Test and Control reaction areas ensuring that the liquid does not mix with the dried latex reagents.

2. Use a sterile loop (or one of the paddles provided) to pick off a suspect colony (at least a 2 mm equivalent area) from a culture media plate and carefully emulsify in the Buffer.

3. For further details of these products please consult your local distributor.

Cultures may be tested at any stage of growth providing that the colonies are of sufficient size. Older cultures, however, may produce stringy reactions making interpretation more difficult.

8. IMPORTANT PROCEDURE NOTES

Do not touch the circles on the reaction cards as this may cause contamination and affect the reaction.

In a high humidity environment do not leave the pouches open for more than 2 minutes. If there is evidence of moisture in the spots do not use.

Do not place the drop of Buffer directly onto the dry latex spots. Pouch clips should be retained for future use to allow multiple packs to be opened. Although suitable for room temperature storage the kit or pouches must not be stored near heat sources or where exposure to sunlight may cause increased temperatures.

9. SPECIMEN COLLECTION AND PREPARATION

Specimens isolated from environmental and clinical samples may be cultured on standard non-selective or selective Legionella culture media. Typical isolation schemes are given in references 3 and 4. To confirm the isolate as a Legionella it is necessary to show a requirement for L-cysteine (Legionella Agar without cysteine CM655 + SR175). This confirmation may be performed before or after the latex test.

The following Oxoid media and supplements may be used for the culture of Legionella before performing the latex test.

BCYE (CM655 + SR110), BPMAα (CM655 + SR110 + SR111), MVY (CM655 + SR110 + SR118), GPVC (CM655 + SR110 + SR152). For further details of these products please consult your local distributor.

Cultures may be tested at any stage of growth providing that the colonies are of sufficient size. Older cultures, however, may produce stringy reactions making interpretation more difficult.

10. TEST METHOD

1. Add 1 drop of DrySpot Legionella Buffer (DR230M) to the small ring (at the bottom of each oval) in both the Test and Control reaction areas ensuring that the liquid does not mix with the dried latex reagents.

2. Use a sterile loop (or one of the paddles provided) to pick off a suspect colony (at least a 2 mm equivalent area) from a culture media plate and carefully emulsify in the Buffer.

3. Ensure that the resulting suspension is smooth.

4. Proceed in the same way to check the correct working of the latex reagent each day before routine tests are performed.

5. Rock the card for up to 60 seconds and look for agglutination under normal lighting conditions. Do not use a magnifying glass.

6. When the test is complete dispose of the reaction cards safely.

Rock the card and look for agglutination. This procedure should be repeated using a Negative Control Strip (DR240M).

The positive control must show agglutination with the dried reagent (of its respective kit) within 1 minute.

The negative control must show no agglutination within 1 minute. Do not use the test if reactions with the control reagents are incorrect.
1. The Legionella pneumophila 2–14 reagent reacted with serogroups 15 and 16. Currently there is only limited data available on these serogroups. It has been demonstrated that a common antigen is shared by serogroups 15 and 16 with Legionella pneumophila serogroups 3 and 4 respectively. L. pneumophila serogroup 15 has not currently been isolated from clinical or environmental samples in Europe or and has only been isolated once in the USA. This most recent serogroup to be designated contains only one strain (Lancing-3 (ATCC® 35253)). A 15th serogroup was proposed from studies of the Jena-1 isolate until further analysis showed that the strain did not form a unique serogroup but was a member of serogroup 4 L. pneumophila (monoclonal group Portland 1). Additional internal data has been collected which demonstrates that the DrySpot Legionella pneumophila serogroups 2-14 Test Kit is able to detect the Legionella pneumophila serogroup 15 as well as detecting L. pneumophila serogroups 2-14. However, as only one serogroup 15 strain is available for testing, it is not thought appropriate to rename the serogroup 2-14 latex reagent based on the results from a single isolate. The Legionella kits benefit the user by allowing discrimination of samples into three groups: L. pneumophila serogroup 1, L. pneumophila serogroups 2-15 (with the 2-14 reagent) and other Legionella species in a fast and simple screening procedure.

2. The false positives given by the Legionella species kit are known cross-reactions reported in the literature.

3. The reagents of the Three Agglutination Legionella Test Kits have been tested for cross-reactivity against a panel of organisms listed below. No cross-reactivity was observed with any of the organisms.

**L. pneumophila** serogroups 1 and 2–14 reagents agglutinate with the isolate then this cross reaction should be suspected.


The DrySpot Legionella Latex Test was evaluated in a clinical and an environmental laboratory. A total of 207 isolates were tested, covering Legionella pneumophila serogroups 1–14 and non-pneumophila Legionellae. Each isolate was confirmed by serology. The results of the trial are summarised below:

<table>
<thead>
<tr>
<th>Legionella Latex Kit/Serology</th>
<th>Number</th>
<th>%</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Legionella pneumophila serogroup 1</td>
<td>140</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>legionella pneumophila serogroups 2-14</td>
<td>138</td>
<td>100</td>
<td>97.8</td>
</tr>
<tr>
<td>Other Legionella included in the kit</td>
<td>136</td>
<td>100</td>
<td>94.4</td>
</tr>
</tbody>
</table>

The Mixing Paddles provided are not sterile. They may be sterilised by autoclaving if required.

The test is designed to differentiate between different species and serotypes of Legionella. Cultures should be confirmed as Gram-negative rods which do not grow on cysine-deficient media.

A negative Latex Agglutination Test does not mean that the culture is not a Legionella species. It only indicates that the culture is not L. pneumophila serogroup 1 (when tested with the L. pneumophila serogroup 1 Test Kit), not L. pneumophila serogroup 1 (when tested with the L. pneumophila serogroup 2–14 reagent agglutinate with the isolate then this cross reaction should be suspected).

Cross reactions with the Legionella Species Test Kit have been reported to occur occasionally with certain serotypes of other Legionellae (e.g. L. parisiensis, L. sainthelenae, L. steigerwaltii, L. wadsworthii, L. sanitricus, L. taissonensis, L. gratiana, L. cincinatiensis).

11. **READING AND INTERPRETATION OF RESULTS**

**Positive Result**

A result is positive if agglutination of the latex particles from the respective kit occurs within 1 minute. This indicates the presence of Legionella.

**Negative Result**

A negative result is obtained if no agglutination occurs and a smooth blue suspension remains after 60 seconds in the test area. Reactions occurring after 60 seconds should be ignored.

12. **UNINTERPRETABLE RESULT**

The test is uninterpretable if the Control Reagent shows agglutination. This indicates that the culture causes autoagglutination.

13. **GRANULAR OR STRINGY REACTIONS**

Occasionally granular or stringy reactions may be seen due to the particulate nature of the test material. When such reactions are seen to occur they should be interpreted using the following criteria:

The result is positive when, using the Test Reagent, greater clearing of the blue background occurs compared with the reaction of the Control Reagent. The result is negative when there is no difference between clearing of the blue background using the Test and Control Reagents.

14. **LIMITATIONS**

The Legionella pneumophila 2–14 reagent with the isolate then this cross reaction should be suspected.

Cross reactions with the Legionella Species Test Reagent have been reported to occur occasionally with certain serotypes of other Legionellae (e.g. L. parisiensis, L. sainthelenae, L. steigerwaltii, L. wadsworthii, L. sanitricus, L. taissonensis, L. gratiana, L. cincinatiensis).

15. **PERFORMANCE CHARACTERISTICS**

The Legionella kits benefit the user by allowing discrimination of samples into three groups: L. pneumophila serogroup 1, L. pneumophila serogroups 2-15 (with the 2-14 reagent) and other Legionella species in a fast and simple screening procedure.

The false positives given by the Legionella species kit are known cross-reactions reported in the literature.

16. **REFERENCES**

7. Data on file, Oxoid Ltd.

**Catalogue Number**

IFU X5782B

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**Printed in the UK**

**Oxoid Limited, Warde Road, Basingstoke, Hampshire, RG24 BPW, UK**

**Manufacturer**

**Consult Instructions for Use**

**Temperature Limitation**

**Batch Code**

**Use By**