PRO-LAB DIAGNOSTICS

LEGIONELLA AGGLUTINATION LATEX REAGENTS

(for *in vitro* diagnostic use)

PRODUCT CODE PL.215, PL.216, PL.217, PL.218, PL.219, PL.325, PL.326, PL.327, PL.328, PL.329, PL.330, PL.331, PL.332.

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INTENDED USE

The PRO-LAB *Legionella* Agglutination Latex Reagents are intended for the presumptive identification of *Legionella pneumophila* serogroups 2 to 14 culture colonies from agar plates[1].

SUMMARY AND EXPLANATION

In 1976 the Centre for Disease Control (C.D.C.) was involved in an intensive investigation into the cause of an outbreak of acute febrile illness in Philadelphia[2,3]. The condition, subsequently called Legionnaires Disease, was found to have been caused by a gram negative rod which was named *Legionella* Disease Bacterium.

The manifestation of Legionnaires Disease range from asymptomatic infection or mild influenza-like symptoms to severe, sometimes fatal, bronchopneumonia.

The PRO-LAB *Legionella* Agglutination Latex Reagents provide a fast and simple screening procedure for the predominate *Legionella* serogroups.

PRINCIPLE OF THE TEST

PRO-LAB *Legionella pneumophila* serogroup agglutination reagents consist of buffered suspension of latex particles coated with purified antibodies. The antibodies are specifically directed against surface antigens on *Legionella pneumophila* serogroup. When one drop of a suspension of suspected *Legionella* colonies is mixed with a drop of latex reagent and the organism is one of the *Legionella pneumophila* serogroups, it will bind to a specific anti-Legionella sensitized latex. The mixture will cause an agglutination that is visible and the resultant clumping is graded visually.

REAGENTS AND MATERIALS AVAILABLE

Latex particles coated with IgG are prepared from rabbit antisera produced against individual *Legionella pneumophila* serogroups 2 to 14. The reagents are each packaged in 2.7 ml amount per bottle.

The following are available (Catalogue numbers):

PL.215	*L. pneumophila* serogroup 2	2.7 ml
PL.216	*L. pneumophila* serogroup 3	2.7 ml
PL.217	*L. pneumophila* serogroup 4	2.7 ml
PL.218	*L. pneumophila* serogroup 5	2.7 ml
PL.219	*L. pneumophila* serogroup 6	2.7 ml
PL.325	*L. pneumophila* serogroup 7	2.7 ml
PL.326	*L. pneumophila* serogroup 8	2.7 ml
PL.327	*L. pneumophila* serogroup 9	2.7 ml
PL.328	*L. pneumophila* serogroup 10	2.7 ml
PL.329	*L. pneumophila* serogroup 11	2.7 ml
PL.330	*L. pneumophila* serogroup 12	2.7 ml
PL.331	*L. pneumophila* serogroup 13	2.7 ml
PL.332	*L. pneumophila* serogroup 14	2.7 ml

STORAGE

Reagents should be stored at 2-8°C. **DO NOT FREEZE.** Reagents stored under these conditions will be stable until the expiry date shown on product label.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Biological safety cabinet.
2. Bunsen burner.
3. Buffered Charcoal Yeast Extract media.
4. Inoculating loop.
5. Rotary mixer.
6. Test tubes.
7. Phosphate Buffered Saline (PBS, pH 7.4).

MATERIALS REQUIRED BUT NOT PROVIDED, AVAILABLE FROM PRO-LAB

1. Negative control latex particles are coated with normal rabbit IgG and packaged 1.5 ml per bottle.
   Available as Catalogue Number: PL. 223 Negative control 1.5 ml
2. Control antigens of *Legionella pneumophila* serogroups 1 to 14 grown on artificial medium and killed by formalin. The control antigen is packaged 1.5 ml per bottle.
   Available as Catalogue Number: PL. 334 Positive Control 1.5 ml
3. Test cards with circled areas for mixing reagents and test samples.
4. Mixing sticks.

PROCEDURE

1. Allow specimens and reagents to reach room temperature before use.
2. Pick as many suspected colonies as possible from the Buffered Charcoal Yeast Extract medium and resuspend the colonies in about 1 ml of PBS (pH 7.4). Suspected colonies refer to ones showing typical morphology and no growth on blood agar. Ideally, the suspension should have a turbidity of approximately 10^8 CFU per ml However, as little as two colonies in 1.0 ml of PBS is sufficient.
3. Resuspend the Latex Agglutination Reagents by gentle agitation.
4. Add 1 drop of cell suspension with 1 drop of each of the latex reagents onto the circled areas of the slide provided.
5. Mix each circled area with a new mixing stick.
6. Place slide on the rotary mixer (160 rpm) for 2 minutes or gently rock test card manually.
7. Read visually by examining the degree of agglutination and grade the agglutination.

Definition of agglutination grading:

0 = Identical to negative control, homogeneous suspension of PBS and latex reagent with no agglutination.
1+ = Fine granulation with a turbid background.
2+ = Small visible groupings with a turbid background.
3+ = Medium clumps with a clear background.
4+ = Large clumps with a clear background.

INTERPRETATION OF RESULTS

Any test that is graded 2+ to 4+ with a latex reagent control latex is considered positive, providing that the negative control is shown to be negative.

QUALITY CONTROL

All latex reagents must agglutinate the positive control at a 3+ to 4+ clumping. The negative control latex reagent must not agglutinate any of the control antigens. Otherwise, the test is considered invalid.

LIMITATIONS

1. The latex agglutination test is presumptively diagnostic. Confirmation by biochemical tests should be done whenever possible.
2. A negative latex agglutination test does not mean the culture is not a *Legionella* species. It only indicates that the culture is not *Legionella pneumophila* serogroups 2 through 14.

PRECAUTIONS

1. Reagents are for *in vitro* diagnostic use only.
2. Universal precautions should be taken in handling, processing and discarding all clinical specimens. All test materials should be considered potentially infectious during and after use and should be handled and disposed of appropriately.
3. Do not use the Latex Reagents if autoagglutination is visible. Autoagglutination indicates that contamination or deterioration has occurred.
4. For best results, it is recommended that fresh cultures be used. Older cultures may be mucoid and thus, a smooth suspension should be made. This may be accomplished by vortex or other suitable method.
5. Reagents contain a small amount of sodium azide. Sodium azide can react explosively with copper or lead plumbing if allowed to accumulate. Although the amount of sodium azide in the reagents is minimal, large quantities of water should be used if the reagents are flushed down the sink.
6. These reagents contain materials of animal origin and should be handled as a potential carrier and transmitter of disease.

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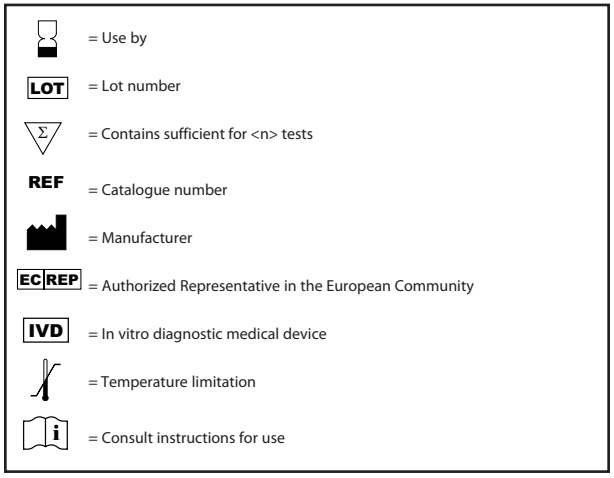
REFERENCES

1. **Sedgwick, A.K. and Tilton, R.C.** 1983. Identification of *Legionella pneumophila* by Latex Agglutination. J. Clin. Microbiol. **17**: 365-368.
2. **Brenner,D.J., Steigerwalt, A.G., Gorman, G.W., Wilkinson, H. W., Bibb, W. F., Hackel, M., Tyndall, R.L., Campbell, J., Feeley, J.C., Thacker, W.L., Skaliy, W.T., Martin, W.T., Brake, B.J., Fields, B.S., McEachern, V,H., Corcoran, L.K.,** 1985. Ten New Species of *Legionella*. Intern. J. System. Bacteriol. **35**:50-59.
3. **Reingold, A.L., Thomason, B.M., Brake, B.J., Thacker, L., Wilkinson, H.W., Kuritsky, J.N.** 1984. *Legionella pneumophila* in the United States: The Distribution of Serogroups and Species Causing Human Illness. J. Infect. Disease. **149**:819.

Also available from Pro-Lab:

PL.380 *Legionella pneumophila* serogroup 1 Latex Reagent (Latex particles coated with monoclonal antibodies) 1.1 ml per bottle

PL.226 *Legionella pneumophila* serogroup 1 Latex Agglutination Kit 20 tests



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