

Rapid agglutination test for direct identification of *Legionella* spp.

DESCRIPTION

Legionella Latex Kit is a rapid agglutination test on card for direct identification of *Legionella pneumophila* and commonly isolated *Legionella* species grown on selective media. The test allows the separate identification of *L. pneumophila* Serogroup 1 and Serogroups 2-15 and commonly isolated *Legionella* species.

PACKAGING

- LEGIONELLA 1 LATEX REAGENT (2.5 mL): dropper bottle containing latex particles coated with polyclonal rabbit antibodies raised against *L. pneumophila* Serogroup 1.
- LEGIONELLA 2-15 LATEX REAGENT (2.5 mL): dropper bottle containing latex particles coated with polyclonal rabbit antibodies raised against *L. pneumophila* Serogroups 2-15.
- LEGIONELLA SPECIES LATEX REAGENT (2.5 mL): dropper bottle containing latex particles coated with polyclonal rabbit antibodies raised against 10 commonly isolated *Legionella* spp (see table).
- POSITIVE CONTROL (1 mL): dropper bottle containing a suspension of inactivated *Legionella* antigens.
- Disposable agglutination cards (30 x 6 wells).
- Disposable mixing sticks (2 x 25).

NECESSARY ITEMS NOT CONTAINED IN THE PACKAGE

Disposable pipettes and loops, Physiological solution, Timer.

METHOD PRINCIPLE

Latex particles are coated with polyvalent antibodies raised against a wide range of *Legionella* antigens. Mixed with a suspension of legionellae, latex particles aggregate to give visible agglutination.

TEST PROCEDURE

- Allow the reagents and positive control to reach room temperature.
- Dispense 1 drop of POSITIVE CONTROL on a well of an agglutination card.
- Dispense 1 drop of physiological solution onto each of 3 wells of the agglutination card. Using a disposable loop, remove well-isolated colonies from the selective agar plate. Mix the colonies with the saline and emulsify to obtain a heavy and homogeneous suspension. Suspensions must only be made from colonies with morphologies resembling *Legionella* spp.
- Add 1 drop of LEGIONELLA 1 LATEX REAGENT to the well with the positive control and 1 drop to one well of the bacterial suspension. Add 1 drop of LEGIONELLA 2-15 LATEX REAGENT to the second suspension and 1 drop of LEGIONELLA SPECIES LATEX REAGENT to the third suspension. **Do not allow the dropper to touch the bacterial suspension.**
- Mix the wells content using a new mixing stick for each well and rock the card gently two or three times. Excessive rocking of the card is not necessary. Examine for agglutination within a maximum of 2 minutes. If there is agglutination it will be clearly visible to the naked eye.

INTERPRETATION OF RESULTS

Agglutination is considered to be a positive reaction and the results should be interpreted as indicated in the table below:

Test Reagent 1	Test Reagent 2-15	Test Reagent Species	Interpretation
+	-	-	<i>L. pneumophila</i> 1 present
-	+	-	<i>L. pneumophila</i> 2-15 present
-	-	+	<i>Legionella</i> spp present*
-	-	-	No <i>Legionella</i>
+	+	+	Possible non-specific agglutination**
+	+	-	Possible non-specific agglutination**
+	-	+	Possible non-specific agglutination**
-	+	+	Possible non-specific agglutination**

**Legionella* species (10 target species): *L. micdadei*, *L. bozemanii* 1, *L. bozemanii* 2, *L. dumoffi*, *L. longbeachae* 1, *L. longbeachae* 2, *L. jordanis*, *L. gormanii*, *L. anisa*, *L. feelei*.

**A non-specific agglutination pattern does not preclude the presence of *Legionella* bacteria but results have to be interpreted as inconclusive.

LIMITATION OF USE

- The clinician should be interpreted the results in the context of all available clinical and laboratory informations.
- Identification with Legionella Latex Kit is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.

PRECAUTION

Legionella Latex Kit is designed for *in vitro* diagnostic use and must be used only by properly trained operators, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store Legionella Latex Kit at 2-8 °C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions Legionella Latex Kit will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After the use Legionella Latex Kit, and the material that comes into contact with the sample must be decontaminated and disposed according to the techniques used in the laboratory for decontamination and disposal of potentially infectious materials.

PRESENTATION

Product	Ref.	Contents
Legionella Latex Kit	96142	50 tests

TABLE OF SYMBOLS

 In Vitro Diagnostic Medical Device	 Do not reuse	 Manufacturer	 Contains sufficient for <n> tests	 Temperature limitation
 Catalogue number	 Fragile, handle with care	 Use by	 Caution, consult accompanying documents	 Batch code



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Rev.1 / 25.08.2015