

## LEGIONELLA LATEX SPP

For *in Vitro* diagnostic use

Latex for the rapid confirmatory identification of *Legionella spp.*

### INTENDED USE

Latex for agglutination test for confirmatory identification of *Legionella spp.* The test is suitable for organisms derived from patients with suspected pneumonia or from environmental sources.

### PRINCIPLE OF THE METHOD

The test latex used is coated with immunoglobulins which have been specially processed to minimise cross reactions with potentially cross reacting organisms.

. Reagent test LSPP contains latex particles coated with polyclonal rabbit antibodies raised against 10 commonly isolated *Legionella* species : *L. micdadei*, *L. bozemanii* 1 & 2, *L. dumoffii*, *L. longbeachae* 1 & 2, *L. jordanis*, *L. gormanii*, *L. anisa* and *L. feelei*.

### MATERIALS PROVIDED

**REAG TEST LSPP** : 2,5 ml; latex particles coated with polyclonal rabbit antibodies against 10 commonly isolated *Legionella* species *L. micdadei*, *L. bozemanii* 1 & 2, *L. dumoffii*, *L. longbeachae* 1 & 2, *L. jordanis*, *L. gormanii*, *L. anisa* and *L. feelei*. Contains 0.099% sodium azide.

### WARNINGS AND PRECAUTIONS

#### Safety:

- The reagent supplied is for *in vitro* diagnostic use only.
- Sodium azide, which is used as a preservative in the latex reagent, can react with lead or copper plumbing to form potentially explosive metal azides. Dispose by flushing with a large volume of water to prevent azide build-up.
- Appropriate precautions should be taken when handling or disposing of potential pathogens. Decontamination of infectious material can be achieved with sodium hypochlorite at a final concentration of 3% for 30 minutes. Liquid waste containing acid must be neutralised before treatment.

#### Procedural:

- For the instruction for use and materials/reagents required to test performance make reference to Instruction For Use of: **Legionella Rapid Latex Test Kit (Reference 271050)**.
- The kit is intended for professional use only.
- Allow all reagents to reach room temperature before use.
- Do not dilute any of the kit reagents
- Do not intermix reagents from different batches of kits.
- Do not freeze any of the kit reagents

### STORAGE AND SHELF LIFE












Legionella Latex SPP must be stored at 2-8°C. The latex must not be used after the expiry date printed on the label.

### SPECIMENS

The sample consists of colonies isolated on an selective agar medium (e.g. Legionella BGYE Selective Agar, REF 549995).

### LIMITATIONS OF USE

- Results should be interpreted by the clinician in the context of all available clinical and laboratory information.
- Stringy reactions on the card may not be true positive reactions and further tests are required.
- Old and/or mucoid cultures may not give a smooth suspension in saline and may give atypical agglutination. These should be pre-treated by boiling as described in the method above.
- Legionella Latex SPP is intended for the identification of *Legionella spp* following culture on selective agar plates. Colonies giving positive results should be confirmed as *Legionella* by their inability to grow on Legionella selective culture media deficient in cysteine (e.g. Legionella Agar w/o Cysteine REF 549943).

 IVD	In Vitro Diagnostic Medical Device	 Temperature limitation	 LOT	Batch code (EXXX)	 Manufacturer	 Keep dry	 Non-sterile
 Consult Instructions for use	Use by (year/month)	 REF	Catalogue number	 Do not reuse	 Fragile, handle with care	 Keep away from heat	

**REF 271053** LEGIONELLA LATEX SPP, 1 x 50 tests

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