

## 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. (**black cap**)

**CONTROL +**: 1 ml; **POSITIVE CONTROL**: suspension of inactivated *Legionella* antigens reactive with Reagents L1, L2-15 and LSPP. Contains 0.099% sodium azide. (**red cap**)

**SAMPLE DILUENT**: 1 x 10 ml; 0.9% Saline containing 0.095% sodium azide (**vial**)

**Disposable agglutination cards**: 9 cards, each with 6 black agglutination areas

**Mixing Sticks**: 50 disposable mixing sticks

### Instruction for use

### 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 kit must be stored at 2-8°C. The reagents 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 test

**REAG TEST LSPP** 2.5 mL (dropper black cap)  
**CONTROL +:** 1.0 mL (dropper red cap)  
**SAMPLE DILUENT** 1 x 10.0 mL (vial)  
**DISPOSABLE AGGL. CARDS (SLIDE)** 9 cards with 6 wells each  
**MIXING STICKS:** 2x25 disposable mixing sticks  
**INSTRUCTIONS FOR USE** 1 item

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