

LEGIONELLA LATEX 01

For *in Vitro* diagnostic use

Latex for the rapid confirmatory identification of *Legionella pneumophila* 01.

INTENDED USE

Latex for agglutination test for confirmatory identification of *Legionella pneumophila* Serogroup 01. 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 L1 contains latex particles coated with polyclonal rabbit antibodies raised against *L. pneumophila* Serogroup 01.

MATERIALS PROVIDED

REAG TEST L1 : 2,5 ml; latex particles coated with polyclonal rabbit antibodies against *L. pneumophila* Serogroup 01.

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 01 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 01 is intended for the identification of *L. pneumophila* serotype 01 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 271051 LEGIONELLA LATEX 01 1 x 50 test

REAG TEST L1	2.5 mL (dropper green 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

EDMA CODE 15 01 05 01

