

LISTERIA RAPID LATEX TEST KIT

For professional *in Vitro* diagnostic use onlyLatex slide agglutination test for the presumptive identification of *Listeria* colonies

INTENDED USE

Listeria Rapid Latex Test Kit is a rapid latex agglutination test intended for the presumptive identification of *Listeria spp.* from selective solid media. The test may be used in conjunction with biochemical analysis for full identification of *Listeria spp.* The kit is intended for professional laboratory use only.

PRINCIPLE OF THE TEST

Polyvalent antisera, prepared against purified flagellin proteins from *Listeria monocytogenes* and *Listeria grayi*, are used to coat latex particles. When mixed with a suspension containing *Listeria* species, the latex particles rapidly agglutinate to form visible clumps. *Listeria Rapid Latex Test Kit* detects all motile strains of *Listeria* species to the limit of the sensitivity of the test.

REAGENTS AND MATERIALS PROVIDED

REAG TEST: *Listeria* Latex Reagent: 2.5 mL - Latex particles coated with rabbit antiserum against *Listeria* flagellin antigens. Preserved with 0.02% Thiomersal. (White cap)

CONTROL +: Positive Control: 0.5mL – Preserved with 0.02% Thiomersal. (Red cap)

SAMPLE DILUENT: 0.9% Saline: 5.0mL. Preserved with 0.099% sodium azide. (Black cap)

DISPOSABLE AGGLUTINATION CARDS (SLIDE) : 9 cards, each with 6 black agglutination areas

MIXING STICKS (2x25) : 50 disposable mixing sticks

DISPOSABLE PIPETTE: 1 disposable transfer pipette

INSTRUCTIONS FOR USE

MATERIALS REQUIRED BUT NOT SUPPLIED

Bacteriological loops

Plastic tubes 1 mL

Timer

WARNINGS AND PRECAUTIONS

Safety:

- The reagents supplied in this kit are for *in vitro* diagnostic use only
- Sodium azide, which is used as a preservative in the kit reagents 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 30minutes. Liquid waste containing acid must be neutralised before treatment.
- The positive control has been inactivated during the manufacturing process. However, it should be handled as through potentially infectious.

Procedural:

- *Listeria Rapid Latex Test Kit* should be used according to the kit instructions.
- 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
- Do not allow the latex reagent dropper to touch the bacterial samples.
- Ensure the agglutination slide is clean and dry prior to use.

STORAGE AND SHELF LIFE

Listeria Rapid Latex Test Kit should be stored at 2-8°C when not in use. The kit should not be used after the expiry date printed on the label.

SPECIMENS

Colonies picked from solid selective media for *Listeria*.

PROCEDURE

Allow all the reagents to reach room temperature prior to use.

1. The use of *Listeria* selective media containing esculin is an advantage in differentiating *Listeria sp.* (Esc+) from non-*Listeria sp.* (Esc-)
2. Colonies must be checked for oxidase reactivity before testing; false reactions may occur with oxidase positive cultures. *Listeria sp.* Are oxidase negative.
3. It is important to test only smooth strains. Rough strains will be demonstrated by non-specific clumping/agglutination in saline alone.
4. Maximum flagella production occurs at 30°C or below.

Quality Control:

The following controls should be performed each time the kit is used to confirm that the reagents are functioning correctly:

1-Reagent Control: Add one drop of **REAG TEST** to 1 drop of isotonic saline in the same circle on an agglutination slide. Mix with a mixing stick and observe for agglutination. No agglutination should be seen. If this control shows agglutination, at least one of the reagents is contaminated and they should be discarded.

2-Positive Control: Gently mix the Positive Control by inverting several times. Place 1 drop on a circle of an agglutination slide. Add 1 drop of *Listeria* Latex Reagent to the same circle and mix. Agglutination should be visible within 2 minutes. If no agglutination is seen the reagents should be discarded.

Test Procedure:

1. Dispense 1 drop (50µL) of **SAMPLE DILUENT** on to 1 circle of a clean, dry agglutination slide.
2. Using an inoculating loop, remove a suspected *Listeria* colony from the selective agar plate.
3. Emulsify the colony in the drop of **SAMPLE DILUENT** on the test slide to produce a heavy, smooth suspension.
4. Observe the suspension for any agglutination or clumping which would indicate auto-agglutination. If the suspension remains smooth, proceed to Step 5. If auto-agglutination is seen, the organism cannot be tested using *Listeria Rapid Latex Test Kit*. Alternative test methods should be used.
5. Gently mix the Test Latex Reagent by inverting the vial several times. Add 1 drop of the colony suspension on the slide. Do not allow the dropper to touch the organism suspension.



6. Mix the latex reagent and organism suspension together with a clean mixing stick for 30 seconds. Continue mixing by rocking the slide.
7. Examine for agglutination after 2 minutes from initial mixing of latex and sample.
8. After reading, discard the used mixing sticks and slides into suitable disinfectant.

INTERPRETATION

Agglutination within 2 minutes is a positive result and indicates the presence of *Listeria* spp. No agglutination within 2 minutes is a negative result.

LIMITATIONS OF USE

- 1) Rough strains of *Listeria* species are known to cause non-specific agglutination in saline alone and therefore cannot be tested with *Listeria Rapid Latex Test Kit*.
- 2) Cultures grown at above 30°C may not produce flagella, and therefore fail to give a positive result with *Listeria Rapid Latex Test Kit*.
- 3) Non-motile strains may not be detected by *Listeria Rapid Latex Test Kit*.
- 4) Some *Staphylococcus* species and gram positive bacilli may give false positive reactions.
- 5) Identification with *Listeria Rapid Latex Test Kit* is presumptive and all positive results should be confirmed by biochemical analysis.













PERFORMANCE CHARACTERISTICS

Listeria Rapid Latex Test Kit has been evaluated as a culture confirmation test at both an independent microbiology laboratory and in-house. In total, 105 bacterial isolates were cultured on selective agar plates and colonies tested by *Listeria Rapid Latex Test Kit* and a well-established commercially available test.

Species confirmed by biochemical ID	<i>Listeria Rapid Latex Test Kit</i>	
	+ve	-ve
<i>L. monocytogenes</i>	59	0
<i>L. innocua</i>	22	0
<i>L. seeligeri</i>	9	0
<i>L. welshimeri</i>	7	0
<i>L. ivanovii</i>	4	0
<i>L. grayi</i>	4	0
Total	105	0

BIBLIOGRAPHY

1. WHO Working Group. 1988. Foodborne listeriosis. Bull WHO 66:241-428.
2. Brackett RE. 1988. Presence and persistence of *Listeria monocytogenes* in food and water. Food Technol 42:162.
3. Kerr KG, Dealler SF and Lacy RW. 1988. Listeria in cook-chill food. Lancet 2:37-38
4. Billie J and Doyle MP. *Listeria* and *Erysipelothrix* Chapt 32 in Manual of Clinical Microbiology, 5th Edition 1991. Eds Albert Balows, William J Hausler, Kenneth L Herman D Isenberg, H Jean Shadomy. American Society for Microbiology.

 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

CONTENT (50 tests)

REAG TEST:
CONTROL +:
SAMPLE DILUENT
DISPOSABLE AGGL. CARDS (SLIDE)
MIXING STICKS:
DISPOSABLE PIPETTE:
INSTRUCTIONS FOR USE

REF 271090

2.5 mL (dropper white cap)
 0.5 mL (dropper red cap)
 5.0 mL (black cap)
 9 cards with 6 wells each
 2x25 disposable mixing sticks
 1 disposable transfer pipette
 1 item

EDMA CODE 15 01 13 01

