LK07 – HiListeria™ Latex Test Kit

Product Code	Reagents provided**	LK07	
		25 Nos.	50 Nos.
LK07a	Listeria Latex Reagent	1.5 ml	3.0 ml
LK07b	Listeria Positive Control	0.25 ml	0.5 ml
LK07c	Sample diluent	2.5 ml	5.0 ml

**** Agglutination slides and mixing sticks are provided in the kit.**

Introduction

Contaminated foods including dairy and non-dairy products are the primary sources of Listeria transmission in both sporadic and outbreak cases (1-3). Due to the association of Listeria with food borne infections, the wide spread distribution of Listeria species in the environment and the high rates of intestinal carriage by many animal species (4), rapid detection of Listeria species is important in the microbiological quality surveillance of foods.

Intended Use

HiListeria™ Latex Test Kit is a rapid latex slide agglutination test for the presumptive identification of Listeria spp. from solid selective media. The test may be used in conjunction with biochemical analysis for full identification of Listeria spp. This kit is intended for *in vitro* diagnostic use only. Not for Medicinal Use.

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. HiListeria™ Latex Test Kit detects all motile strains of Listeria species to the limit of the sensitivity of the test.

Kit Contents

LK07a Listeria Latex Reagent

Latex particles coated with rabbit antiserum against Listeria flagellin antigens. Preserved with 0.02% Thiomersal.

LK07b Listeria Positive Control

Preserved with 0.02% Thiomersal.

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LK07c Sample diluent (0.85% Isotonic Saline)

Preserved with 0.1% Sodium Azide.

Instructions for Use

- Disposable agglutination slides
- Disposable mixing sticks

Additional Requirement

- Micropipettes and tips
- Bacteriological loops (PW012 HiFlexiLoop 2)

Warnings

Safety:

1. The reagents supplied in this kit are for *in vitro* diagnostic use only. Not for Medicinal Use.

2. The isotonic saline supplied in this kit contains 0.099% sodium azide as preservative. Sodium azide may react with lead and copper plumbing to form potentially highly explosive metal azides. Upon disposal flush with a large volume of water to prevent further azide build up.

Specimen Collection and Handling

Colonies picked from solid selective media can be tested with HiListeria™ Latex Test Kit and may be used directly for biochemical analysis with HiListeria™ Latex Test Kit.

1. The use of Listeria selective media containing esculin i.e. Listeria Oxford Medium Base (M1145 + FD071* and FD126*) is an advantage in differentiating Listeria sp.(Esc+) from non-Listeria sp.(Esc-)

Note: FD071*Oxford Listeria Supplement. For more details refer HiMedia Product Manual.

FD126* Listeria Moxalactam Supplement. For more details refer HiMedia Product Manual.

2. Colonies must be checked for oxidase reactivity before testing; false reactions may occur with oxidase positive cultures. Listeria spp. 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.

Procedure

Method for identification from selective solid media

1. Place a disposable slide on the work bench.

2. Add 20µl of saline to one well on the disposable slide.

3. Using a mixing stick or inoculating loop; emulsify the suspect colony in the 20µl of saline to produce a heavy smooth suspension. Suspensions should be made from colonies with morphology resembling Listeria species.

4. Observe the suspension for any agglutination or clumping which would indicate autoagglutination. If the suspension remains smooth, proceed to step 5 (See limitations of use, note 1).

5. Gently mix the Listeria Latex Reagent by inverting the vial several times. Place 20µl of reagent into same well adjacent to the Suspension. Mix the Latex Reagent and organism suspension with a clean mixing stick spreading the mixture over the entire area of the well and gently rock the slide. After mixing, discard the mixing stick into any suitable disinfectant.

6. Examine for agglutination within a maximum of 2 minutes.

7. After reading, discard the used slides into suitable disinfectant.

Storage and Shelf Life

HiListeria™ Latex Test Kit should be stored at 2-8^{O}C. Do not freeze. The kit should not be used after the expiry date printed on the outside of the carton.

Quality Control

Organism	**Agglutination with latex Reagent**
Listeria monocytogens	+
Key : + is agglutination , - is no agglutination	

Performance & Evaluation

The following controls should be performed each time the kit is used to ensure valid test performance:

1. Reagent Control (LK07a)

Add 20µl of Listeria latex Reagent to 20µl of saline in the same well on a disposable slide, mix and observe for agglutination at 1 minute. No agglutination should occur. If this control shows agglutination either the reagent or the saline is probably contaminated and should be discarded.

2. Positive Control (LK07b)

Place 20µl of positive control into a well on a disposable slide. Place 20µl of latex reagent into the same well next to the positive control. Mix the latex reagent and the positive control with a clean mixing stick

spreading the suspension over the entire area of the well. Gently rock and examine for agglutination within a maximum of 2 minutes. Easily discernible agglutination with the test latex indicates normal reagent function.

Test Procedure

Method for identification from selective solid media

1. Place a disposable slide on the work bench.

2. Add 20µl of saline to one well on the disposable slide.

3. Using a mixing stick or inoculating loop; emulsify the suspect colony in the 20µl of saline to produce a heavy smooth suspension. Suspensions should be made from colonies with morphology resembling Listeria species.

4. Observe the suspension for any agglutination or clumping which would indicate autoagglutination. If the suspension remains smooth, proceed to step 5 (See limitations of use, note 1).

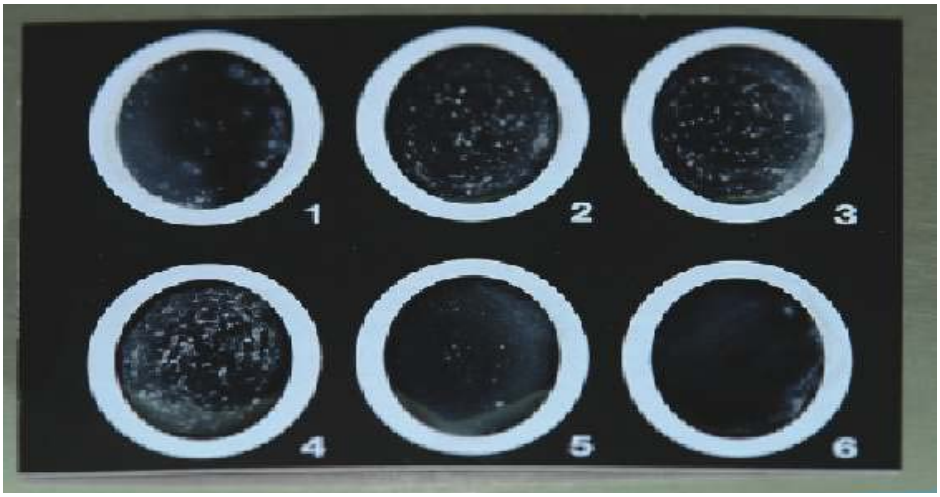
5. Gently mix the Listeria Latex Reagent by inverting the vial several times. Place 20µl of reagent into same well adjacent to the Suspension. Mix the Latex Reagent and organism suspension with a clean 4 mixing stick spreading the mixture over the entire area of the well and gently rock the slide. After mixing, discard the mixing stick into any suitable disinfectant.

6. Examine for agglutination within a maximum of 2 minutes.

7. After reading, discard the used slides into suitable disinfectant.

Interpretation

Agglutination within 2 minutes is a positive result and indicates the presence of Listeria species in the sample. Absence of agglutination indicates that Listeria species are not present in the test culture or that the level present is below the sensitivity of the test system.



1. *L. monocytogenes* (ATCC 19111) 2*. L.innocua* (ATCC 33090)

3. *L. ivanovii* (ATCC 19119) 4. *L. grayi* (ATCC 19120)

5. Positive control 6. Negative control

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 HiListeria™ Latex Test Kit.

2. Cultures grown at above 30°C may not produce flagella, and therefore fail to give a positive result with HiListeria™ Latex Test Kit.

3. Non- motile strains may not be detected by HiListeria™ Latex Test Kit.

4. Some Staphylococcus species and Gram positive bacilli may give false positive reactions.

5. Identification with HiListeria™ Latex Test Kit is presumptive and all positive results should be confirmed by biochemical analysis. (eg. Using KB012- HiListeria™ Identification Kit and KBM003- HiMotility™ Biochemical kit for Listeria, Listeria Identification System)

Precautions

Read the procedure carefully before starting the experiment.

Performance Characteristics

HiListeria™ Latex Test Kit was tested on colonies from a well characterized panel of 105 Listeria spp. and found to confirm all of these colonies.

Species(confirmed by Biochemical ID)	HiListeria™ Latex Test Kit +ve	HiListeria™ Latex Test Kit -ve
L. monocytogenes	59	0
L.innocua	22	0
L.seeligeri	9	0
L.welshimeri	4	0
L. Ivanovii	4	0
L.grayi	4	0
Total	105	0

References

1) WHO Working Group.1998.Foodborne listeriosis. Bull WHO 66: 241- 428.

2) Brackett RE. 1988. Presence and persistence of Listeria monocytogenes in food and water. Food Technal 42: 162

3) Kerr KG, Dealler SF and Lacy RW. 1988. Listeria in cook chill food. Lancet2:37-38.

4) BillieJ 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.

Other Suggested Reading Material Gellin BG and Broome CV. 1989. Listeriosis. JAMA 216:1313- 1320.

McLaughlin J. 1988. The identification of Listeria species. Public Health Laboratory Service. DMRQC Newsletter3:1-3.

Disposal

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 neutralized before treatment.

Technical Assistance

At HiMedia, we pride ourselves on the quality and availability of our technical support. For any kind of technical assistance, mail to mb@himedialabs.com.

IVD In vitro diagnostic medical device

CE Marking

Consult instructions for use

Do not use if package is damaged

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