LK02 - HiSalmonella™ Latex Test Kit

Product Code	Reagents provided**	LK02	
		25 Nos.	50 Nos.
LK02a	Salmonella Latex Reagent	1.5 ml	3.0 ml
LK02b	Positive Control	0.25 ml	0.5 ml
LK02c	Sample diluents	2.5 ml	5 ml

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

Intended Use

HiSalmonella™ Latex Test Kit is a latex slide agglutination test for the confirmatory identification of presumptive *Salmonella* colonies from selective agar plates. The kit is intended for *in vitro* diagnostic use only. Not for Medicinal Use.

Principle of the Test

Latex particles are coated with polyvalent antisera raised against a wide range of *Salmonella* antigens. When mixed with a suspension of *Salmonella* organisms, the latex particles rapidly agglutinate to form visible clumps. HiSalmonella™ Latex Test Kit detects >99% of motile *Salmonella* species and early investigations have indicated that specific non-motile species may also be detected.

Kit Contents

LK02a Salmonella Latex Reagent

Latex particles coated with rabbit antiserum against Salmonella antigens. Preserved with 0.099% Sodium azide.

1. LK02b Positive Control

Inactivated preparation of Salmonella antigens preserved with 0.099% Sodium azide.

2. LK02c Sample diluent (0.85% Isotonic saline)

Preserved with 0.099% Sodium azide

Instructions for Use

- Disposable agglutination slides
- Disposable mixing sticks

Additional Requirement

- Bacteriological loops (PW012 Hi-FlexiLoop 2)

ISO 9001-2008 CERTIFIED
WHO GMP CERTIFIED
CE
ISO 13485-2003 CERTIFIED

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- Micropipettes and tips

Warnings

Safety :

1. The reagents supplied in this kit are for *in vitro* diagnostic use only.

2. 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.

3. 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.

4. The positive control has been inactivated during the manufacturing process. However, it should be handled as though potentially infectious.

Specimen Collection and Handling

Colonies grown on selective agar plates can be tested with HiSalmonella™ Latex Test Kit.

Procedure

1. HiSalmonella™ Latex Test Kit should be used according to the kit instructions.
2. Allow all reagents to reach room temperature before use.
3. Do not dilute any of the kit reagents.
4. Do not intermix reagents from different batches of kits.
5. Do not freeze any of the kit reagents.
6. Be careful only to record agglutination. Reactions that are “curdy” or “stringy” may not be true agglutination.
7. Ensure the agglutination slide is clean and dry prior to use.

Storage and Shelf Life

HiSalmonella™ 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 carton label.

Quality Control

Organism	Agglutination with latex Reagent
S. typhimurium (ATCC 14028)	+
Key : + is agglutination , - is no agglutination	

Performance & Evaluation

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

1. Reagent Control: Add 20µl of Salmonella latex reagent (LK02a) to 20µl of saline solution (LK02c) in the same circle on a slide. Mix and spread the liquid over the entire area of the circle with a mixing stick. Rock the slide gently for 2 minutes and observe for agglutination. If any agglutination is seen, either the latex or the saline is contaminated and should be discarded.

2. Positive Control: Add 20µl of positive control (LK02b) to one circle on the test tube. Add 20µl of Salmonella latex (LK02a) to the same circle and mix. Do not allow the micropipette tip to touch the positive control. Rock the slide gently within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, the reagents may have deteriorated or become contaminated and should be discarded.

Test Procedure

1. Dispense 20µl of LK02c isotonic saline into a circle of a HiSalmonella™ Latex Test Kit agglutination slide.

2. Using an inoculating loop, remove a colony from the selective agar plate (Xylose Lysine Deoxycholate Agar i.e. XLD, M031) and emulsify the colony in 20µl of saline to produce a heavy smooth suspension. Suspensions should only be made from colonies with morphologies resembling *Salmonella* spp.

3. Rock the slide gently for upto 2 minutes and observe for autoagglutination or clumping. If the suspension remains smooth, proceed to Step 4 (see Limitations of Use Note 1).

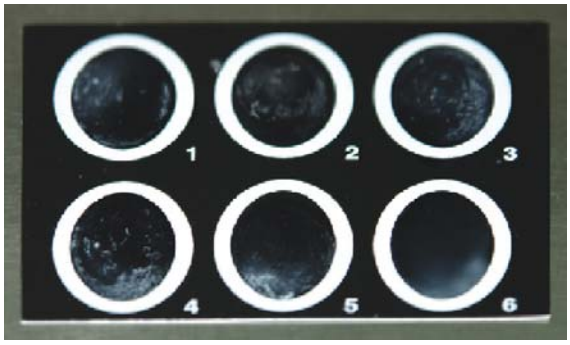
4. Mix the Salmonella latex reagent by gently inverting and add 20µl next to the bacterial suspension. Do not allow the micropipette tip to touch the suspension.

5. Mix the latex reagent and the bacterial suspension with a clean mixing stick and rock the slide gently two or three times. Excessive rocking of the slide is not necessary. Examine for agglutination within a maximum of 2 minutes.

6. After reading, discard the used mixing sticks and slides into a suitable disinfectant.

Interpretation

Agglutination within 2 minutes is a positive result and indicates the presence of *Salmonella* in the sample. Absence of agglutination indicates that *Salmonella* is not present in the test culture.



1. *S. typhimurium* (ATCC 14028) 2. *S. enteritidis* (ATCC 13076)

3. *S. typhi* (ATCC 19430) 4. *S. choleraesuis* (ATCC 12011)

5. Positive control 6. Negative control

Limitation of Use

1. Results should be interpreted in the context of all available clinical and laboratory information.

2. Rough strains of *Salmonella* are known to cause non-specific autoagglutination in saline alone and therefore cannot be tested with HiSalmonella™ Latex Test Kit.

3. Some non-motile strains can not be detected by HiSalmonella™ Latex Test Kit.

4. Some oxidase positive organisms may give false positive reactions.

5. Old stock cultures of Enterobacteriaceae on nutrient agar slopes may cause non-specific agglutination whereas old stocks of *Salmonella* may give false negative results. Fresh subcultures should be prepared for testing.

6. Identification with HiSalmonella™ Latex Test Kit is presumptive and all positive results should be confirmed by further identification tests and serotyping of pure cultures.

Precautions

Read the procedure carefully before starting the experiment.

Performance Characteristics

HiSalmonella™ Latex Test Kit has been evaluated in comparison with a well-established commercially available latex agglutination test for *Salmonella*. 126 isolates of *Salmonella spp.* and a range of 58 potentially cross-reacting bacteria were tested in both products.

	HiSalmonella™ Latex Test Kit			
		+ve	-ve	Total
Commercial Test	+ve	135*	1*	136
	-ve	0	48**	48
	Total	135	49	184

Sensitivity: 135/136= 99.3%

Specificity: 48/48=100%

Concordance: 183/184=99.5%

*1 sample was negative in HiSalmonella™ Latex Test Kit but equivocal in the commercial test. This sample was subsequently identified as *Salmonella Bergen.*

**Of the 135 isolates in this group, 11 were cross reactants in both tests. These were isolates of *C. diversus* (1), *A.baimannii* (2), P. *stuartii* (1), *B.cereus* (2), *S.aureus* (4), *Strep spp.*

However, all of the above either did not grow or showed very typical morphologies, when cultured on Salmonella selective media. In the case of *B. cereus*, agglutination was atypical (stringy).

***1 *S. dublin* was repeatedly negative in both tests.

Reproducibility

Intra-batch reproducibility was established by testing sensitivity and specificity of 1 batch of product against serial dilutions of reference and kit control antigens and a panel of 34 bacterial samples. Different operators carried out tests on 3 separate occasions. End-point titres obtained with reference/control antigens and qualitative results with the panel were identical in the three assays.

Inter-batch reproducibility was examined by testing sensitivity and specificity of 3 batches of product against serial dilutions of reference and kit control antigens, and a panel of 34 bacterial samples. Between the 3 batches, variation in end point titre was minimal (1 doubling dilution) and qualitative results with the panel correlated 100%.

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	CE Marking
	Consult instructions for use
	Do not use if package is damaged
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