LK03– HiStaph Latex Test Kit

Product Code	Reagents provided**	LK03	
		50 Nos.	100 Nos.
LK03a	Staph Latex Reagent	3.0 ml	6.0 ml
LK03b	Positive Control	0.5 ml	1.0 ml

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

Intended Use

HiStaph Latex Test Kit is a rapid latex slide agglutination test for the confirmatory identification of presumptive Staphylococcus aureus colonies from primary plate culture. The kit is intended for *in vitro* diagnostic use only. Not for Medicinal Use.

Principle of the Test

Latex particles are coated with fibrinogen (to which coagulase binds) and IgG (which binds with Protein A). When mixed with a suspension of S. aureus, the latex particles rapidly agglutinate to form visible clumps. No obvious agglutination occurs in the absence of coagulase/Protein A-positive Staphylococci.

Kit Contents

1. **LK03a Staph Latex Reagent**
   Latex particles coated with human fibrinogen and IgG. Preserved with 0.099% sodium azide.
2. **LK03b Staph Positive Control**
   Inactivated preparation of S.aureus preserved with 0.099% sodium azide.

Instructions for Use

- Disposable agglutination slides
- Disposable mixing sticks

Additional Requirement

- Micropipettes and tips
- Bacteriological loops (PW012 Hi-FlexiLoop 2).

Warnings

Safety:

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

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

Registered Office :
23, Vadhani Industrial Estate,LBS Marg,
Mumbai - 400 086, India.
Tel. : (022) 4017 9797 / 2500 1607
Fax : (022) 2500 2286

Commercial Office
A-516, Swastik Disha Business Park,
Via Vadhani Indl. Est., LBS Marg,
Mumbai - 400 086, India
Tel: 00-91-22-6147 1919
Fax: 6147 1920, 2500 5764
Email : info@himedialabs.com
Web : www.himedialabs.com

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. The IgG and fibrinogen used to sensitize the latex reagent are derived from human plasma which has been tested and found negative for the presence of antibodies to HIV-1, HIV-2 and HCV, and HbsAg. It should nevertheless be handled as though potentially infectious.

4. 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.

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

Specimen Collection and Handling

Select 1-2 isolated colonies grown for 18-24 hours at 35-37°C on primary isolation medium such as Columbia blood agar (M144) with 5% blood. The morphology of the colonies tested should resemble that of S. aureus. Pure single colonies should be tested to minimize the possibility of erroneous results. If necessary, isolate by streaking on to a new agar plate. Colonies with atypical morphologies can be tested for Gram-positive staining to maximize the probability that Staphylococci have been selected for testing.

Procedure

1. HiStaph 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 slide is clean and dry prior to use.

Storage and Shelf Life

HiStaph 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.aureus (ATCC 25923)	+
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. Positive Control: Add 20 µl of positive control (LK03b) to one circle on the test slide. Mix the HiStaph latex by gentle inversion and add 20µl to the same circle and mix with a mixing stick. Rock the slide gently. Within 2 minutes, agglutination, indicating a positive result, should be visible. If no agglutination is seen, a fresh kit should be used.

2. Negative Control: Mix the Staph latex by gentle inversion and add 20 µl to a circle on the test slide. Using a known coagulase/Protein A-negative Staphylococcus, e.g. S. epidermidis, take one fresh colony of 18-24 hour growth and emulsify in the 20 µl of latex reagent on the slide. Gently rock the slide for 2 minutes. No agglutination should occur.

Test Procedure:

1. Mix the Staph latex by gentle inversion and add 20 µl to a circle of a clean dry, test slide.

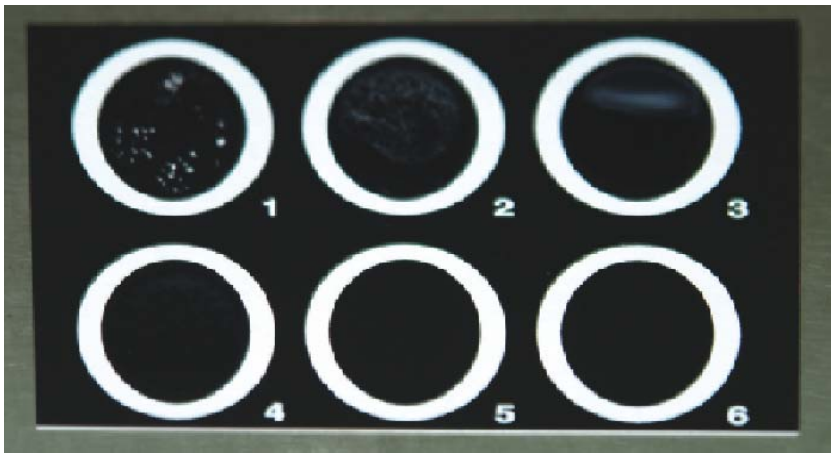
2. Using a sterile loop, pick one colony of the organism to be tested and emulsify in the 20 µl of latex reagent on the slide. Spread over the area of the circle with a mixing stick.

3. Gently rock the slide for up to 2 minutes and observe for agglutination.

4. After reading, discard used slides and mixing sticks into suitable disinfectant.

Interpretation

Agglutination within 2 minutes is a positive result and indicates the presence of S. aureus. No agglutination indicates the absence of S. aureus and of other coagulase/Protein A-positive strains of Staphylococcus.



1. S. aureus (ATCC 25923) 2. Positive control 3. E. coli (ATCC 25922)

4. Negative control

Limitations of Use

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

2. Test only pure, single colonies since mixed colonies may give erroneous results.

3. Cultures older than 30 hours may auto-agglutinate.

4. Media with a high salt content, such as Mannitol Salt Agar (M118), inhibit Protein production and this may lead to false negative results.

5. Rough strains of Staphylococcus may cause false positive reactions. These strains are rare and distinguishable from smooth strains by their colonial morphology. If suspected, these can be confirmed by emulsifying in a 20 µl of saline and examining carefully for a smooth suspension.

6. Stringy reactions on the slide may not be true positive reactions and further biochemical tests are required.

7. Some yeasts may cause false positive results.

8. All coagulase positive strains of Staphylococcus will react with HiStaph latex and S.aureus will therefore not be distinguishable from S.intermedius and S.hyicus. However, the latter two strains are infrequently isolated from human sources and are more commonly found in animals or as saprophytes.

9. HiStaph Latex Test Kit is intended for the identification of presumptive S.aureus. Colonies giving positive results should be confirmed as S.aureus by biochemical tests.

Precautions

Read the procedure carefully before starting the experiment.

Performance Characteristics

HiStaph Latex Test Kit has been evaluated in comparison with a well established commercially available latex agglutination test for S. aureus. 121 isolates of S.aureus and other closely related strains of Staphylococcus and a range of 56 potentially cross-reacting bacteria were tested in both products.

	HiStaph Latex Test Kit			
		+ve	-ve	Total
Commercial Test	+ve	63*	0	63
	-ve	0	114	114
	Total	63	114	117

Sensitivity: 63/63 = 100%

Specificity: 114/114 = 100%

Concordance: 177/177 = 100%

*Of the 63 isolates in this group, 9 were cross reactants in both tests. These were isolates of C. diversus (1), A. baimannii (2), P. stuartii (1), B. cereus (2), K. oxytoa (1), Strep spp (2) However , all of the above either do not grow, or show very atypical morphologies, when cultured on Staphylococcus-selective media (Mannitol Salt Agar M118). In the case of B. cereus, agglutination was atypical (stringy).

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 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 bacterial samples. Between the 3 batches, no variation in end-point titres was seen 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.

In vitro diagnostic medical device

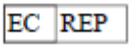
CE Marking

Consult instructions for use

Do not use if package is damaged

HiMedia Laboratories Pvt. Limited,
Reg. Off: 23 Vadhani Industrial Estate,
LBS Marg, Mumbai - 400086, India
Works: B/4-6, M.I.D.C., Dindori, Nashik, India
Customer Care No: 022-6116 9797
Email : techhelp@himedialabs.com

www.himedialabs.com



CE Partner 4U ,Esdoornlaan
13, 3951 DB Maarn The
Netherlands,
www.cepartner 4u.eu

PILK03_O/1216 LK03-04