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STAPHY LATEX TEST

NEW IMPROVED

RAPID LATEX AGGLUTINATION TEST FOR THE PRESUMPTIVE IDENTIFICATION OF STAPHYLOCOCCUS AUREUS

INTRODUCTION
Staphy Latex Test is a rapid latex agglutination test for the detection of Staphylococci species that produce clumping factor and/or Protein A from those species that do not.

SUMMARY
The genus Staphylococcus contains thirty-two species and fifteen subspecies, which are widespread in nature. The three major species include *Staphylococcus aureus*, *Staphylococcus epidermidis* and *Staphylococcus saprophyticus*. Of these, *Staphylococcus aureus* is considered the pathogenic strain causing abscesses, boils, carbuncles, acne and impetigo. Less commonly, *Staphylococcus aureus* has also been found to be the causative organism for pneumonia, osteomyelitis, endocarditis and food poisoning. 95% of pathogenic strains of *Staphylococcus aureus* possess Protein A on its cell surface and have the ability to produce coagulase, a property unique to it.
Staphy Latex Test has been designed to react with those species of Staphylococci possessing clumping factor and/or Protein A or a combination of both.

PRESENTATION

REF	104500050
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PRINCIPLE
Staphy Latex Test is based on the principle of agglutination. The latex particles are coated with human IgG and fibrinogen. On mixing the latex reagent with colonies of staphylococci which have clumping factor or Protein A present, the human fibrinogen will bind with coagulase and the IgG will bind with Protein A to give visible agglutination of latex particles indicating a positive result. If neither clumping factor nor Protein A is present, no agglutination will occur thereby indicating a negative result.

REAGENTS AND MATERIALS PROVIDED WITH THE KIT
A. Reagents
1. *Staphylococcus aureus* test reagent.
2. *Staphylococcus aureus* control reagent.
3. *Staphylococcus aureus* positive control.

B. Accessories
1. Disposable black coated slides.
2. Dispensing pipettes.
3. Mixing sticks.

C. Package Insert

ADDITIONAL MATERIAL REQUIRED BUT NOT PROVIDED
Stopwatch, High intensity direct light source, Isotonic saline, Pipettes, Sterile bacteriological loops, Bunsen burner, Disinfectant and Quality control organisms.

REAGENT
1. *Staphylococcus aureus* test reagent: A uniform suspension of polystrene latex particles coated with human IgG and fibrinogen.
2. *Staphylococcus aureus* control reagent: Uncoated, plain, uniform suspension of polystrene latex particles.
3. *Staphylococcus aureus* positive control: Reactive with latex test reagent and non-reactive with control reagent.

Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, sensitivity and performance.

REAGENT STORAGE AND STABILITY
1. Store the reagent at 2-8^{0} C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial labels.

NOTE
1. Reagent for laboratory and professional use only. Not for medicinal use.
2. All the reagents derived from human source have been tested for HBsAg and Anti-HIV antibodies and are found to be non-reactive. However, handle the material as if infectious.

3. Reagent contains 0.1% Sodium Azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
4. The reagent can be damaged due to microbial contamination or on exposure to extreme temperatures.
5. Shake the *Staphylococcus aureus* test reagent well before use to disperse the latex particles uniformly and improve test readability.
6. To avoid contamination of the reagent during dispensing, do not touch the dropper tip to the specimen on the reaction card. Ensure appropriate caps on reagent bottles are securely fitted after each use to prevent contamination and drying out of the reagents.
7. Only a clean and dry glass slide must be used. Clean the slide with distilled water and wipe dry.
8. Accessories provided with the kit only must be used for optimum results.

SPECIMEN COLLECTION AND PREPARATION

Specimens used for testing should be fresh 18 to 24 hour cultures / subcultures taken directly from the culture medium. Staphylococcal isolates grown on non-selective media such as blood agar or nutrient agar should be used to avoid stringy reactions. Wherever possible, pure cultures should be used for the test procedure.

TEST PROCEDURE

1. Bring the reagents to room temperature before testing.
2. Mix the reagent well before use.
3. Place 1 drop of Staphylococcus aureus test reagent into a circle on the test slide.
4. Using a sterile bacteriological loop, carefully pick 2-3 suspected staphylococcal colonies and transfer on the test circle.
5. Using the mixing stick, mix the culture emulsion and the reagent uniformly over the entire circle.
6. Immediately start the stopwatch. Rock the slide gently back and forth, observing for agglutination macroscopically for up to **one minute**.
7. Similarly test the control reagent with 2-3 suspected staphylococcal colonies.

INTERPRETATION OF TEST RESULTS

Positive Result: Agglutination on the test circle and no agglutination on the control circle at the end of one minute is a positive result. This indicates the presence of coagulase or Protein A.

Negative Result: No agglutination on the test circle as well as on the control circle at the end of one minute is a negative result. This indicates the absence of coagulase or Protein A.

Invalid Result: Non-specific results are indicated if the test reagent as well as the control reagent both shows autoagglutination. If the organism continues to produce autoagglutination, the test result is uninterpretable. (Refer Pt. 7 in limitations).

VALIDATION CRITERIA

The positive control may be used to validate the performance of the *Staphylococcus aureus* test reagent as well as the *Staphylococcus aureus* control reagent. Refer to the test procedure mentioned above using positive control instead of suspected staphylococcal colonies.

Agglutination on the test circle and no agglutination on the control circle at the end of one minute validates the performance of the *Staphylococcus aureus* test reagent as well as the *Staphylococcus aureus* control reagent.

LIMITATIONS

1. Some rare strains of Staphylococcus other than *Staphylococcus aureus* may give positive coagulase results and may also agglutinate latex reagents. These include *S. hyicus*, *S. intermedius*, *S. lugdunensis* and *S. schleiferi*.
2. Staphylococci isolated from urine specimens giving a weak positive or stringy result may be *Staphylococcus saprophyticus*.
3. Organisms such as *E. coli* and *C. albicans* are capable of agglutinating latex particles non-specifically. Also, some organisms possessing immunoglobulin or plasma-binding factors may show agglutination. To overcome these potential nonspecific results and isolate staphylococci, a gram stain should be performed.
4. The amount of Protein A expressed by *Staphylococcus aureus* is dependent on the medium and other growth conditions. Rare strains of *Staphylococcus aureus* that do not produce coagulase but still express some Protein A on their cell surface may yield a weak positive reaction. If such a strain is suspected, alternate identification methods should be used.
5. High salt concentrated media are known to destabilize latex solutions producing variable results.
6. A limited number of methicillin resistant *Staphylococcus aureus* strains may produce weak levels of clumping factor and Protein A. These strains may fail to react with **Staphy Latex Test**.
7. Autoagglutination may occur if rough strains of staphylococci are tested or if a culture is incubated beyond 36 hours. If the test colonies appear rough or autoagglutination is suspected, then the organism should be subcultured and retested at 18-24 hours. If the organism continues to produce autoagglutination, the test result is uninterpretable.

REMARKS

1. Cultures stored for a long period of time may produce non-specific results.
2. Do not pipette with the mouth.

3. Do not read the results beyond one minute.
4. Care should be taken when testing organisms directly from selective media.
5. Good laboratory practices must be followed for incineration and disposal of microbiological specimens and other material used.
6. It is recommended that results of the tests obtained should be correlated with clinical findings to arrive at a final diagnosis.
7. There is no reuse protocol for this product.
8. Any colonies of bacteria tested positive by **Staphy Latex Test** should be confirmed as *Staphylococcus aureus* by biochemical tests.

PERFORMANCE CHARACTERISTICS

Ninety-six specimens - out of which seventy-one positive and twenty-five negative specimens were tested with **Staphy Latex Test** and compared with a standard laboratory test i.e., Slide Coagulase Test in a reputed reference laboratory in India. The following are the results:

SPECIMEN DATA	TOTAL	**Staphy Latex test**	Slide Coagulase Test
Number of specimens tested	96	96	96
Number of Known *S. aureus* coagulase positive specimens	71	68	71
Number of Known *S. aureus* coagulase negative specimens	25	25	25

Based on this evaluation: Sensitivity of **Staphy Latex Test** is 95.8%. Specificity of **Staphy Latex Test** is 100%.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

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SYMBOL KEYS

 Temperature limitation	 Manufacturer	Latex Agglutination Test — Rapid Latex Agglutination Test for the Presumptive Identification of *S. aureus*
 Use by	 Consult Instructions for use	CONTROL + — Positive Control
 Date of Manufacture	REF — Catalogue Number	CONTROL — Control Reagent
LOT — Batch Number/ Lot Number	IVD — *In vitro* Diagnostic Medical Device	 Contains sufficient for <n> tests
 This side up	EC REP — Authorised Representative in the European Community	

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