DENKA SEIKEN CO., LTD

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-Read this product insert carefully before use-

STAPHYLO LA "SEIKEN"

Screening of *Staphylococcus aureus* by slide latex agglutination

INTENDED USE

STAPHYLO LA "SEIKEN" is a reagent for the screening of *Staphylococcus aureus* on primary cultured agar plates utilizing slide latex agglutination.

CHARACTERISTICS

STAPHYLO LA "SEIKEN" was developed for the screening of *S. aureus.*

1. Results of this kit correspond to those of conventional methods, i.e. the coagulase test.
2. Samples can be taken directly from cultured isolates.
3. Easy to use, with quick reaction time (only 20 seconds).

SUMMARY AND EXPLANATION

S. aureus is a typical causal microorganism for purulent diseases, such as wound infection and also a leading cause of food poisoning. *S. aureus* is widely known to cause Staphylococcal Scalded Skin Syndrome (SSSS), and Toxic Shock Syndrome (TSS). Methicillin resistant *S. aureus* (MRSA) is a known cause of nosocomial infections including serious sepsis and enteritis in patients with impaired immunological function or postoperative patients.

Catalase positive and Gram-positive *S. aureus* are now classified into 32 species. Screening of the clinically important *S. aureus* from other Staphylococci is based on the presence of the following proteins:

1) Staphylocoagulase (free coagulase)
   A protein produced by *S. aureus*, which activates prothrombin resulting in blood coagulation.
2) Clumping factor (bound coagulase)
   A protein produced on the cell wall by *Staphylococcus aureus*, which in the presence of fibrinogen induces clumping of cells.
3) Protein A
   A protein produced by *S. aureus*, which binds specifically to the Fc component of immunoglobulin G.

PRINCIPLE OF THE PROCEDURE

Latex particles, sensitized with fibrinogen and immunoglobulin G, react specifically with the clumping factor and protein A in the *S. aureus* cells to cause agglutination. The kit utilizes slide latex agglutination based on this principle.

CONTENTS

1.	**Sensitized Latex:** A latex suspension sensitized with human fibrinogen and rabbit plasma, containing 0.08 w/v% sodium azide as a preservative.	**6 mL×1vial**
2.	**Test cards:**	**30 pieces**
3.	**Mixing sticks:**	**120 sticks**
4.	**Product insert:**	**1/sheet**

MATERIALS NOT PROVIDED

1. Specimen: Colonies grown on enrichment agar plates for less than 24 hours or colonies grown on selective agar plates for less than 48 hours.
2. Equipment: Microbiological needle or loop.
   Timer

WARNINGS AND PRECAUTIONS

1. General precautions

1. This reagent is for *in-vitro* diagnostic use only.
2. It is strongly recommended that skilled laboratory personal familiar with the procedure should use this kit. Before proceeding with the test, read agglutination patterns routinely in a clinical setting.
3. The test kit should be used according to the kit insert/instructions. DENKA SEIKEN cannot guarantee its performance if used otherwise.

2. Precautions for measurement

1. Pay close attention to the reaction time as indicated in the test procedure, as a prolonged reaction time may lead to “false positive” because of self-agglutination of bacterial cells or mucous substances in the sample.
2. Mix the specimen and the sensitized latex carefully until a uniform suspension is obtained. Insufficient mixing (stirring) may lead to errors with the results.
3. Do not freeze the kit. If frozen the kit may give incorrect results. The reagent should be kept at room temperature for 30 minutes before use.
4. Reagents with different lot numbers should not be interchanged or mixed for use.
5. Do not dilute the reagent.
6. The reagent bottles should be discarded after use. Do not use the used bottles for other purposes.
7. If damage to the kit is suspected do not use the kit.

3. Precautions for handling

1. All equipment, samples should be handled as potentially infectious, protective equipment (safety spectacles, gloves, masks etc.) should be worn at all times.
2. Components of this kit have been prepared from human derived sera negative for HBs antigen and HIV antibody, and HCV antibody. However, this product should be treated as a potential biohazard and handled with appropriate caution.
3. In case of spillage, disinfect area with 70% ethanol solution, then clean with disposal absorbent paper, absorbent cotton, etc.
4. The latex contains sodium azide. If reagent comes into contact with the skin, mucous membranes or eyes wash immediately with copious amounts of water. Seek medical attention if adverse reactions or any side effects develop.

4. **Precautions for waste**

1. All specimens and equipment used in the test should be sterilized by one of the following methods after use:
    1) Soak in 2 vol% glutaraldehyde for 1 hour or longer.
    2) Soak in 0.5 w/v% sodium hypochlorite for 1 hour or longer.
    3) Autoclave at 121°C for 20 minutes or longer.
2. Components of this kit contain 0.08 w/v% sodium azide as a preservative. As sodium azide may react with lead and copper piping to form highly explosive metal azide, solutions containing this reagent should be disposed of by flushing with copious amounts of water.
3. Waste materials should be disposed of in accordance with local and national regulations.

STORAGE

Storage: 2-10°C protected from light (before and after opening vials)
Shelf life: Up to the expiry date on the label.

PROCEDURE

1. Prepare the test card for latex agglutination by folding along the dotted line. Hold the vial in a vertical position and place one drop (about 50 µL) of the sensitized latex onto the circle.
2. Using a microbiological loop or needle, take three to five colonies and add onto the circle.
3. Mix the materials in the circle with a mixing stick to make uniform suspension.
4. Under well-lit conditions, observe the card for agglutination, while gently rocking the card back and forth by hand for approximately 20 seconds.

INTERPRETATION OF RESULTS

Judgment is made according to the following interpretation:

Agglutination is observed in the circle within 20 seconds	Positive
No agglutination is observed within 20 seconds.	Negative

QUALITY CONTROL

The agglutination pattern should be confirmed with a positive control strain, which has been identified as *S. aureus*. Recommended *S. aureus* strains: ATCC25923 and ATCC6538P

LIMITATIONS

1. This kit is for screening pure cultured specimens. Identification should be based on biochemical property test.
2. Certain hemolytic streptococci and Gram-negative bacilli are known to react with protein in plasma resulting in a “false positive”. To avoid this samples should be confirmed as catalase positive, Gram-positive cocci.
3. Depending upon strains, amounts of Protein A and clumping factor on the Staphylococcal selective agar plates are restrained. Even if typical colonies of *S. aureus* are observed on the selective agar plates, however, are judged as “negative”, with this kit, the colony should be retested after cultured with the enrichments agar plates (BHI agar plate, HI agar plate), or should be confirmed by a biochemical property test or coagulase test.

PERFORMANCE

The results of examination of 135 strains of *S. aureus,* and 10 strains of non-S. aureus-staphylococcal bacteria for coagulase, clumping factor and protein A are summarized in the table below:

	STAPHYLO LA SEIKEN	
Strains	Positive	Negative
S. aureus: 135 strains	134	1*
Non-S. aureus-staphylococcal bacteria: 10 strains	0	10

* Clumping factor and non Protein A producing strain

BIBLIOGRAPHY

Essers, L. et al.: Rapid and Reliable Identification of *Staphylococcus aureus* by a Latex Agglutination Test, J. Clin. Microbiol., 1980,12, p.641.

ORDERING INFORMATION

STAPHYLO LA “SEIKEN” 100 tests/kit
Product code number: 296146

ORDERING

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SYMBOL GLOSSARY

IVD	*In Vitro* Diagnostic Medical Device		Used by
REF	Catalogue number	LOT	Batch code
Σ	Contains sufficient for <n> tests		Upper and lower limit of temperature
	Consult Instructions for Use	CE	CE marked product

EC REP Authorized representative in the European Community

Manufacturer

EC REP

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