IVD

# Auxiliary Reagents for Staphylococcal Coagulase Typing

### INTENDED USE

Serotyping of *Staphylococcus aureus* coagulase in conjunction with Staphylococcal Coagulase Typing Antisera supplied by DENKA SEIKEN CO., LTD.

### SUMMARY AND EXPLANATION

Auxiliary Reagents for Staphylococcal Coagulase Typing are reagents using on the serotyping test of Staphylococcaol coagulase with Staphylococcal Coagulase Typing Antisera.

### **PRODUCT**

 Diluent 20 mL 1 vial Solution containing polypeptone, sodium citrate, and 0.08 w/v% sodium azide.

Normal rabbit serum
 Normal rabbit serum
 3 mL 1 vial

Normal rabbit plasma (lyophilized)
 ML
 vial Lyophilized normal rabbit plasma containing sodium citrate

### **PRECAUTIONS**

### 1. General precautions

- 1) For in vitro diagnostic use only.
- 2) Only bacteriological trained laboratory staff should handle the reagents.
- 3) Reagents should only be used for the intended use.
- 4) Reagents should be used according to the described procedures.

### 2. Handling precautions

- All specimens, samples and containers coming into contact with samples should be treated as infectious.
- If reagent comes into contact with skin, eyes, or mouth wash immediately with copious amounts of water, seek medical attention if necessary.
- 3) Do not freeze the reagents or use past the expiration date as this may result in poor reagent performance.
- 4) Reagents should be allowed to stand at 15°C-25°C for at least 30 minutes before use.
- 5) Used containers should not be used for other purposes.
- 6) Reagents with different lot numbers should not be mixed.
- 7) Special precautions should be taken to ensure that the reagent caps are not exchanged.
- 8) Avoid microbial contamination of opened reagent bottles. Do not use reagents if they are contaminated or cloudy.

### 3. Precautions for disposal

- The reagent contains 0.08 w/v% sodium azide. Sodium azide may react with lead or copper to form explosive heavy metal azides. The reagent should be disposed with a large amount of water.
- 2) All specimens, spills, inoculated products and equipment used in this test should be treated by one of the following methods.
  - [1] Soaking in 0.1 w/v% hypochlorite for 1 hour or more.
  - [2] Autoclave at 121°C for 20 minutes or more.

## PERFORMANCE CHARACTERISTICS

When the serotyping test is performed using coagulase specific antisera and this product with reference strains, positive result shown with the corresponding strain and negative result shown with a strain of a different serotype

Staphylococcal Coagulase Typing Antisera supplied by DENKA

### STORAGE / SHELF LIFE

Storage: 2°C-10°C.

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Shelf life: Up to the expiry date on the label.

#### **PACKAGE**

Auxiliary Reagents for Staphylococcal Coagulase Typing

<ul> <li>Diluent</li> </ul>	20 mL	1 vial
<ul> <li>Normal rabbit serum</li> </ul>	3 mL	1 vial
<ul> <li>Normal rabbit plasma (lyophilized)</li> </ul>	3 mL	1 vial

Please feel free to contact us at the following with your questions or comments:

TEL: +81-3-3669-9421 FAX: +81-3-3669-9390

### Symbols

Lot Batch code

Use by

In Vitro Diagnostic Medical Device

Temperature limitation (Store at)

Catalogue number

Consult Instruction for use

Cont. Contents of kit



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### **TEST PROCEDURE**

For use of this product follow the instruction manual packaged in