IVD

Auxiliary Reagents for Hemolytic Streptococcus Typing

INTENDED USE

Serotyping of group B hemolytic streptococci in conjunction with Group-B Streptococci Typing Antisera supplied by DENKA SEIKEN CO., LTD.

SUMMARY AND EXPLANATION

Auxiliary Reagents for Hemolytic Streptococcus Typing are reagents for the preparation of test antigens for the serotyping of Hemolytic Streptococcus. The test antigens are suitable for the agglutination test with Group-B Streptococci Typing Antisera.

PRODUCT

Set: contents

1. Swine pancreas extract 5 mL 4 vials

Extraction of porcine spleen.

2. Phenol red solution 5 ml 1 vial

Solution containing phenol red and 0.08 w/v% sodium azide.

3. PH correction solution 5 mL 2 vials Tris buffer.

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

- 1) 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.
- Avoid microbial contamination of opened reagent bottles. Do not use reagents if they are contaminated or cloudy.

3. Precautions for disposal

- Some of 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.
- 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.

TEST PROCEDURE

For use of this product follow the instruction manual packaged in Group-B Streptococci Typing Antisera supplied by DENKA SEIKEN CO., LTD.

PERFORMANCE CHARACTERISTICS

When the serotyping test is performed using test antigens prepared by the product with reference strains, agglutination is observed with the corresponding antiserum, but not observed with differently serotypes of antisera.

STORAGE / SHELF LIFE

Storage: 2°C-10°C.

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

PACKAGE

Auxiliary Reagents for Hemolytic Streptococcus Typing

Set: Swine pancreas extract 5 mL 4 vials Phenol red solution 5 mL 1 vial PH correction solution 5 mL 2 vials

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

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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