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In Vitro Diagnostic Reagents Ref. (62E) No. 1454

# Clostridium perfringens type A Antisera "SEIKEN"

(Heat resistant CI. welchil Hobbs 1952)

The product is an antisera which is used for the serological test of heat resistant Clostridium perfringens type A and is a liquid reagent which contains specific agglutinins to each sero-type.

The Serotype is identified by the slide agglutination method. Each antiserum is prepared by hyperimmunizing rabbits with each standard strains and inactivating the serum at 56 °C for 30 minutes. After removing cross agglutinins by absorption, the sera are sterilized by anti-bacterial filtration, and sodium azide is added at 0.1 w/v% as a preservative.

#### **PRODUCTS**

Polyvalent serum 4 vials

I (type 1 to 5)

II (type 6 to 9)

II (type 10 to 13)

IV (type 14 to 17)

Monovalent serum 17 vials

type 1 to 17

#### INTENDED USE

This reagent is used for serotyping heat resistant C. perfringens type A.

#### PRINCIPLE OF THE MEASUREMENT

When this reagent is mixed with cells of heat resistant C. perfringens type A, an antigen antibody reaction occurs and produces agglutinating clusters which can be seen with the naked eye. Serotyping can be performed using this reaction.

#### **PROCEDURES**

After isolating organism using conventional procedures, carry out serotyping on the organism whose bacteriological and biochemical features are identical to those of heat resistant C. perfringens.

At first, judge of agglutination is shown below using polyvalent serum. When agglutination is observed in any polyvalent serum, check the specimen again using the same procedure and each monovalent serum for serotyping and confirm the presence of agglutination.

#### Test Method

- 1. Using a glass pencil, divide a clean glass slide into several sections and put a drop of sera in the center of each section and put a drop of physiological saline in the center of the control section.
- 2. Put one loopful of the antigenic suspension in the vicinity of the drop of serum or physiological saline and mix the antigen and serum or antigen and physiological saline well using a platinum loop.
- 3. After tilting the glass slide back and forth, observe whether agglutination occurs with the naked eye. In addition, as a control, check whether spontaneous agglutination occurs with the reaction of antigen and physiological saline.

#### INTERPRETATION

Interpretation should be done as follows:

Reaction between physiological saline and antigen solution	Reaction between serum and antigen solution	Interpretation
When spontaneous agglutination is not observed.	When strong agglutination is observed within one minute.	Positive (+)
	When agglutination is not observed within one minute.	Negative
When spontaneous agglutination is observed.	Indeterminant	

- 1. Very weak agglutination which occurs after one minute in the serum-antigen reaction should be considered as a negative result.
- 2. The antigen type of the specimen is determined according to the name of the monovalent serum which gave a positive result.
- 3. If no agglutination is observed in the reaction with any of the sera, heat the antigenic suspension at 100°C for 60 minutes or 121°C for 15 minutes. Repeat the same procedure after cooling. If agglutination still does not occur, an antigen type other than 1-17 is suspected.
- 4. When agglutination is observed in the physiological saline control, test it again using another selected colony.

#### PERFORMANCE CHARACTERISTICS

#### 1. Sensitivity

When the standard strain of which the serotype is known and which was provided by NIH (National Institute of Health Japan) reacted with one drop of this antiserum on the glass slide, granular agglutination is observed.

#### 2. Specificity

When the antisera were tested in the same way as in the sensitivity test, it agglutinated with only the standard strain which matched the tested serum, but no agglutination was observed with the naked eye with the mismatched standard strain.

#### PRECAUTIONS

- 1. All live cells, glass slides and test tubes, etc. used in this test should be sterilized by either soaking in 0.1% sodium hypochlorite solution for more than 1 hour or by autoclaving at 121 °C for longer than 20 minutes.
- 2. If the serum freezes, it may produce sediment when thawed. Take care not to freeze the antisera.
- 3. This reagent contains 0.1 w/v% sodium azide as a stabilizer. Sodium azide may react with lead and copper pipes to form highly explosive metal azides. Upon disposal, flush away with a large volume of water to prevent azide accumulation.

## STRAGE AND EXPIRATION

Store the reagent at 2-10°C, up to expiration date on the label.

### PACKAGES

Each type 2 ml in a vial with a syringe Set 21 vials