1996.9

Aストレプト AD「生研」
In Vitro Diagnostic Reagents
Ref. (63E) No. 1836

A STREPT AD "SEIKEN"

A kit for the detection of Group A Streptococcus by slide latex agglutination **for 50 tests**

Hemolytic Streptococcus has been grouped into 20 groups (A－V, except I, J) according to serological differences shown by C-polysaccharides possessed by the organism.[1)]

In particular, Group A Streptococcus is known as a causative agent of upper respiratory tract infection such as sore throat evoking occasionally mixed infection with other bacteria, secondary infection and secondary diseases.

On the mucous membrane, in addition to upper respiratory tract infection, the organism causes tympanitis and pneumonia, and on the skin it causes inflammatory diseases such as pyoderma and erysipelas and, in some cases, results in lymphoadenitis, sepsis or acute bacterial endocarditis. It is also known to cause scarlet fever. Immunological disorders as secondary diseases following Group A Streptococcal infection such as glomerulonephritis or rheumatic fever makes this infection very serious.

Identification of this organism from the pharynx of patients has been conducted by observing hemolysis on blood agar plate and sensitivity to Bacitracin as screening followed by biochemical and serological examinations. The sensitized latex reagent in this test kit has been prepared by coating polystyrene latex particles with purified rabbit antibody to Group A Streptococcus and it is capable of forming an agglutinate in the presence of Group A Streptococci in a specimen prepared by nitrite extraction.[2)]

The test kit has been developed for the direct detection of Group A Streptococcus from patient specimens.

CHARACTERISTICS

1. The agglutination pattern is easy to read.
2. Test procedures are very simple and the reaction time is short.
3. Detection sensitivity is high and correlation with the culture method is good.
4. The test has excellent specificity.

KIT COMPOSITION

1. **Sensitized latex** 2 ml 1 vial
   Latex suspension sensitized with specific antibodies (rabbit IgG) against Group A Streptococcus containing 0.1 w/v% sodium azide as a preservative.
2. **Control latex** 2ml 1 vial
   Latex suspension coated with non-immune rabbit globulins containing 0.1 w/v% sodium azide as a preservative.
3. **Positive control** 1 ml 1 vial
   Suspension of inactivated Group A Streptococcus containing 0.1 w/v% sodium azide as a preservative.
4. **Extraction reagent-1** 5 ml 1 vial
   An acetic acid solution
5. **Extraction reagent-2** 5 ml 1 vial
   A sodium nitrate solution
6. **Extraction reagent-3** 5 ml 1 vial
   A Tris buffer solution
7. **Sample cup** 55 pcs

8. **Dropping pipet** 55 pcs
9. **Sterilized swab** 55 pcs
10. **Test card** 50 sheets

INTENDED USE

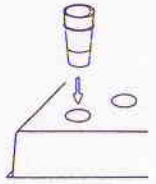
This test kit is intended for use in detecting beta Hemolytic streptococcus (group A).

PRINCIPLE

The principle of measurement is slide latex agglutination in which the latex particles sensitized with antibodies against Group A streptococci, agglutinate by reacting specifically with each the streptococcal antigen which is extracted by nitrite on the agglutination plate.

PROCEDURE

1. **Reagents and materials necessary for the test**
   A STREPT AD "SEIKEN" 1 box
2. **Sample collection**
   A sample is collected by swabbing the pharynx of the patient with a sterilized swab supplied with the kit.
3. **Reagent preparation**
   The reagents supplied are ready to use.
4. **Procedures**
   [Extration of sample]



1) Take a reagent stand and place a sample cup in place on the stand. (The following procedures are all carried out in the sample cup kept in the reagent stand.)

2) Place swabs from a patient in the sample cup.

3) Add two drops of Extraction reagent-1 to the sample cup.

4) Add two drops of Extraction reagent-2 to the cup.

4) Hold the test card for two minutes while tilting it gently so that the mixture covers the whole area of each circle.

5) Read results under sufficient light.

NOTE

[Interfering substances]

In order to provide a reliable diagnosis, it is important to carefully collect specimens from the pharynx. If the swab touches the oral cavity, especially the surface of the tongue during sample taking, it may give a non-specific reaction.

INTERPRETRATION

1. **Interpretation**

   Interpret the results as follow. Initially, check that the control latex has not agglutinated.

Results	Interpretation	Figure
Distinct agglutination of the sensitized latex particles is observed.	Positive	
No agglutination of the sensitized latex particles is observed.	Negative	
Agglutination of the control latex particles is observed.	Invalid	Take a new sample and retest.

2. **Caution for interpretation**

   Although Group A Streptococcus does not belong to the normal flora in the human pharynx, it is known that there are carriers in whose pharynx Group A Streptococcus is present without the development of any apparent symptoms. Therefore, in judging infection, diagnosis based upon clinical symptoms is important for positive specimens using this test.

3. **Confirmation of reagent validity**

   Dispense one drop of positive control onto a swab and repeat the above procedures to check for a positive pattern and the validity of the reagents.

PERFORMANCE AND INTERFERING SUBSTANCES

1. **Sensitivity**

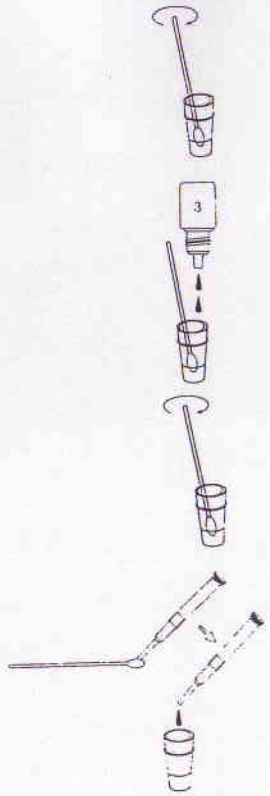
   The sensitivity of this test using clinical materials (samples from patients) is 10^4 CFU (colony forming unit) per swab when measured by quantitative culture method.

2. **Specificity**

   The test did not show cross reactions with Group B Streptococci, Group D Streptococci, Group G Streptococci, Staphylococcus aureus and Haemophilus influenzae.

3. **Reproducibility**

   Group A Streptococcus strains kept in our laboratory were tested 10 times with the kit and all of them were positive in the test.



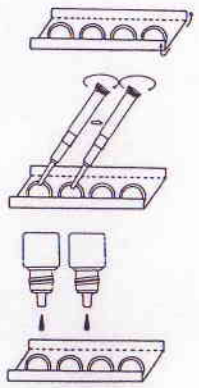
5) Mix the contents of the sample cup well by rotating the swab in the sample cup while pressing it into the bottom of the cup. Leave the cup undisturbed for 5 minutes.

6) Add two drops of Extraction reagent-3 to the cup.

7) Mix the contents well by rotating the swab in the sample cup as in 5).

8) Absorb the solution soaked into the swab with a dropping pipet and mix it with the solution in the sample cup (leaving the dropping pipet standing in the sample cup).

[Slide latex agglutination]



1) Prepare a slide agglutination plate by bending it along the dotted line.

2) Place drops of the liquid in the cup onto two circles on a test card (one drop per circle). Spread the liquid to cover the whole area of the circles with the dropping pipet.

3) Add a drop of sensitized latex reagent to one of the two circles and the control latex reagent to the other.

4. **Test range**
   A sample containing the organisms at more than 10^4 CFU/swab can be detected.

CORRELATION

A better than 94% correspondence in results has been confirmed between this test and quantitative culture tests using clinical specimens. (This correspondence was obtained by calculation excluding specimens showing less than 1×10^3 CFU per swab.)

PRECAUTIONS

1. The test should be used only for in vitro diagnostic purposes.
2. Do not freeze the reagents. Bring the reagents to room temperature at least 30 minutes before use.
3. Latex reagent vials and the positive control should be shaken well before use in order to provide a uniform suspension.
4. When dispensing these reagents, vials should be kept upright.
5. Take care not to mix the caps of the reagents.
6. Live cells and instruments used for the tests should be disposed of after soaking in 0.1% sodium hypochlorite solution (available chlorine approximately 1000 ppm) for 1 hour or more, or after autoclaving at 121°C for 20 minutes or more.
7. Refrain from using a more than one kit of different manufacturing lot numbers together.
8. Sodium azide contained in some of the reagents may react with lead and copper piping to form highly explosive metal azides. Upon disposal of the reagents, flush them away with a large volume of water to prevent accumulation of azides.

STORAGE AND SHELF LIFE

Storage: 2－10 ℃

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

PACKAGE

A STREPT AD "SEIKEN" 50 tests 1 box

REFERENCES

1. Lancefield, R. C. et al.: A SEROLOGICAL DIFFERENTIATION OF HUMAN AND OTHER GROUPS OF HEMOLYTIC STREPTOCOCCI, J. Exp. Med., **57**, 571 (1933).
2. El Kholy, A. et al.: Serological Identification of Group A Streptococci from Throat Scrapings Before Culture, J. Clin. Microbiol., **8**, 725 (1978).

DENKA SEIKEN CO., LTD.
3-4-2 Nihonbashikayaba-cho, Chuo-ku, Tokyo, Japan