Instructions for use

IMMULEX *STREPTOCOCCUS* GROUP ANTISERA

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IMMULEX™ *STREPTOCOCCUS* GROUP ANTISERA

For *in vitro* diagnostic use

Intended use
The ImmuLex™ Streptococcal Group Antisera on latex are intended for streptococcal serotyping of group A, B, C, D, F, G or L.

Description
Each bottle contains latex particles coated with group specific streptococcal antiserum (A, B, C, D, F, G or L) raised in rabbits (0.0975% sodium azide as preservation).
Cross-reactions in the antisera have been removed by absorption. Each bottle contains reagent for approximately 75 tests. All products are sold as ready-to-use.

Principle
The ImmuLex™ *Streptococcus* antisera are for rapid latex agglutination testing for streptococcal serotyping using a bacterial suspension (bacterium from a blood agar plate suspended in physiological saline) or a nitrous acid extraction of group specific antigens.

Before using the latex reagent, it is very important to bring the vial to room temperature and shake it. Use the reagent while the latex particles are in homogeneous solution. When mixing the latex reagent with a homologue antigen, the latex particles will agglutinate and form large aggregates visible to the naked eye. The reaction is performed on a reaction card. Disposable reaction cards can be ordered separately.

Limitations
The ImmuLex™ Streptococcal Group Antisera are intended for serotyping of pure cultures of streptococci and must only be used as a supplement for the ImmuLex™ *Streptococcus* Group Kit. It is well known that *Enterococcus* species (group D antigen) and *Streptococcus* group D strains can cross-react in antiserum directed against other *Streptococcus* groups.[1,2,3,4] The latex product for group D does not have any cross-reaction with the other group antigens.
If there is a positive reaction with the group D latex product, it is a *Streptococcus* group D strain.

Materials required but not provided
- 5-10 % blood agar plate
- Physiological saline pH 7.4
- Pipette (droplet off approx. 10 µL)
- 1 µL inoculation loop
- Gloves
- Tubes
- Fume hood
- Incubator (35-37 °C)
- 2 vials of Extraction Reagent 1 (red cap) - Article number 86255
- 2 vials of Extraction Reagent 2 (yellow cap) - Article number 86256
- 2 vials of Neutralising Reagent 3 (blue cap) - Article number 86257

Procedure
Do not perform more than 3 reactions simultaneously before reading the result.

1. Use a Todd Hewitt broth culture showing visible growth or a culture from a 5-10% blood agar plate or a chocolate agar plate depending on the bacterium to be serotyped. All cultures should be prepared by growing them overnight at 35-37 °C.

2. Allow the latex reagent to reach room temperature before use.
3. Shake the latex reagent vial and use the reagent while the latex particles are in homogeneous solution. For each reaction, set of a drop of approximately 10 µL (squeeze the vial gently) of latex reagent onto the reaction card.
4. Prepare the bacterial culture as follows. Suspend 1 µL inoculation loop of bacterium culture from a 5-10% blood agar plate in 250 µL physiological saline pH 7.4 and add 10 µL of this bacterial suspension on the reaction card next to the latex reagent.

Rock the reaction card for 30 seconds. Any agglutination after 30 seconds is not a positive reaction

If there is no reaction using bacterial suspension or if the reaction is indistinct, follow the procedure described below.

Warning: The combination of reagent 1, 2, and 3 produces hazardous fumes. The below steps must be performed under a fume hood and wearing gloves.

Warning: Regents from SSI Diagnostica contain sodium nitrite solutions. The reagents are classified as harmful and labelled:

⚠ **Warning**
H302: Harmful if swallowed.
P301+P312: If swallowed, call a POISON CENTER or doctor/physician if you feel sick.

1. Add one drop of reagent 1 (red cap) to a tube.
2. Suspend a 1 µL inoculation loop of bacteria culture from a 5-10% blood agar plate in reagent 1 in the tube.
3. Add one drop of reagent 2 (yellow cap) to the tube and mix.
4. Wait minimum 10 minutes (maximum 60 minutes).
5. Add one drop of reagent 3 (blue cap) to the tube and mix.
6. For each reaction add one drop of latex reagent on the reaction card (approximately 10 µL, squeeze the bottle gently).
7. For each reaction add 10 µL of the bacterial extract on the reaction card. For negative control use a mixture of one drop reagent 1, 2, and 3, respectively.
8. Mix the latex drop and the bacterial extract drop with a mixing stick. Use a separate stick for each reaction.
9. Spread to cover the area of the circle.
10. Rock the card slowly and observe for agglutination within 30 seconds. Any agglutination after 30 seconds is not a positive reaction.

Interpretation
A positive result in one of the latex reagents identifies the group.
Example: If there is only a positive reaction in the group B latex reagent, the strain is a *Streptococcus* group B.
As the group antigen D is known to cross-react with other *Streptococcus* groups, there may be more than one positive reaction with the latex reagents. If, however, there is a positive reaction in the group D latex reagent, the strain is a *Streptococcus* group D or an *Enterococcus* species (which also have the group D antigen).

The group D latex reagent is developed to identify the following species:
S. alactolyticus, *S. bovis*, *S. durans*, *S. hazem*, *S. gallolyticus*, *S. equinus*, *E. faecium*, and *E. faecalis*
Positive and negative reactions are shown in figure 1.

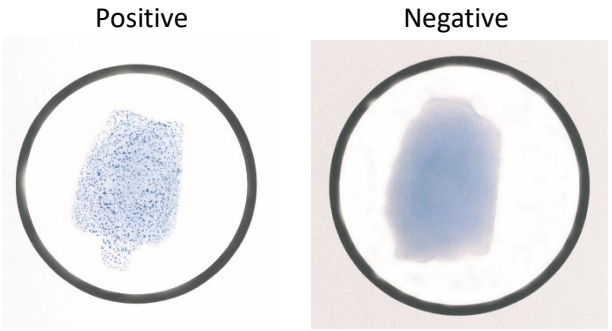

Figure 1. Illustration of a positive (left) and a negative (right) latex agglutination on a reaction card.

Quality certificate
SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485. Certificate of analysis can be downloaded from our website: ssidiagnostica.com.

References
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2. Birch, BR. et al., J Clin Pathol, 37: 1289-1292, 1984.
3. Finch, RG., Phillips, I. J Clin Pathol, 30: 168-170, 1977.
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