Instructions for use

IMMULEX™ *STREPTOCOCCUS* GROUP KIT

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Intended use
The ImmuLex™ *Streptococcus* Group Kit is intended to be used for streptococcal serotyping of group A, B, C, D, F, and G.

Principle
The ImmuLex™ *Streptococcus* Group Kit is a rapid latex agglutination test 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.

Description
The ImmuLex™ *Streptococcus* Group Kit consists of:

Latex reagents:
Six vials (Group A, B, C, D, F, and G) each with 1.5 mL (approx. 75 tests) ready-to-use reagent plus 50 disposable reaction cards and mixing sticks.

Extraction Reagent 1 (red cap):
Two vials each containing 2 mL of sodium nitrite solution. The reagent is 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.

Extraction Reagent 2 (yellow cap):
Two vials containing 2 mL each of an acid solution.

Neutralizing Reagent 3 (blue cap):
Two vials each containing 2 mL of a neutralizing solution (0.0975% sodium azide added as preservation).

Limitations
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[1-4].

Materials required but not provided

- 5-10% blood agar plate
- Physiological saline pH 7.4
- Pipette (droplet off approximately 10 µL)
- 1 µL inoculation loops
- Gloves
- Tubes

- Fume hood
- Incubator (35-37 °C)

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 (see table 1). 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. Suspend 1 μ L inoculation loop of bacterium culture from a 5-10 % blood agar plate in 250 μ L physiological saline pH 7.4 and add 10 μ L of this bacterial suspension on the reaction card next to the latex reagent. If there is no reaction using bacterial suspension or if the reaction is indistinct, follow the procedure described below
5. Mix the two drops with a mixing stick. Use a new stick for each reaction
6. Spread to cover the area of the circle.
7. Rock the card slowly and watch for agglutination. Rock the card for 30 seconds. Any agglutination after 30 seconds is not a positive reaction.

   Positive and negative reactions are shown in figure 1.

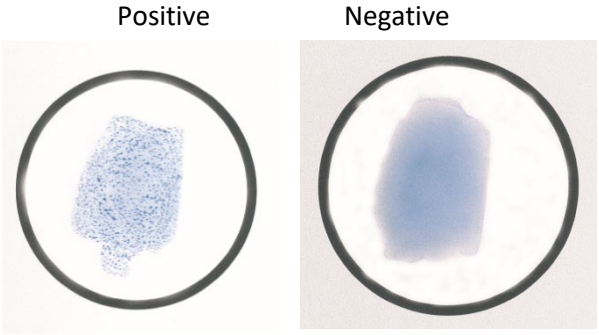

Figure 1. Illustration of a positive (left) and a negative (right) latex agglutination on a reaction card.

Follow the procedure below if there is no reaction using bacterial suspension or if the reaction is indistinct.

Nitrous acid extraction of bacterial antigen:

1. **Warning:** The combination of reagent 1, 2, and 3 produces hazardous fumes. Step 3-6 in the below procedure is recommended to be performed under a fume hood and wearing gloves.
2. Add one drop of reagent 1 (red cap) to a tube.
3. Suspend a 1 µL inoculation loop of bacterial culture from a 5-10% blood agar plate in the tube containing reagent 1.
4. Add one drop of reagent 2 (yellow cap) to the tube and mix.
5. Wait minimum 10 minutes (maximum 60 minutes). Add one drop of reagent 3 (blue cap) to the tube and mix.
6. Follow the latex procedure mixing the bacterial extract with the latex reagents.

NB: Rock the card for 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*.

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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Information and ordering
SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark
T +45 4829 9100
info@ssidiagnostica.com
www.ssidiagnostica.com
shop.ssidiagnostica.com

Presafe Denmark A/S

Quality System DS/EN ISO 13485

6th edition • March 2022 • 86468