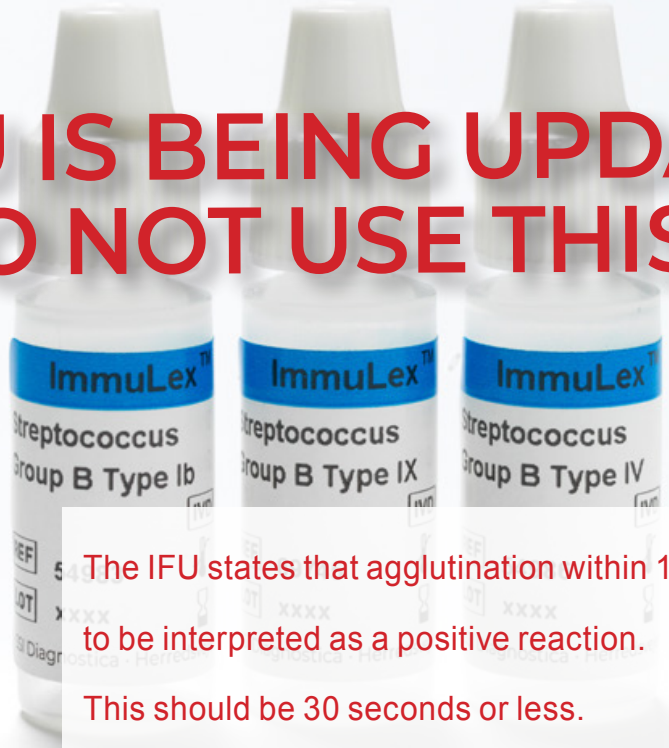
SSI DIAGNOSTICA

Instructions for use

IMMULEX™ STREP-B KIT AND IMMULEX™ *STREPTOCOCCUS* GROUP B ANTISERA

IFU IS BEING UPDATED
DO NOT USE THIS IFU



The IFU states that agglutination within 10 seconds or less is to be interpreted as a positive reaction.

This should be 30 seconds or less.

This means that agglutination between 10 and 30 seconds would mistakenly be interpreted as a negative reaction.

EN

IMMULEX™ STREP-B KIT AND IMMULEX™ *STREPTOCOCCUS* GROUP B ANTISERA

For *in vitro* diagnostic use

Intended use

The SSI Diagnostica ImmuLex™ Strep-B Kit and ImmuLex™ *Streptococcus* group B antisera are intended for visual qualitative confirmation, serogrouping and serotyping of *Streptococcus agalactiae*[1,2] by use of a rapid agglutination test.

It is important to use only pure culture isolates of *Streptococcus* for determination of bacterial antigens.

Description

The ImmuLex™ Strep-B Kit consists of 10 bottles (Ia to IX) containing latex particles coated with *S. agalactiae* Group B streptococci (GBS) type antiserum raised in rabbits (0.0975% sodium azide as preservation) plus 50 disposable reaction cards and mixing sticks.

The ImmuLex™ *Streptococcus* group B antisera are available in the types Ia to IX, containing latex particles coated with GBS type antiserum raised in rabbits (0.0975% sodium azide as preservation).

Cross-reactions have been removed by absorption. Each bottle contains 1.5 mL ready-to-use reagent, enough for approximately 75 tests.

Principle

The rapid agglutination test is performed by mixing a drop of ImmuLex™ solution and a drop of streptococcal culture solution on a reaction card. The aggregates consist of streptococcal bacteria and latex particles from the ImmuLex™ solution. These aggregates are formed as a result of an antigen-antibody reaction between the pneumococcal capsule (antigen) and its homologue antibodies coated on the latex particles. No agglutination and no aggregation will show if the test is negative (see figure 2).

Precautions

- Before using SSI Diagnostica *Streptococcus* antisera products, confirm that the isolate/strain is a pure culture of *Streptococcus*.

- Before use of the ImmuLex™ solution, it is very important to bring the bottles to room temperature and to shake the solution. Use the solution immediately while the latex particles are still homogeneously dispersed in the ImmuLex™ solution.

- For the ImmuLex™ agglutination test, please make sure the result is read within 10 seconds. Therefore, do not perform more than 3 reactions simultaneously before reading the result.

- Some isolates/strains and in particular non-capsulated (rough) isolates/strains may self-agglutinate and cause false positive reactions.

- If an isolate is difficult to serotype, this may be because the isolate did not grow well and therefore also the polysaccharide capsule was not expressed well. A well-expressed polysaccharide capsule is crucial for serotyping. In such cases try to regrow the isolate several times, grow the isolate on 10% blood agar instead of 5% blood agar, grow it in Serum broth instead of Todd Hewitt broth or grow the isolate in air with 5% CO_2 instead of in air without additional CO_2.

- The ImmuLex™ products have only been validated for confirmation and serotyping of *Streptococcus* and by the below described method.

- Excessive amount of culture compared to ImmuLex™ solution might cause false positive reactions.

- ImmuLex™ products that have accidentally been frozen should not be used.

- Do not use the ImmuLex™ products after the expiry date.

- Inspect the bottle before use to ensure it is intact. Any damaged bottles should be discarded.

Materials provided

The ImmuLex™ Strep-B Kit consists of 10 bottles (Ia to IX) containing latex particles coated with GBS type antiserum. Each bottle contains 1.5 mL ready-to-use reagent, enough for approximately 75 tests. Furthermore, it contains 50 disposable reaction cards and mixing sticks.

The ImmuLex™ *Streptococcus* group B antisera Ia to IX contains 1.5 mL ready-to-use reagent, enough for approximately 75 tests.

Materials required but not provided

- 5-10% blood agar plate or Todd-Hewitt broth
- Physiological saline pH 7.4
- Pipette (droplet of approximately 10 µL)
- 1 µL inoculation loops
- Mixing sticks (included in the kit)
- Incubator (35-37 °C)

Storage and stability

The ImmuLex™ Strep-B Kit and the ImmuLex™ *Streptococcus* group B antisera must be stored at 2-8 °C in a dark place. Stored under these conditions the ImmuLex™ solutions may be used up to the date of expiry shown on the product label.

Do not freeze the product. If the ImmuLex™ solutions have accidentally been frozen, it should not be used.

The in-use stability is not affected by working with the ImmuLex™ solution on the bench throughout the day if it is stored at 2-8 °C when not in use.

Preservative

The ImmuLex™ solutions contain less than 0.1% sodium azide (NaN_3) as a preservative.

Sample collection and storage

For sample collection and storage please follow your local standard procedure.

Quality control

Before use, check the bottles to ensure that there is no damage and/or leak. In case of damage or leak discard the bottles.

As positive agglutination controls, *Streptococcus* strains with known serotypes should be used.

As negative agglutination controls, physiological saline, or growth media (without any strains) and *Streptococcus* strains with known serotypes should be used. These negative controls should show no agglutination.

Before using a new lot, or a new shipment of the same lot or if the product is used by a new operator, please perform quality control testing with positive and negative controls of *Streptococcus* strains with known serotypes before testing of isolates/strains.

Procedure

Use an overnight Todd-Hewitt broth culture showing visible growth **or** a few colonies from a 5-10% blood agar plate.

1. Allow the ImmuLex™ solution to reach room temperature.

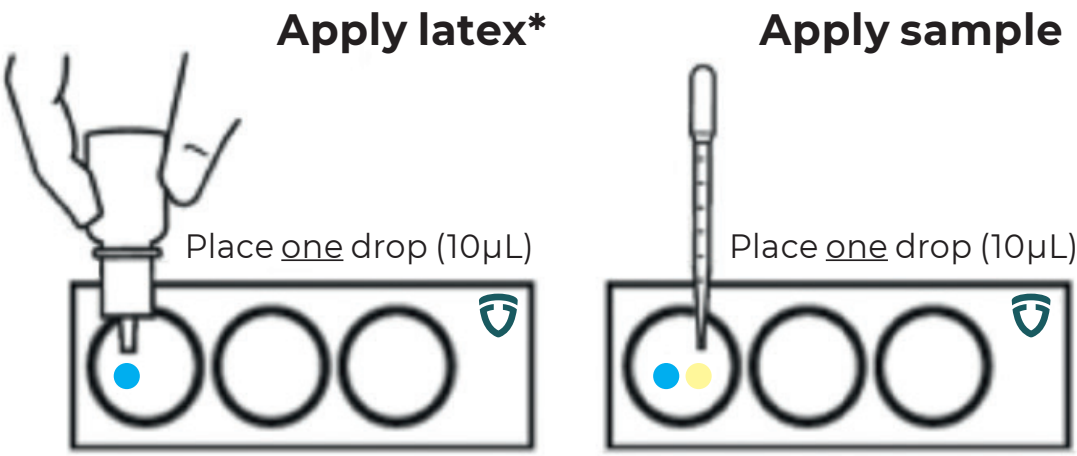
2. Gently shake the ImmuLex™ solution and use it immediately while the latex particles are still homogeneously dispersed in the ImmuLex™ solution. It is not recommended to perform more than 3 reactions simultaneously before reading the result.

3. Apply one drop (10 µL) of ImmuLex™ solution in one of the circles of the reaction card (one drop for each reaction). NB. Hold the bottle vertically and press gently. Place the drop on the card, it should NOT be a free falling drop (see figure 1).

4. Add a drop (10 µL) of a freshly grown broth culture next to the ImmuLex™ solution on the reaction card. Alternatively, freshly grown colonies from a blood agar plate can be suspended in physiological saline (1 µL inoculation loop of colonies resuspended well in 100 µL saline) and a drop of this solution can be used.

5. Mix the two drops (ImmuLex™ solution and culture) with a mixing stick. Use a separate mixing stick for each reaction.

6. Spread the mix to cover the area of the circle by rocking the card slowly and observe for agglutination within 5-10 seconds (see figure 2). Agglutination visible within 10 seconds from mixing start is a positive reaction (see figure 2). Any agglutination after 10 seconds is not a positive reaction.



Mix and interpret

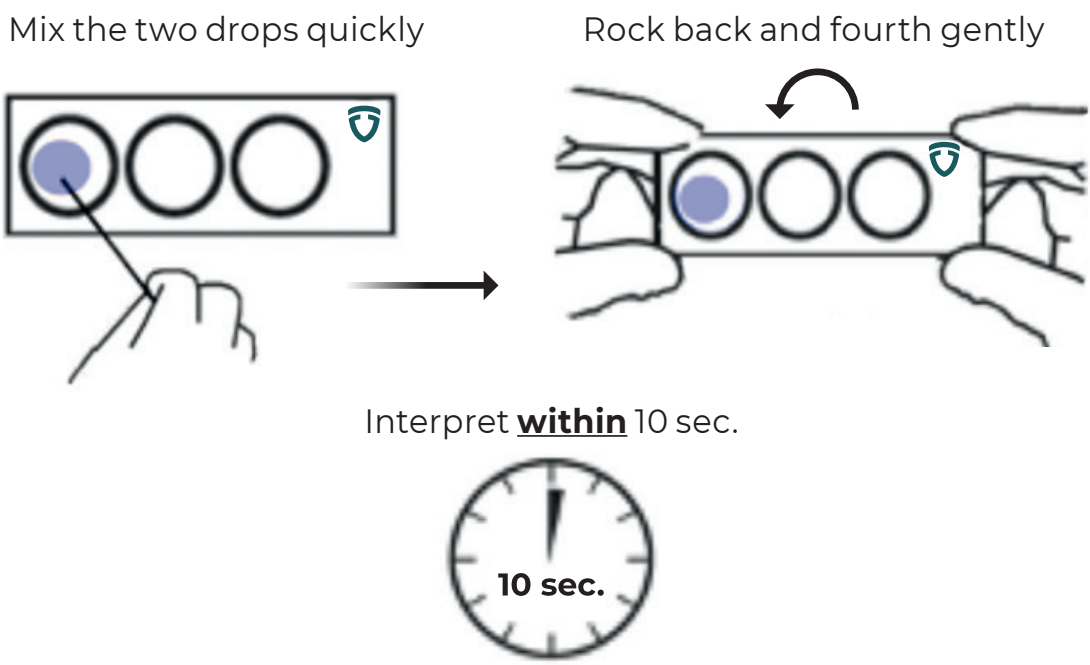
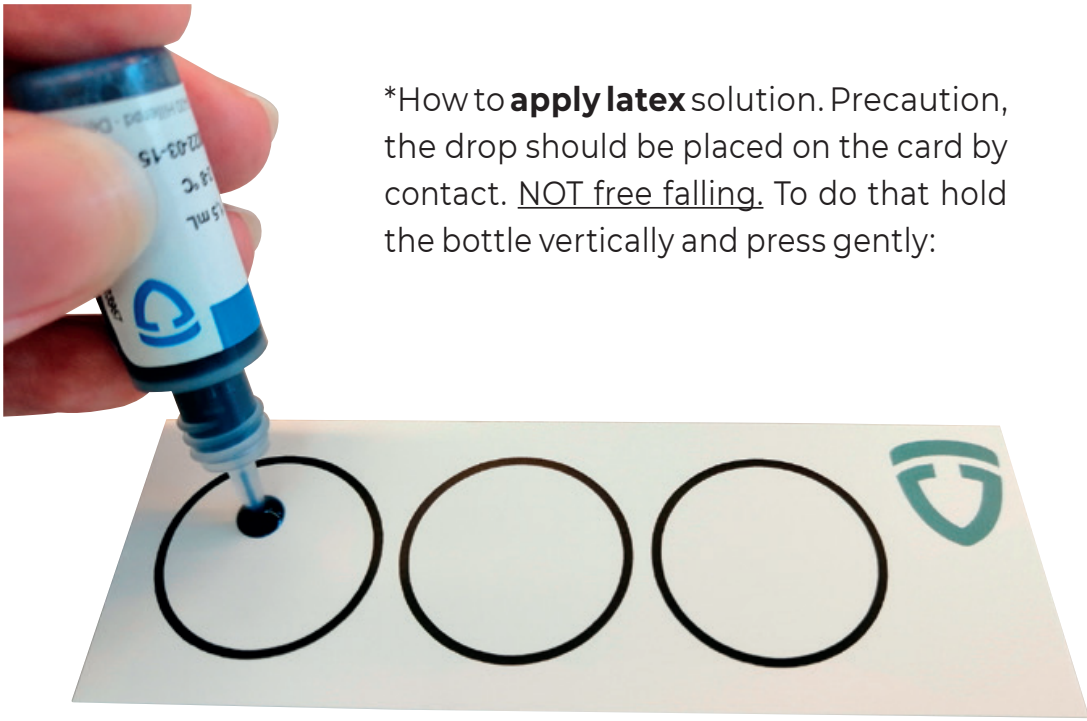


Figure 1. Quick guide to ImmuLex™



*How to **apply latex** solution. Precaution, the drop should be placed on the card by contact. NOT free falling. To do that hold the bottle vertically and press gently:

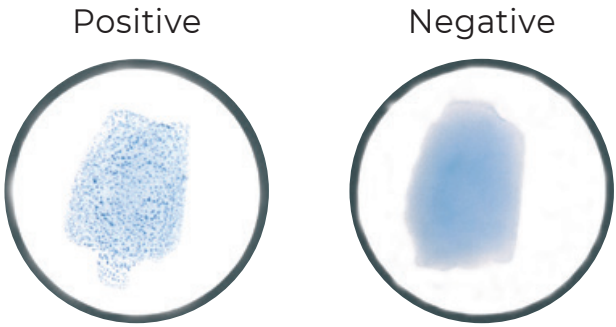


Figure 2. Positive and negative ImmuLex™ agglutination reactions on a reaction card. The positive reaction to the left shows ImmuLex™ solution agglutinating and forming large visible aggregates. The negative reaction to the right shows the ImmuLex™ solution with no agglutination.

Interpretation of results

Agglutination visible within 10 seconds from mixing start is a positive reaction (see figure 2). Any agglutination after 10 seconds is not a positive reaction.

Disposal

Follow your local procedures and/or national guidelines for disposal of biological materials.

Limitations

The culture must be confirmed *Streptococcus* before serotyping using ImmuLex™ *Streptococcus* antisera products from SSI Diagnostica.

Performance

Sensitivity, specificity and repeatability

	Percent (number positive/actual positive)	95% confidence interval
Sensitivity	100% (46/46)	92%-100%
Specificity	100% (180/180)	98%-100%
Repeatability	100% (339/339)	99%-100%

Table 1: Sensitivity, specificity and repeatability for streptococcus antisera

Reproducibility

The reproducibility within the different groups of antisera and all antisera combined is 100% (confidence interval 99.4%-100%). Therefore, all produced antisera have a high level of reproducibility throughout time and lots.

Incident reporting

Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the member state in which the user and/or patient is established.

Quality certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 13485.

Presafe Denmark A/S

Quality System
DS/EN
ISO 13485

IVD

CE

REF

Article number	Product	Number of tests	Packing
54991	ImmuLex™ Strep-B kit,	75 per vial	1 box with 10 x 1.5 mL vials
54982	ImmuLex™ type Ia	75	1.5 mL vial
54983	ImmuLex™ type Ib	75	1.5 mL vial
54984	ImmuLex™ type II	75	1.5 mL vial
54985	ImmuLex™ type III	75	1.5 mL vial
54986	ImmuLex™ type IV	75	1.5 mL vial
54987	ImmuLex™ type V	75	1.5 mL vial
54988	ImmuLex™ type VI	75	1.5 mL vial
54989	ImmuLex™ type VII	75	1.5 mL vial
54990	ImmuLex™ type VIII	75	1.5 mL vial
69745	ImmuLex™ type IX	75	1.5 mL vial

References

1. H.-C. Slotved et al. (2003), JCM, vol. 41, no. 9, p. 4445-4447.
2. Baharak Afshar et al. (2011), JCM, vol. 49, p. 1475-1482.

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

SSI Diagnostica A/S
Herredsvejen 2
3400 Hillerød
Denmark

ssidiagnostica.com

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