SSI DIAGNOSTICA

Instructions for use

ImmuLex™ *S. pneumoniae* Omni kit

ENGLISH

IMMULEX™ *S. PNEUMONIAE* OMNI KIT

For *in vitro* diagnostic use

Intended use

The ImmuLex™ *S. pneumoniae* Omni kit is intended for qualitative detection of the bacterium *Streptococcus pneumoniae* (*S. pneumoniae*) directly from a positive blood culture or pure isolates cultured from a blood culture on a plate. The kit will detect capsulated *S. pneumoniae* belonging to the first 92 serotypes identified. The kit is for *in vitro* diagnostic use only.

Description

The ImmuLex™ *S. pneumoniae* Omni kit includes materials for approximately 75 tests. The kit contains 3 vials - one vial with ready-to-use ImmuLex™ *S. pneumoniae* Omni latex reagent (1 mL), a positive control (500 µL), a negative control (500 µL), and 25 disposable reaction cards. The latex reagent consists of latex particles coated with pneumococcal antiserum. The antiserum is from rabbits. ImmuLex *S. pneumoniae* Omni kit is for use by laboratory professionals and/or healthcare professional only for qualitative detection of *S. pneumoniae*.

Principle

When mixing the latex reagent and the sample (blood culture or isolate) an agglutination can be visually interpreted if a specific antigen from one of the 92 *S. pneumoniae* serotypes is present. If no specific antigens are present, no agglutination can be observed.

Precautions

- Test results should be read within the recommended reading time.
- Do not use the test after the kit lot or components expiry date.
- Do not mix the components of the kit lot with components from other kit lots.
- Let the kit components equilibrate to room temperature before testing.
- Latex reagents that have accidentally been frozen should not be used.
- Before use check the vial to ensure there is no damage and/or leaks – In case of damage or leaks discard the vials.
- Charcoal from the blood culture bottle might be interpreted as false positive results.

Materials provided

- 25 disposable reaction cards
- ImmuLex™ *S. pneumoniae* Omni latex reagent, ready to use (1 mL), for approximately 75 tests
- Positive control (500 µL)
- Negative control (500 µL)

Materials required but not provided

For blood cultures:

- Blood culture bottle (validated with aerobic/ anaerobic BACTEC™ and BacT/ALERT).
- Pipette (10-200 µL)
- Mixing sticks

For pure 5-10% blood agar plate cultures:

- Physiological saline (0.9% NaCl)
- Tube (that can withstand boiling/heating)
- 10 µL inoculation loops
- Pipette (10-200 µL)
- Mixing sticks
- Toothpicks
- Water bath, heating block or thermomixer (99-100°C)

Storage and stability

Please find the information on the box and labels. Please note that the kit should be stored at 2-8° C and should only be held at room temperature when in use. Stored under these conditions the kit may be used up to the date of expiry shown on the product label. Do not freeze the product.

Preservative

The ImmuLex™ *S. pneumoniae* Omni latex reagent contains less than 0.1% sodium azide (NaN_3) as a preservative.

Sample collection and storage

Follow the local standard procedure for performing blood cultures. Note that this product has been validated using BacT/ALERT and BD BACTEC™ blood cultures. For sample storage please follow your local procedure.

Quality control

For quality control testing this kit provides a positive and a negative control. They are used as described in the procedure. Follow your local or state requirements for frequency of quality control testing. Before using a new lot of a kit, or a new shipment of the same lot, or by a new operator, please perform quality control testing before testing of samples. Before use check the vial to ensure there is no damage and/ or leaks – In case of damage or leaks discard the vials.

Procedure

The positive and negative controls should follow the same procedure as if they were samples. The positive control should show agglutination. The negative control should not show any agglutination (see the section “Interpretation of results”).

1. Allow the latex reagent to reach room temperature before use.
2. Gently shake the latex reagent vial and use the reagent while the latex particles are in homogeneous solution.

3. **Apply latex** reagent, one drop (10 µL), on the reaction card. NB. Hold the bottle vertically and press gently. Place the drop on the card, it should NOT be a free falling drop.
4. **Apply sample**, one drop (10 µL), next to the drop of latex reagent. NB. See the section "Sample preparation" before this step.

Before starting with step 5 please read and ensure that the process is understood as this step is time sensitive. Refer to the quickguide as well.

5. **Mix** the drop of latex with the drop of sample with a mixing stick (use a separate stick for each reaction). Gently move the card back and forth vertically. The result should be interpreted within a maximum of 10 seconds of both mixing and moving the card. Any agglutination after 10 seconds is not a positive reaction (see the section "Clinical sensitivity and specificity").

Sample preparation

Sample preparation for blood cultures (without charcoal):

For blood culture bottles, take out a sample and use it directly for testing, no further sample preparation is needed.

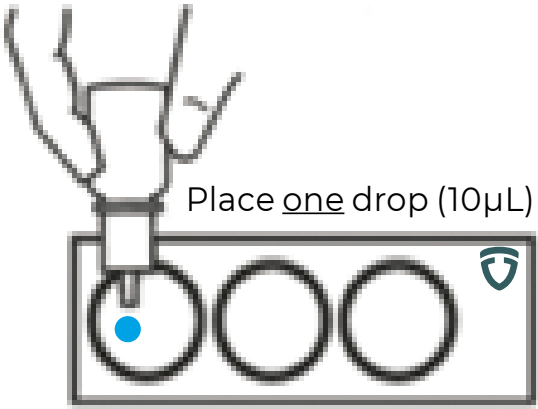
Sample preparation for blood cultures (with charcoal):
For blood culture bottles containing charcoal, it is recommended to perform a negative control using media from a non-cultured blood culture bottle. If false positive results are observed, the blood culture should be centrifuged for 30 seconds (max 2000xg) prior to testing to remove charcoal interfering with reading of the test. As an alternative to centrifugation, the blood culture sample can be filtered e.g. with a 0.8 µm filter prior to testing.

Sample preparation for pure isolate from blood agar plates:

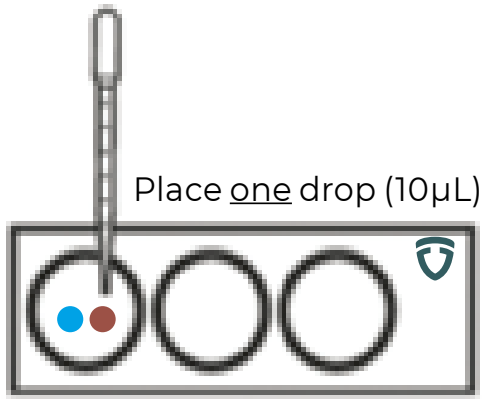
1. Add 200 µL physiological saline (0.9% NaCl) to a tube.
2. Take 10 µL pure bacterial culture (colonies) with an inoculation loop from a 5-10% blood agar plate and suspend it well in the 200 µL saline. NB. Always use fresh cultures.
3. Boil the bacterial suspension at 100°C, for 5 min.
4. Centrifuge the tube for 1 min (max 2000xg).
5. For testing use the supernatant as the sample

Quick guide

Apply latex*



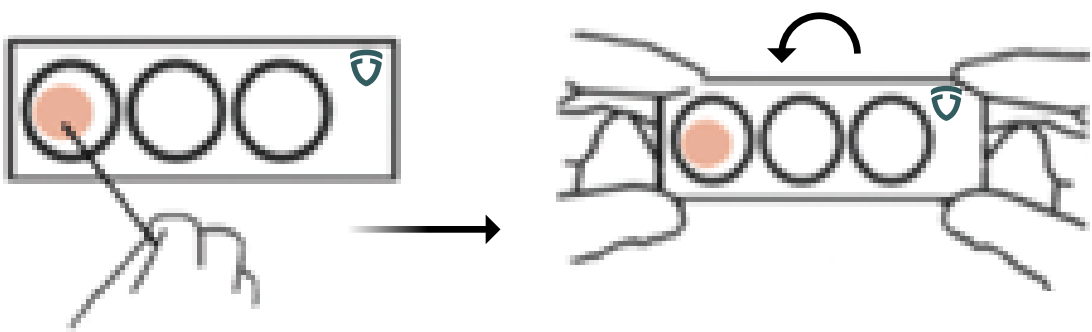
Apply sample



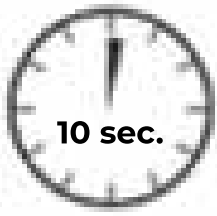
Mix and interpret

Mix the two drops quickly

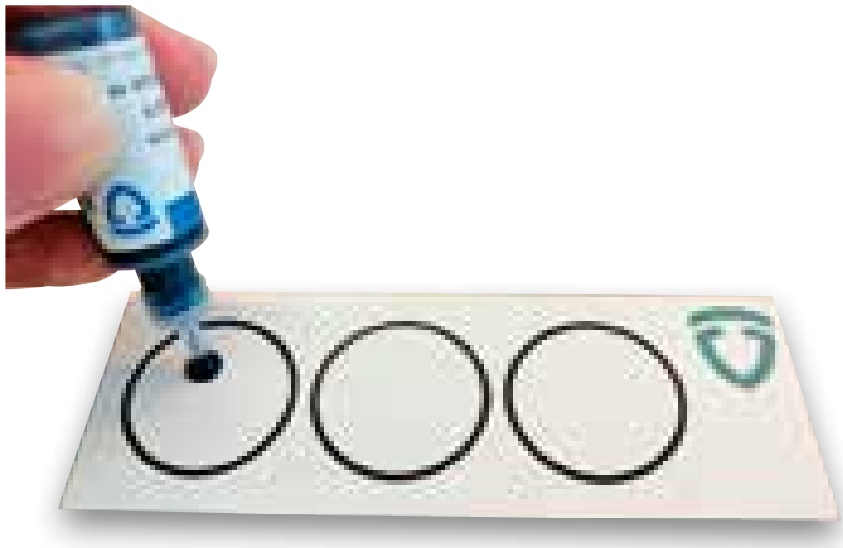
Rock back and fourth gently



Interpret **within** 10 sec.



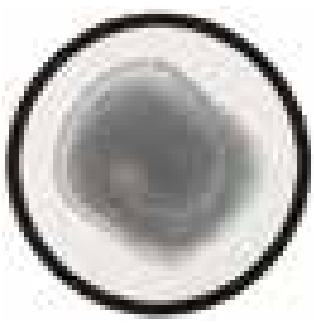
*How to **apply latex** solution. Precaution, the drop should be placed on the card by contact. NOT free falling. To do that hold the bottle vertically and press gently:



Interpretation of results

Interpretation of the quality control included in the kit should be as follows:

The **positive control** shows agglutination (blue granules) and the **negative control** shows no agglutination.



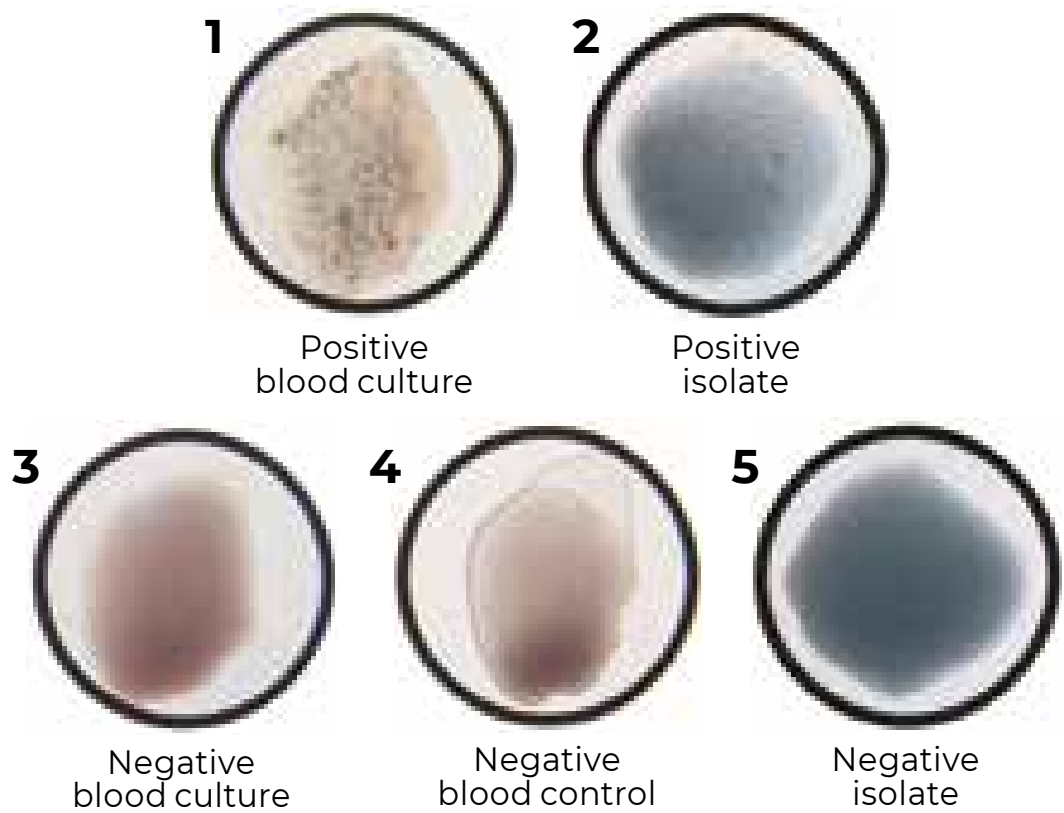
Positive control

Negative control

A **positive *S. pneumoniae*** blood culture or pure isolate will show visible agglutination (see example 1 and 2 respectively).

A **negative *S. pneumoniae*** blood culture or pure isolate will show NO visible agglutination (see example 3, 4, and 5 respectively). Please note that some granules can be shown (example 4), however, this is not considered a true positive reaction.

DO NOT interpret the results after more than 10 seconds as any reaction seen after 10 seconds cannot be considered a true positive result.



Disposal

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

Limitations

- The ImmuLex™ *S. pneumoniae* Omni kit is only validated on BacT/ALERT and BD BACTEC™ blood culture bottles.

- Only validated on 5-10% blood agar plates for pure cultures.

- The ImmuLex™ *S. pneumoniae* Omni kit is not intended to be used for whole blood samples. Only samples from blood culture bottles can be used.

- Non-serotypeable, rough or non-capsulated *S. pneumoniae*, and *S. pseudopneumoniae* have not been validated using the ImmuLex™ *S. pneumoniae* Omni kit. α-haemolytic streptococci might cause false positive especially if the results are interpreted after the recommended reading time.

- A negative result does not exclude an *S. pneumoniae* infection. The result of this test as

well as culture, serology, or other antigen detection methods should be used in conjunction with clinical findings to make an accurate diagnosis.

Clinical sensitivity and specificity

In total 257 blood cultures, 186 *S. pneumoniae* positive blood cultures and 59 other bacteria positive blood cultures, as well as 12 negative blood cultures, were examined with the ImmuLex™ *S. pneumoniae* Omni kit. All blood culture bottles (BacT/ALERT®) were collected at a Danish hospital and sent to SSI Diagnostica for testing. For blood culture bottles, weak cross-reactions to *Enterococcus faecalis, Enterococcus faecium, Klebsiella pneumoniae, Klebsiella oxytoca, Staphylococcus aureus, Escherichia coli,* and *Salmonella* were observed, if interpretation time exeeded the 10 seconds which is recommended.

ImmuLex™ *S. pneumoniae* Omni kit[1] Blood cultures	
Sensitivity	98% (182/186) (95% CL : 95-99%)
Specificity	96% (68/71) (95% CL : 88-99%)

Analytical sensitivity and specificity

Ninety-two serotypes of *S. pneumoniae* (see the section "Serotypes") and 27 cross-reacting bacteria were cultured separately in 8-10 mL sheep blood in BACTEC™ blood culture bottles at a concentration of 10 CFU/mL.

The cross-reacting bacteria included *E. faecalis* (n=9), *E. faecium* (n=1), *K. oxytoca* (n=1), *K. pneumoniae* (n=1), *Streptococcus* group A, B, C, G, and L (n=9), *S. oralis* (n=2), *S. mitis* (n=1), *S. aureus* (n=1), *Salmonella* (n=1), and *E. coli* (n=1).

The blood culture bottles were incubated in BD BACTEC™ 9240 until a positive culture was indicated by the system.

ImmuLex™ *S. pneumoniae* Omni kit	**Sheep blood culture bottle[2]**	**Pure plate culture[1]**
Sensitivity	99% (91/92)	100% (92/92)
Specificity	100% (27/27)	100% (27/27)

Serotypes

S. pneumoniae serotypes that are validated using ImmuLex™ *S. pneumoniae* Omni kit:
1, 2, 3, 4, 5, 6A, 6B, 6C, 6D, 7F, 7A, 7B, 7C, 8, 9A, 9L, 9N, 9V, 10F, 10A, 10B, 10C, 11F, 11A, 11B, 11C, 11D, 12F, 12A, 12B, 13, 14, 15F, 15A, 15B, 15C, 16F, 16A, 17F, 17A, 18F, 18A, 18B, 18C, 19F, 19A, 19B, 19C, 20, 21, 22F, 22A, 23F, 23A, 23B, 24F, 24A, 24B, 25F, 25A, 27, 28F, 28A, 29, 31, 32F, 32A, 33F, 33A, 33B, 33C, 33D, 34, 35F, 35A, 35B, 35C, 36, 37, 38, 39, 40, 41F, 41A, 42, 43, 44, 45, 46, 47F, 47A, 48.

Reproducibility and repeatability

There is no significant lot-to-lot variation of the ImmuLex *S. pneumoniae* Omni kit. Interpretation of results using the ImmuLex *S. pneumoniae* Omni kit is independent of operator, lot, and time.

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.

REF 91398 IVD CE

References

1. Poster “Rapid detection of *Streptococcus pneumoniae* in spiked sheep blood culture” presented at 9th International symposium on Pneumococci & pneumococcal diseases (ISPPD), Hyderabad, India, 2014.
2. Poster “ImmuLex™ *S. pneumoniae* Omni - a new latex agglutination test for rapid detection of *S. pneumoniae* in blood cultures and plate cultures” presented at 9th International symposium on Pneumococci & pneumococcal diseases (ISPPD), Hyderabad, India, 2014.

Information and ordering

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