

Instruction For Use

IMMULEX™

S. PNEUMONIAE

OMNI KIT



IMMULEX™ S. PNEUMONIAE OMNI KIT

Intended use

The Immulex™ *S. pneumoniae* Omni Kit is intended for detection of all 92 *Streptococcus pneumoniae* (*S. pneumoniae*) serotypes directly from a positive blood culture, cerebrospinal fluid (CSF) or a pure culture isolate. The kit is for *in vitro* diagnostic use only.

Description

The Immulex™ *S. pneumoniae* Omni Kit contains 3 vials - one vial with 1 mL (approx. 75 tests) ready-to-use latex reagent, a positive control (500 µL) and a negative control (500 µL). In addition, it contains 25 disposable reaction cards. The latex reagent consists of latex particles coated with pneumococcal antiserum raised in rabbits against all 92 *S. pneumoniae* serotypes.

Principle

When mixing the latex reagent with a homologue antigen, the latex particles will agglutinate and form large aggregates visual for the naked eye. The reaction is performed on a reaction card. The Immulex™ *S. pneumoniae* Omni Kit is not intended to be used for whole blood.

Materials Required but not Provided

For blood cultures:

- Blood culture bottle (aerobic/anaerobic BACTEC™ and BacT/ALERT®) indicating growth of cocci.
- Pipette (approx. 10 µL)
- Mixing sticks

For pure 5-10% blood agar plate cultures:

- Phosphate Buffered Saline (PBS) pH 7.4
- Tube (that can withstand boiling/heating)
- 10 µL inoculation loop
- Pipette (approx. 10 µL)
- Mixing sticks
- Water bath or Thermomixer (99-100°C)

Procedure

For blood cultures (preparation):

For pediatric blood culture bottles, it is recommended either to run a negative control using media from a pediatric blood culture bottle or centrifuge some of the blood culture for 30 sec. prior to testing (as the charcoal in the bottles can interfere with reading of the test).

For culture supernatant (preparation):

1. Add 200 μL PBS to a tube.
2. Take 10 μL pure bacterium culture from a 5-10% blood agar plate and suspend in the 200 μL PBS.
3. Boil/heat (99-100°C) the bacterial suspension for 5 min.
4. Centrifuge the tube for 1 min.
5. For testing use the supernatant as the sample.

Testing:

1. Allow the latex reagent to reach room temperature before use.
2. Shake the latex reagent vial and use the reagent while the latex particles are in homogeneous solution.
3. Set of a drop of approx. 10 μL (squeeze the bottle gently) latex reagent on the reaction card.
4. Sample: Apply a drop (approx. 10 μL) of positive blood culture medium or bacterial supernatant next to the drop of latex reagent.
5. **Important:** Mix the drop of latex with the drop of sample and read the result (while mixing) within max. 10 sec. Use a separate stick for each reaction.

- Any agglutination after 10 sec. is not a positive reaction (see Clinical sensitivity and specificity page 6-8).
- Positive and negative control: Mix one drop (approx. 10 μ L) of the positive/negative control, respectively, with one drop (approx. 10 μ L) of latex reagent and read the result within 10 sec.

Interpretation of results

Figure 1 shows examples of four reactions. From left to right: Number 1 is a positive reaction using a pure culture sample while number 2 is a positive reaction where the sample is from a blood culture bottle. Number 3 and 4 are negative reactions, where the samples are from blood culture bottles. Notice that reaction 3 shows some granules, but this is not a true positive reaction.

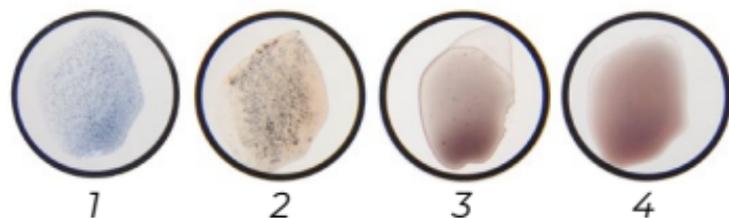


Figure 1. Reactions with Immulex™ *S. pneumoniae* Omni Kit

Analytical sensitivity and specificity

Ninety-two serotypes of *S. pneumoniae* were cultured separately in a concentration of 10 CFU/mL in 8-10 mL sheep blood in BACTEC™ blood culture bottles.

Furthermore, 27 cross reacting bacteria were cultured in a concentration of 10 CFU/mL in 8-10 mL sheep blood in BACTEC™ blood culture bottles. These included 9 *E. faecalis*, 1 *E. faecium*, 2 *K. oxytoca/pneumoniae*, 9 *Streptococcus* group A, B, C, G and L, 2 *S. oralis*, 1 *S. mitis*, 1 *S. aureus*, 1 *Salmonella* and 1 *E. coli*.

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

Table 1. Analytical sensitivity and specificity for both sheep blood culture samples and pure culture isolates.

ImmuLex™ <i>S. pneumoniae</i> Omni Kit	Sheep Blood Culture ¹	Pure Plate Culture ²
Sensitivity	99% (91/92)	100% (92/92)*
Specificity	100% (27/27)	100% (27/27)

*Serotype 5 took a little longer time to form agglutinations.

Clinical sensitivity and specificity

186 *S. pneumoniae* positive blood cultures and 59 other bacteria positive blood cultures (42 patients) were examined along with 12 negative blood cultures. All blood culture bottles (BacT/ALERT®) were collected at a Danish hospital and sent to SSI Diagnostica for testing.

For the aerobic blood culture bottle and CSF: cross-reactions towards other bacteria species have not been observed when the ImmuLex™ *S. pneumoniae* Omni kit reaction is read within 10 sec.

For the anaerobic blood culture bottle: Three cross-reactions were observed when the ImmuLex™ *S. pneumoniae* Omni kit reaction is read within 10 sec.: 2 *S. haemolyticus* (serogroup C) and *P. aeruginosa*/
B. thetaiotaomicron.

For aerobic and anaerobic blood culture bottles: Weak cross-reactions towards *E. faecalis*, *E. faecium*, *K. pneumoniae*, *K. oxytoca*, *S. aureus*, *E. coli* and *Salmonella* have been detected after 15-30 sec. of mixing. It is therefore important not to exceed 10 sec. while mixing. If a result from a blood

culture is unclear, it is recommended to retest the sample. The retest should be performed using either a 0.8 µm filtered sample or by making a short centrifugation (min. 30 sec.) of the sample.

Twelve *S. pneumoniae* positive CSF samples were examined along with 170 negative CSF samples. All positive CSF samples were collected by a hospital in Cameroon and all negative CSF samples were purchased from Lee Biosolutions, USA and sent to SSI Diagnostica for testing.

Table 2. Clinical sensitivity and specificity for human blood cultures and human CSF samples.

ImmuLex™ <i>S. pneumoniae</i> Omni Kit	Human Blood Culture ²	Human CSF
Sensitivity	98% (182/186)	100% (12/12)
Specificity	96% (66/69)	98% (168*/170)

* Two samples were tested positive and confirmed positive with ImmuView *S. pneumoniae* and *L. pneumophila* urinary antigen test and another lateral flow test for *S. pneumoniae*. It was not possible to culture any bacteria from the samples, which can be caused by too many times of freezing and thawing of the sample.

Storage and Shelf Life

Sodium azide has been added as a preservative to a final concentration of 0.0975%.

The kit must be stored at 2-8°C in a dark place. Do not freeze (if the reagents accidentally have been frozen, they should not be used).

Expiry date is printed on the label.

Quality Certificate

SSI Diagnostica is quality assured and certified in accordance with ISO 13485.

Certificate of analysis can be downloaded from our website www.ssidiagnostica.com



Quality System

DS/EN

ISO 13485

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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