IMMULEX™
S. PNEUMONIAE OMNI

SSI Diagnostica

IMMULEX™ S. PNEUMONIAE OMNI

For *in vitro* diagnostic use

Application

The ImmuLex™ *S. pneumoniae* Omni is a ready-to-use latex test for detection of all 92 *Streptococcus pneumoniae* serotypes directly from a positive blood culture or from a pure culture.

Description

The ImmuLex™ *S. pneumoniae* Omni contains a bottle of latex particles coated with pneumococcal antiserum raised in rabbits (0.0975 % sodium azide as preservation). The ImmuLex™ *S. pneumoniae* Omni is provided in 1 mL vials sufficient for 75 tests. The kit also includes a positive and a negative control, and 25 reaction cards.

Principle

The ImmuLex™ *S. pneumoniae* Omni provides a rapid latex agglutination test for detection of *Streptococcus pneumoniae*.

Limitations

The ImmuLex™ *S. pneumoniae* Omni is not intended to be used for whole blood or Cerebro Spinal Fluid (CSF).

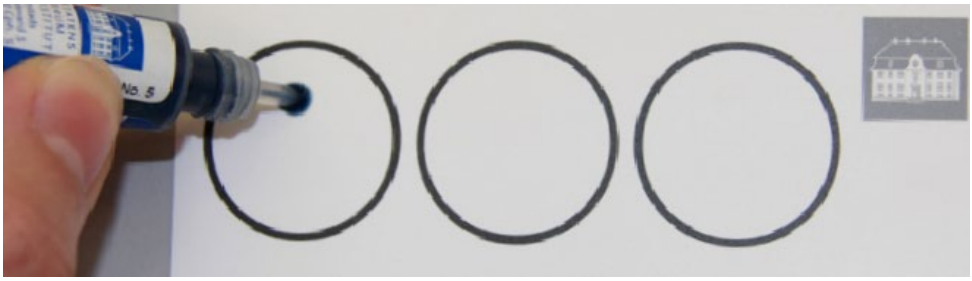
Materials Required but not Provided

- Blood culture bottle (aerobic/anaerobic BACTEC™ and BacT/ALERT®) indicating growth of cocci or pure culture
- Phosphate buffered saline (pH 7.4) (for pure culture testing)
- Pipette or any other utility that can make a droplet of approximately 10 µL
- Mixing stick
- Syringe with a 0.8 µm sterile filter

Procedure – Blood Culture Bottle

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 second prior to testing. As the charcoal in the bottles can interfer with the reading of the test.

1. Take the blood culture bottle where growth has been detected.
2. Bring the bottle with latex suspension to room temperature and shake well.
3. For each reaction set of a drop of approx. 10 µL (squeeze the bottle gently) of latex reagent on to the reaction card. See picture on next page.
4. Apply a drop (approximately 10 µL) of positive blood culture medium next to the drop of latex suspension.



5. Important: Read the result while mixing the two drops for maximum 10 seconds. Use a separate stick for each reaction. *
6. Negative control: Instead of 10 µL blood culture medium use a drop from the negative kit control, and mix with one drop (10 µL) latex solution.

* See Cross-reactions p. 6.

Procedure – Pure Culture

1. Add 200 µL PBS to a tube.
2. Suspend a 10 µL inoculation loop of bacteria culture from a 5-10 % blood agar plate in the 200 µL PBS.
3. Boil the bacterial suspension for 5 minutes.
4. Centrifuge the bacterial suspension for 1 minute.
5. For each reaction set of a drop of approx. 10 µL (squeeze the bottle gently) of latex reagent on to the reaction card. See picture on next page.
6. For each reaction add 10 µL of the bacterial supernatant on the reaction card.

7. Important: Read the result while mixing the two drops for maximum 10 seconds. Use a separate stick for each reaction. *
8. Negative control: Instead of 10 µL blood culture medium use a drop from the negative kit control, and mix with one drop (10 µL) latex solution.

* See Cross-reactions p. 6.

Interpretation of results

Figure 1 shows four reactions. From left to right: Circle 1 and 2 are postive reactions - the first in pure culture, and the second in blood culture. Circle 3 and 4 are negative reactions, both in blood culture. Notice that circle 3 shows some granules, but this is not a true positive reaction.

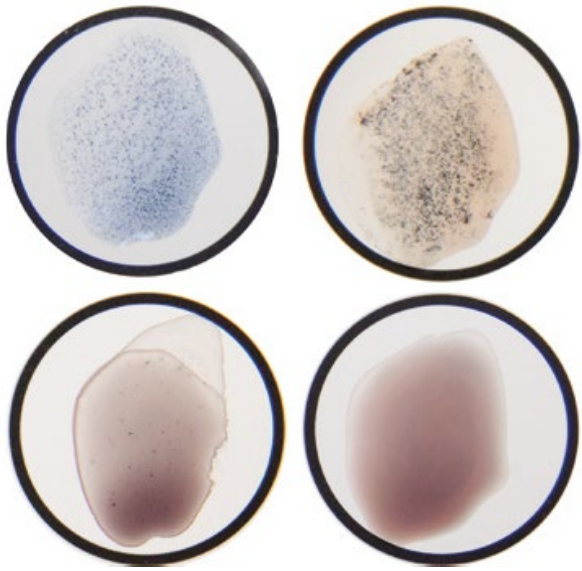


Figure 1. Reactions with ImmuLex™ *S. pneumoniae* Omni

Cross-reactions

For the aerobic blood culture bottle: Cross-reactions towards other bacteria species have not been observed within 10 seconds while mixing.

For the anaerobic blood culture bottle: Three cross-reactions to Streptococcus haemolyticus C (n=2) and Pseudomonas aeruginosa/ Bacteroides thethaiothaomicron (n=1) have been observed within 10 seconds while mixing. Please see table below.

For both blood culture bottles: Weak cross-reactions from *E. faecalis*, *E. faecium*, *K. pneumonia*, *K. oxytoca*, *S. aureus*, *E. coli* and *Salmonella* have been detected after 15-30 seconds of mixing when testing other Streptococci. **It is therefore important not to exceed 10 seconds 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 (minimum 30 seconds) of the sample.

Sensitivity and Specificity

ImmuLex™ *S. pneumoniae* Omni	Positive Blood Culture	Negative Blood Culture
Sensitivity (n = 186): 98 %	182	4
Specificity (n = 69): 96 %	3	66

Storage and Shelf Life

Store at 2-8 °C in a dark place. Expiry date is printed on the package. Do not freeze (if the reagents have accidentally been frozen, they should not be used).

Quality Certificate

SSI Diagnostica's development, production and sales of *in vitro* diagnostics are quality assured and certified in accordance with ISO 9001 and ISO 13485.

Information and Ordering

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