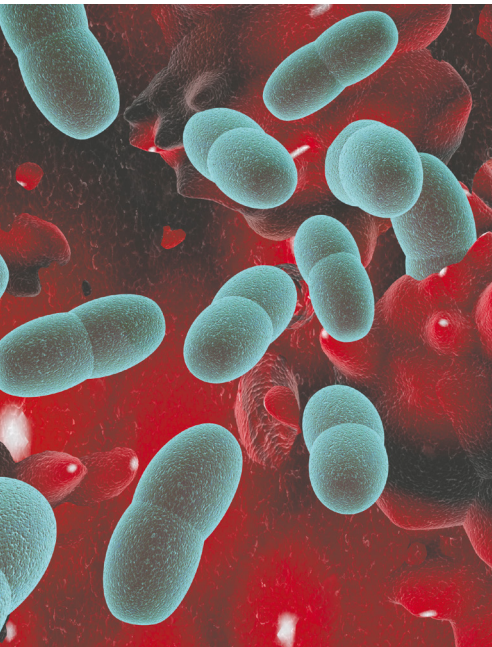


IMMULEX™
S. PNEUMONIAE OMNI

STATENS
SERUM
INSTITUT



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 and 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

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

* If you use a different blood culture medium, you are welcome to contact SSI Diagnostica, and we will perform a test with the specific culture medium.

Procedure – Blood Culture Bottle

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 add a drop (approximately 10 µL, squeeze the bottle gently) of latex suspension in the circle on the reaction card.
4. Apply a drop (approximately 10 µL) of positive blood culture medium next to the drop of

latex suspension.

5. Mix the two drops with a mixing stick for 10 seconds and read the result within the 10 seconds. Use a separate stick for each reaction. *
6. Negative control: It is important to run a negative control simultaneously to the test. Instead of 10 μL blood culture medium use a drop from the negative control bottle, and mix with 10 μL latex solution.

*Any agglutination after 10 seconds is not a positive reaction (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 add one drop of latex reagent on the reaction card (approximately 10 μL , squeeze the bottle gently).
6. For each reaction add 10 μL of the bacterial supernatant on the reaction card.
7. Mix the two drops with a mixing stick for maximum 10 seconds and read the result

within the 10 seconds. Use a separate stick for each reaction. *

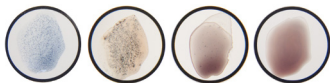
8. Negative control: It is important to run a negative control simultaneously to the test. Instead of 10 μ L blood culture medium use a drop from the negative control bottle, and mix with 10 μ L latex solution.

* Any agglutination after 10 seconds is not a positive reaction (see Cross-reactions p. 6).

Interpretation of results

Figure 1 shows four reactions. From left to right: Circle 1 and 2 are positive 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

When testing with blood culture media, cross-reactions towards other bacteria species have not been observed within 5 seconds after mixing. Weak cross-reactions from *E. faecalis*, *E. faecium*, *K. pneumoniae*, *K. oxytoca*, *S. aureus*, *E. coli* and *Salmonella* have been detected after 10-30 seconds of mixing. When testing other Streptococci, no further cross-reactions were recorded.

It is recommended to retest a sample if the result after 5 seconds is unclear due to cross-reactions. The retest should be performed using a 0.8 µM filtered sample of the blood culture medium.

Sensitivity and Specificity

ImmuLex™ <i>S. pneumoniae</i> Omni	Positive Blood Culture	Negative Blood Culture
Sensitivity (n = 186): 98 %	82	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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