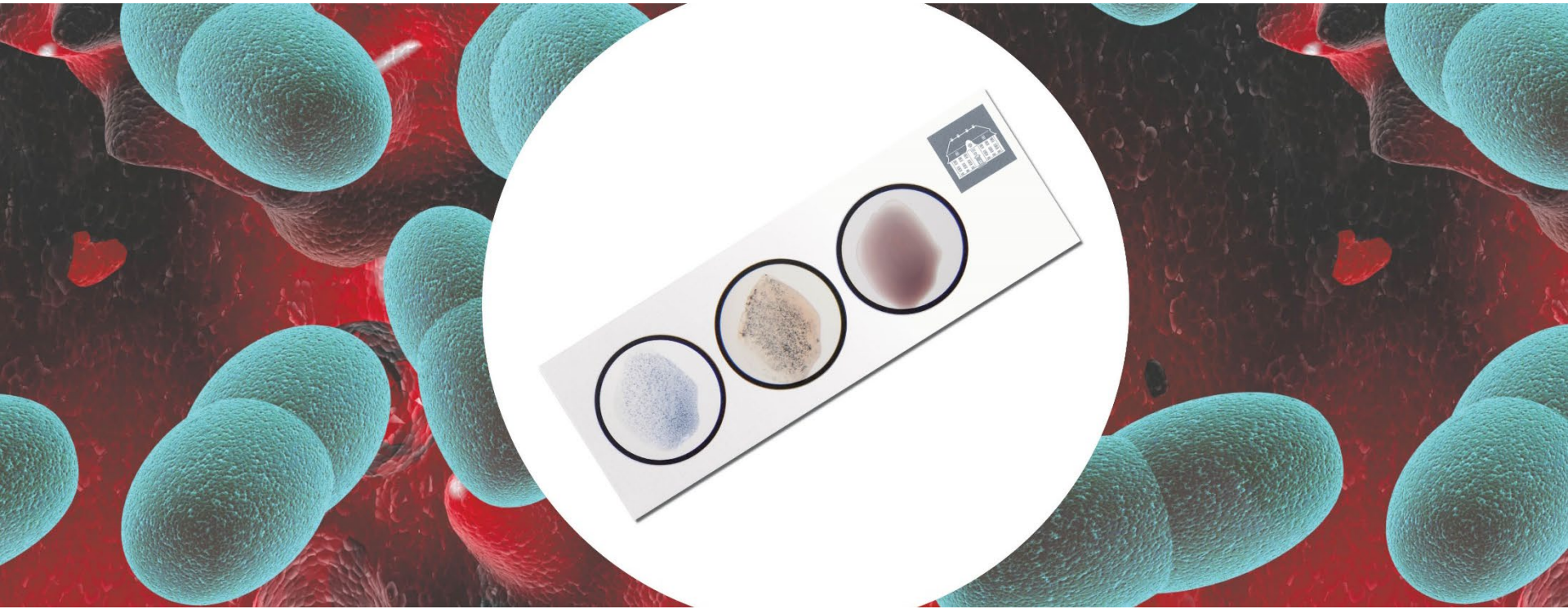
ImmuLex™ *S. pneumoniae* Omni

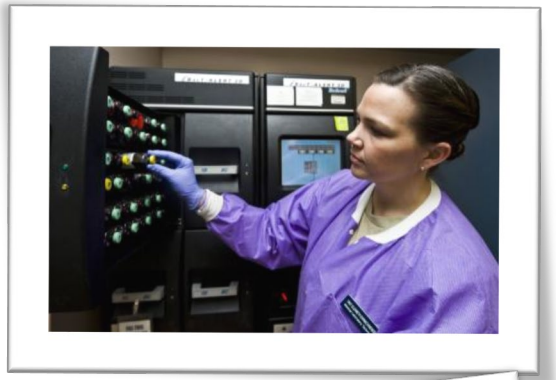
Direct detection of Pneumococcus bacteria from positive blood culture

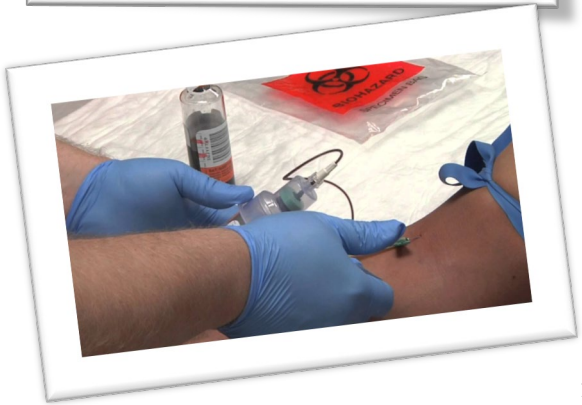


Immulex™ *S. pneumoniae* Omni

Which have blood culture bottles have been validated?

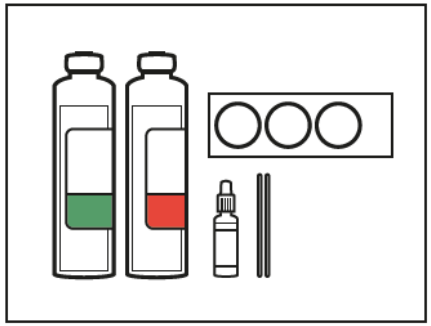
- BacT/ALERT
- BACTEC™





ImmuLex™ *S. pneumoniae* Omni

1.



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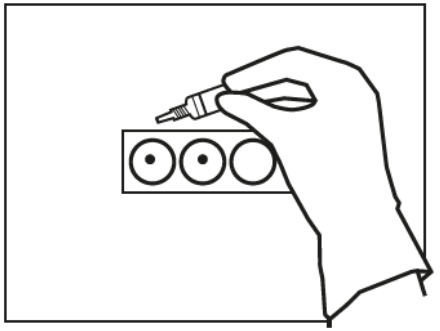

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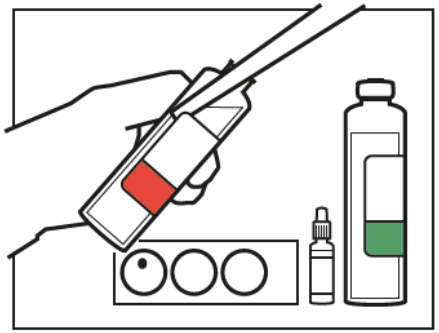

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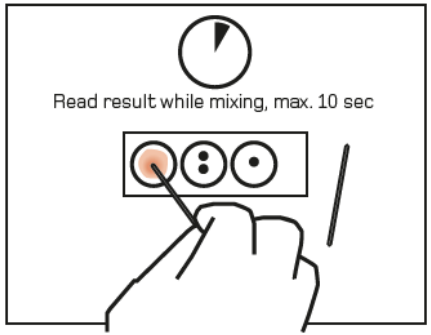

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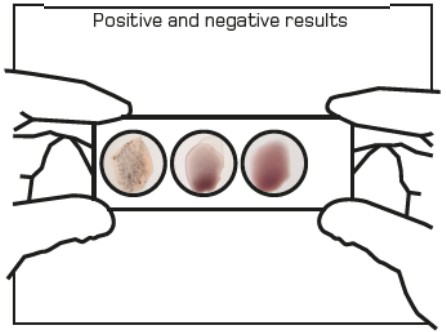
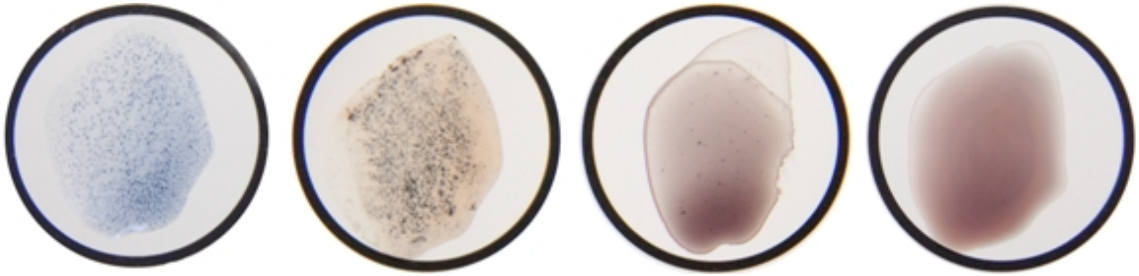


Mix for max. 10 seconds and read the result before mixing the next sample.

ImmuLex™ *S. pneumoniae* Omni

- Read the result within 10 seconds



Positive
pure culture

Positive
Blood culture

Negative

Negative

Clinical sensitivity and specificity for Blood cultures and CSF

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 CSF specificity testing:
Two samples were tested positive with the ImmuLex™ *S. pneumoniae* Omni kit. These were confirmed positive using the 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.

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

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

Analytical sensitivity and specificity

Material:

- Blood culture bottles with Sheep blood spiked with bacteria
  - No pretreatment of blood cultures
- Pure cultures
  - Boil/heat (99-100°C) the bacterial suspension for 5 min and centrifuge the tube for 1 min.
- 92 *S. pneumoniae* serotypes
- Timer

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

ImmuLex™ *S. pneumoniae* 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.

ImmuLex™ *S. pneumoniae* Omni

Data præsenteret på ISSPD-9 2014

METHODS

155 *S. pneumoniae* positive blood cultures (BacT/ALERT®) were tested in ImmuLex™ *S. pneumoniae* Omni (SSI Diagnostica).

RESULTS

All 155 positive *S. pneumoniae* blood cultures were positive using the ImmuLex™ *S. pneumoniae* Omni, which equals a sensitivity of 100%.

The result of the comparison study of sensitivity and specificity of the four kits in blood cultures is shown in Figure 1.

All four kits had a high specificity. However, three samples (two *Streptococcus* group C and one *Pseudomonas aeruginosa*) came out positive or inconclusive in all four kits in the anaerobic blood culture bottle (see Figure 1).

Furthermore, 12 negative blood cultures were analysed in all four kits to evaluate that the kits did not cross-react with the combination of blood and culturing media. These were all negative. ImmuLex™ , Slidex® and Dryspot™ were also evaluated on pure cultures (see Figure 2).

All inconclusive results have been calculated as negative in both the sensitivity and specificity calculations.

CONCLUSION

The new ImmuLex™ *S. pneumoniae* Omni can be used for rapid detection of *S. pneumoniae* in blood cultures, and it has a higher sensitivity compared to the three other kits. ImmuLex™ *S. pneumoniae* Omni is a suitable test for both pure culture (5% blood agar plates) and blood cultures. Furthermore, the ImmuLex™ *S. pneumoniae* Omni gives a conclusive result within 5 seconds, and it does not require any sample preparation, when testing blood cultures.

STATENS SERUM INSTITUT

IMMULEX™ *S. PNEUMONIAE* OMNI - A NEW LATEX AGGLUTINATION TEST FOR RAPID DETECTION OF *S. PNEUMONIAE* IN BLOOD CULTURES AND PLATE CULTURES

S. Otte (sot@ssi.dk)[1], M. S. Haugan[2], H. B. Eriksen[2], M. B. Kerrn[1], and P. L. Elverdal[2]
[1]SSI Diagnostica, Statens Serum Institut, Copenhagen, Denmark, [2]Hvidovre Hospital, Denmark

INTRODUCTION

The aim of the study was to evaluate a new latex agglutination test, ImmuLex™ *S. pneumoniae* Omni, for rapid detection of 92 serotypes of *Streptococcus (S.) pneumoniae* in blood cultures and directly from blood agar plates.

METHODS

155 *S. pneumoniae* positive blood cultures (BacT/ALERT®) were tested in ImmuLex™ *S. pneumoniae* Omni (SSI Diagnostica).

Furthermore, ImmuLex™ *S. pneumoniae* Omni was compared with Slidex® pneumo-Kit (Biomérieux), Wellcogen™ *S. pneumoniae* (Remel) and Dryspot™ Pneumo (Oxoid).

For the comparison study 31 *S. pneumoniae* positive blood cultures (22 patients), and 59 different bacteria positive blood cultures (42 patients) were examined along with 12 negative blood cultures. All blood culture bottles were collected at Hvidovre Hospital and send to SSI Diagnostica for testing. ImmuLex™, Slidex® and Dryspot™ were also evaluated against 92 serotypes of *S. pneumoniae* and a panel of 27 clinically relevant cross-reacting bacteria as pure culture on 5% blood agar plates. The Wellcogen™ was not evaluated for pure culture as it is only intended for blood cultures and body fluids.

See Table 1 for sample preparation.

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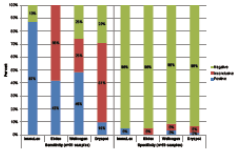

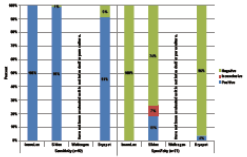

Table 1: Overview of Pneumococcus latex agglutination kits, including sample, preparation and reaction time.

	SAMPLE MATERIAL	PRELIMINARY PREPARATION	REACTION TIME
IMMULEX™	• Blood culture (BC) • Pure culture (PC)	BC: No preparation. PC: Boil 5 minutes and 1 minute centrifugation.	BC: 5 seconds PC: 10 seconds
SLIDEX®	• BacT/ALERT® blood culture • Pure culture	Only on identified pneumococcal bacteria. Pure culture and BacT/Alert® blood culture broths (10 minutes centrifugation).	2 minutes
WELLCOGEN™	• Blood culture • Body fluid	BC: 5-10 minutes centrifugation. PC: 5 minutes boiling, centrifuge or filtrate the sample.	3 minutes
DRYSPOT™	• Blood culture • Pure culture	BC: 5-10 minutes centrifugation. A positive result should be confirmed by performing a Gram stain.	BC: 2 minutes PC: 60 seconds

ACKNOWLEDGEMENTS
A special thanks to Katrine Helander Pedersen, Sabine Maija Stenning and Karina Jane for helping with the development and testing of the ImmuLex™ *S. pneumoniae* Omni.

ImmuLex™ *S. pneumoniae* Omni

Data præsenteret på ISSPD-9 2014

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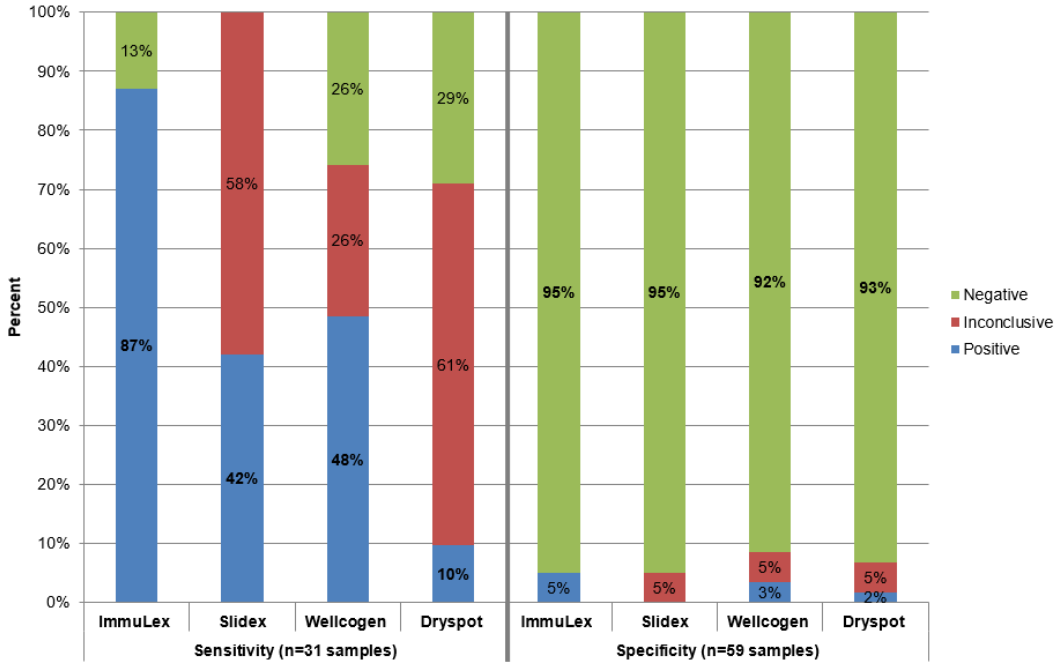

Figure 1: Sensitivity and specificity of ImmuLex™ S. pneumoniae Omni, Slidex® pneumo-Kit, Wellcogen™ S. pneumoniae and Dryspot™ Pneumo when testing in blood cultures.

ImmuLex™ *S. pneumoniae* Omni

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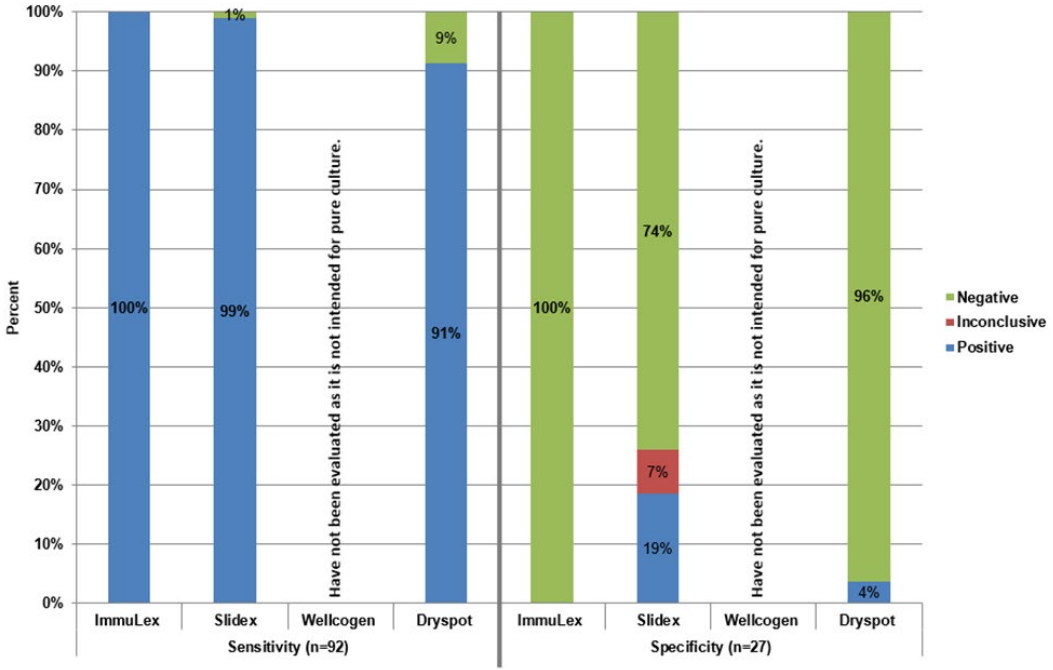

Figure 2: Sensitivity and specificity of ImmuLex™ S. pneumoniae Omni, Slidex® pneumo-Kit, Wellcogen™ S. pneumoniae and Dryspot™ Pneumo when testing pure cultures from 5 % agar plates.

ImmuLex™ *S. pneumoniae* Omni

Competition Overview

Company	Product Name	Vol.	No. of Tests	Serotypes	Sample Material	Preliminary Preparation	Reaction Time	Sensitivity	Specificity
SSI Diagnostica	ImmuLex™ *S. pneumoniae* Omni	1.0 mL	75	92	Blood culture Pure culture	Blood culture: NO preparation Pure culture: 5 minutes boiling and 30 seconds centrifugation	10 seconds	Pure culture: 100% Blood culture: 100%	Pure culture: 100% Blood culture: 100%
Oxoid/Thermo	Dryspot Pneumotest		60	92	Blood culture Pure culture	Blood culture: (5-10 minutes centrifugation). A positive result should be confirmed by performing a Gram stain.	Pure culture 60 seconds. Blood culture 2 minutes	Pure culture: 97.9% Blood culture: 97.3%	Pure culture: 93.2% Blood culture: 98.8%
Remel	Wellcogen		30	92	Blood culture Body fluids (Serum, CFS, Urine)	Blood culture (5-10 minutes centrifugation) Body fluids (5 minutes boiling, centrifuge or filtrate the sample)	3 minutes	CSF: 88% Urine: 44% Serum: 100% Blood culture: 96%	Body fluids: 99.8% CSF: 99.6% Urine: 100% Serum: 100% Blood culture: 99.5%
bioMerieux	Slidex	2.5 mL	50	82	BacT/Alert blood culture broths	Only on identified pneumococcal bacteria. Pure culture and BacT/Alert blood culture broths (10 minutes centrifugation)	2 minutes	Pure culture: 100% (when testing 15 pure cultures)	Pure culture: 100% (when testing 8 pure cultures)
BD	BBL™ Pneumoslide™ test	2.5 mL	50	83	**Not for blood culture**. Only isolated colonies or pure culture	No preparation for pure culture	2-3 minutes	Pure culture: 98,4%	Pure culture: 93%

ImmuLex™ *S. pneumoniae* Omni

- Target Group
  - Clinical microbiology laboratories
  - Reference laboratories

- Key Selling Points
  - Quick detection of all serotypes of *S. pneumoniae*
  - Positive reaction within 10 seconds
  - Can be used directly on blood culture samples
  - High sensitivity and specificity
  - Long shelf life.
    - Minimum 2 years from shipment and 4 years from date from production