

# Phadebact<sup>®</sup>

# Pneumococcus Test

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## Directions for Use

Bactus AB  
Lunastigen 3  
SE-141 44 Huddinge  
Sweden



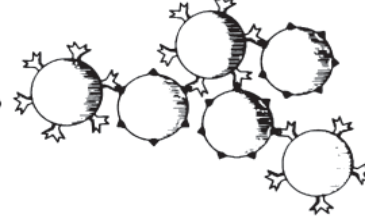
Antibody-coated staphylococci



Microorganism with corresponding antigens



Co-agglutination



### INTENDED USE

Phadebact<sup>®</sup> Pneumococcus Test is intended for the identification of *Streptococcus pneumoniae*.

### SUMMARY AND EXPLANATION OF THE TEST

*Streptococcus pneumoniae* (pneumococcus) is a common inhabitant of the upper respiratory tract of humans and from there it may invade the lungs and the systemic circulation. Consequently, the pneumococcus is the most frequent cause of lobar pneumonia in adults. Bacteremia occurs in about one fourth of these patients, usually early in the course of the disease (1).

The organisms may also extend to the pleural cavity or disseminate to the endocardium and pericardium, the meninges, joints etc with ensuing complications (2).

Pneumococci have also been implicated in infections of the middle ear, mastoid or eye and they are occasionally isolated from peritoneal fluid, urine, vaginal secretions and other clinical specimens. Several methods are known for the identification of pneumococci. Optochin disc sensitivity (ethylhydrocupreine hydrochloride), which is the most widely used method, differentiates the more sensitive pneumococci from most of the other typically more resistant alpha-hemolytic streptococci. Phadebact<sup>®</sup> Pneumococcus Test is based on the co-agglutination technique and allows rapid identification of pneumococcus, using a simple slide technique.

### PRINCIPLE OF THE PROCEDURE

Phadebact<sup>®</sup> Pneumococcus Test is a co-agglutination test containing Pneumococcal Reagent and Pneumococcal Control. The Pneumococcal Reagent is composed of specific antipneumococcal antibodies, raised in rabbits and coupled to the protein A of non-viable staphylococci (3, 4). The Pneumococcal Control is composed of gammaglobulin from non-immunized rabbits, coupled to the staphylococci. When a sample containing pneumococci is mixed with the Pneumococcal Reagent, specific antigens on the cell surface bind to the corresponding specific antibodies. In this way, a co-agglutination lattice is formed, which is visible to the naked eye.

### REAGENTS

Each Phadebact<sup>®</sup> Pneumococcus Test package contains reagents sufficient for 50 determinations. The reagents are coloured blue (Methylene blue) to facilitate interpretation of results.

#### Reactive ingredients

- Pneumococcal Reagent 1 vial  
Specific antibodies raised in rabbit, bound to non-viable staphylococci.
- Pneumococcal Control 1 vial  
Gammaglobulin from non-immunized rabbit, bound to non-viable staphylococci.  
READY TO USE.

#### Other components

- Droppers
- Disposable slides
- Directions for use

#### Precaution

For *in vitro* diagnostic use.

**Warning!** The reagents contain sodium azide (NaN<sub>3</sub>) as a preservative. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. On disposal, flush with a large volume of water to prevent azide build-up. Please refer to decontamination procedures as outlined by CDC.

#### Preparation of reagents

The reagents are READY TO USE.

#### Shelf life and storage

The expiration date is stated on the outer label and the vial labels. It is recommended that the kit be stored at 2-8°C. Reagents must be protected from freezing.

#### SPECIMEN COLLECTION AND HANDLING

Please refer to a standard microbiology textbook regarding information on specimen collection and handling. Samples for investigation can be taken from any part of the body where viable organisms are present. If the sample is to be transported to the laboratory the swab should be immersed in a transport medium such as Stuart's. The swab should reach the laboratory within 24-48 hours. No additives or preservatives need to be used during transport or culturing. Samples from patients taking antibiotics may contain very few or no viable bacteria.

#### PROCEDURE

##### Materials provided

See under REAGENTS.

**Materials required but not provided**

- Primary culture
- Disposable inoculating loops or equivalent
- Clock with easily read minute indicator

**Parameters of the method**

Reaction temperature	room temperature
Reaction time	1 minute
Volume of Pneumococcal Reagent	one drop

**Preparation of samples**

Please refer to a standard microbiology textbook regarding detailed information on preparation of primary cultures.

**Test protocol**

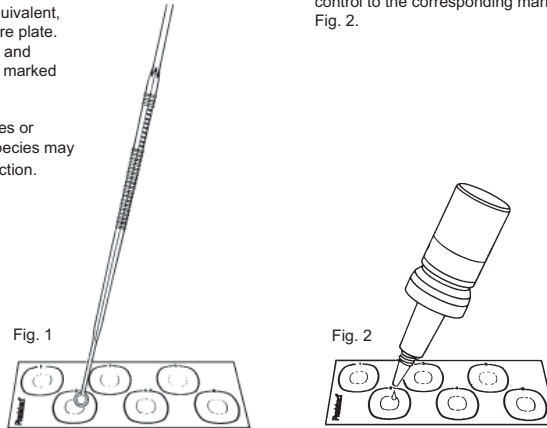
**Note!** Suspend reagents thoroughly by shaking.

Mark one oval each to correspond with control and samples to be tested. Using a disposable loop or equivalent, collect colonies from the culture plate. Spread the colonies smoothly and thoroughly in correspondingly marked ovals on the slide.

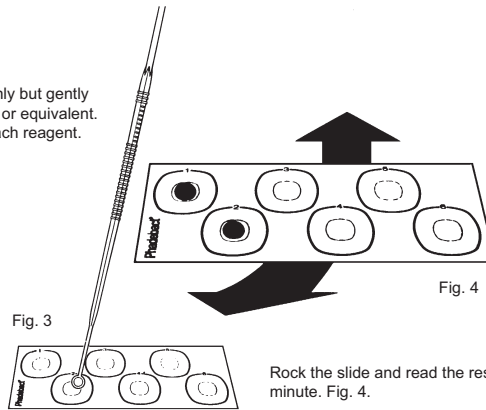
Fig. 1

**Note!** Use of too many colonies or contamination with another species may result in an unsatisfactory reaction.

Add one drop of reagent and one drop of control to the corresponding marked ovals. Fig. 2.



Mix the drops thoroughly but gently with a disposable loop or equivalent. Use a fresh loop for each reagent. Fig. 3.



Rock the slide and read the result within 1 minute. Fig. 4.

**Direct testing of cerebrospinal fluid (CSF)**

For identification of *S. pneumoniae* by direct testing of cerebrospinal fluid please refer to Phadebact® CSF Test.

**Stability of the final reaction mixture**

The co-agglutination reaction is stable, but good laboratory practice dictates that the result be read within 1 minute (observe the risk of drying out of the reagents which may be misinterpreted as a positive reaction).

**Calibration**

No calibration is needed.

**Quality control**

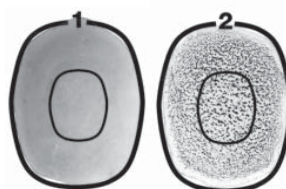
*Positive control*

As a control, an established laboratory strain of pneumococcus should be used (e.g. ATCC 6303). The control strain is treated in an identical manner as the unknown bacteria in the test procedure.

*Negative control*

As a control, an established laboratory strain of  $\alpha$ -hemolytic streptococcus should be used.

Appearance of reaction



No reaction      Positive reaction

**RESULTS**

**Positive result**

A significantly stronger reaction in the Pneumococcal Reagent compared to the Pneumococcal Control constitutes a positive result.

**Negative result**

Lack of reaction in the Pneumococcal Reagent with a negative reaction (slight or no reaction) in the Pneumococcal Control strongly suggests that the bacteria tested is not a pneumococcus or there is insufficient antigenic material in the sample and the test should be repeated using a larger quantity of the specimen.

#### Non-interpretable results

A reaction of equal strength in both the Pneumococcal Reagent and the Pneumococcal Control constitutes a non-interpretable result. The specimen is then not identifiable with Phadebact® Pneumococcus Test. Instead another identification test may be used.

#### LIMITATIONS OF PROCEDURE

Immunological methods, such as co-agglutination, used for the identification of *S. pneumoniae*, contain antibodies directed against the capsular antigens of *S. pneumoniae*. Therefore, those pneumococci not possessing a capsule are non-reactive in an immunological test system. Certain types of *S. pneumoniae* have antigens in common with *H. influenzae* type b and these will thus cross-react.

#### PERFORMANCE CHARACTERISTICS

##### Specificity and sensitivity

A total of 450 specimens including stock culture were investigated (6); 304 *S. pneumoniae* and 146 other alpha-hemolytic bacteria including streptococci of the viridans type.  
303/304 (99.7%) isolates of *S. pneumoniae* were correctly identified by Phadebact® Pneumococcus Test.  
12/146 (8.2%) alpha-hemolytic, non-pneumococcal isolates gave a positive reaction with Phadebact® Pneumococcus Test. These strains were:

4 alpha-hemolytic non-pneumococci	
1 <i>S. viridans</i> group K	NCTC 5338
1 <i>S. sanguis</i>	M 371
1 <i>S. mitis</i> ( <i>S. mitior</i> )	M 524
1 <i>S. salivarius</i>	9332
4 <i>S. milleri</i>	OG 7331
	H 159
	B 575
	7338

#### WARRANTY

The performance data presented here was obtained using the procedure indicated. Any change or modification in the procedure not recommended by Bactus AB may affect the results, in which event Bactus AB disclaims all warranties, expressed, implied or statutory, including the implied warranty of merchantability and fitness for use. Bactus AB and its authorized distributors, in such event, shall not be liable for any damages, whether direct, indirect or consequential.

#### Bibliography

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2. *Manual of Clinical Microbiology*. Ed. by Lennette E H, Spaulding E H and Traut J P, Am Soc Microbiol, Washington DC, 1974.
3. *Christensen P, Kahlmeter G, Johnson S and Kronvall G*: New method for the serological grouping of streptococci with specific antibodies adsorbed to protein A-containing staphylococci. *Inf Imm* 7 (1973) 881-885.
4. *Kronvall G*: A rapid slide agglutination method for typing pneumococci by means of specific antibodies adsorbed to protein A-containing staphylococci. *J Med Microbiol* (1973) 187-190.
5. *Olcén P*: Serological methods for rapid diagnosis of *Haemophilus influenzae*, *Neisseria meningitidis* and *Streptococcus pneumoniae* in cerebrospinal fluid: A comparison of Co-agglutination, Immunofluorescence and Immunoelectroosmophoresis. *Scand J Infect Dis* 10 (1978) 283-89.
6. Data on file, Bactus AB.

#### PRODUCTS

##### Phadebact® COA System

Phadebact® Streptococcus Tests  
Phadebact® Streptococcus Respiratory Test  
Phadebact® Strep A Test  
Phadebact® Strep B Test  
Phadebact® Strep D Tests  
Phadebact® Strep F Test  
Phadebact® Strep Positive Controls  
Phadebact® Pneumococcus Test  
Phadebact® Haemophilus Test  
Phadebact® GC Positive Controls  
Phadebact® CSF Test  
Phadebact® CSF Positive Controls  
Phadebact® Extraction Solutions  
Phadebact® Monoclonal GC Test  
Phadebact® ETEC-LT Test  
Phadebact® Salmonella Test  
Phadebact® Staph Aureus Test

##### Near Patient Testing

Phadirect® Strep A  
Phadirect® Rapid CRP Test

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