Phadebact®
GC Serovar Test

For research use only

Directions for Use

MKL Diagnostics AB
Kung Hans Väg 3
192 68 Sollentuna
Sweden

INTENDED USE
Phadebact® GC Serovar Test is intended for serological classification of Neisseria gonorrhoeae. The co-agglutination technique has been previously applied to the definitive identification of N. gonorrhoeae using mixtures of monoclonal antibodies. Phadebact® GC Serovar Test is based on this co-agglutination technique but reagents are prepared with individual monoclonal antibodies. The reagents are intended for research purpose only e.g. in epidemiological studies (1, 2, 3).

PRINCIPLE OF THE PROCEDURE
The Phadebact® GC Serovar Reagents are composed of 14 different murine monoclonal antibodies, reacting with a gonococcal specific membrane protein called protein I. Gonococci harbouring protein IA are classified to serogroup WI, whereas gonococci containing protein IB are referred to serogroup WII/III. The monoclonal antibodies of the GC Serovar Reagents are coupled to the protein A of non-viable staphylococci. When a sample containing gonococci is mixed with the GC Serovar Reagents, the specific protein I antigens of the cell binds to the corresponding specific monoclonal antibodies. In this way a co-agglutination lattice is formed, which is visible to the naked eye.

REAGENTS
The Phadebact® GC Serovar Panel consists of 14 different murine monoclonal antibodies. Five against Protein IA (WI) and nine against Protein IB (WII/III). Each Phadebact® GC Serovar Test package contains serovar reagents sufficient for 50 determinations.

Reactive ingredients
Phadebact® GC Serovar Test A-Panel
• Phadebact® GC Serovar Reagent: One vial each of Ao, Ar, As, At and Av
Phadebact® GC Serovar Test B-Panel
• Phadebact® GC Serovar Reagent: One vial each of Bo, Bp, Br, Bs, Bt, Bu, Bv, Bx and By
Phadebact® GC Serovar Test
• Phadebact® GC Serovar Reagent: One vial each of Ao, Ar, As, At, Av, Bo, Bp, Br, Bs, Bt, Bu, Bv, Bx and By

Other components
• Droppers
• Directions for Use

Precaution
For in vitro diagnostic use.
Warning! The reagents contain sodium azide (NaN₃) 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.

Storage
It is recommended that the kit be stored at 2-8°C. Reagents must be protected from freezing.

PROCEDURE
Materials provided
See under REAGENTS.

Materials required but not provided
• Primary culture with oxidase positive, gram-negative diplococcal organisms
• Inoculating loops
• Waterbath
• Saline solution 0.9%
• Reaction tray, type Bioplate®
Parameters of the method

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction temperature</td>
<td>room temperature</td>
</tr>
<tr>
<td>Volume of reagents</td>
<td>one drop</td>
</tr>
<tr>
<td>Reaction time</td>
<td>2 minutes</td>
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</tbody>
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Preparation of samples
Please refer to a standard microbiology textbook regarding detailed information on preparation of primary cultures.

After inoculation, the media should be incubated at 35-37°C, in a humid atmosphere containing 3-7% CO₂, for a period of 16-24 hours. Colonies that have been presumptively identified as *N. gonorrhoeae* may then be tested by Phadebact® GC Serovar Test for definitive identification:

- Remove colonies of the presumptively identified *N. gonorrhoeae* from the primary plate making a light suspension in 0.5 ml 0.9% saline.
- **Note!** It is of importance that the pH of the 0.9% saline should be 7.0-7.5. A lower pH may result in non-specific co-agglutination reactions.
- Heat the suspension in a boiling waterbath for at least 5 minutes. To avoid the risk of evaporation, cover the opening of the tube.
- Cool suspension to room temperature.
- Drops of the heat treated suspension are used for testing.

Test protocol

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

- Put one drop of each serovar from the panel on the reaction tray
- Add one drop of the boiled colony suspension.
- Mix the drops.
- Rock the reaction tray, read the result within 2 minutes.

Stability of the final reaction mixture

The co-agglutination reaction is stable, but good laboratory practice dictates that the result be read within 2 minutes (observe the risk of drying out of the reagents which may be misinterpreted as a positive reaction).

Calibration

No calibration is needed.

RESULTS

A reaction in one or several GC Serovar Reagent provides the serological classification of *N. gonorrhoeae*.

WARRANTY

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

Bibliography:

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**® Salmomella Test
**Phadebact**® Staph Aureus Test

**Near Patient Testing**

**Phadirect**® Strep A
**Phadirect**® Rapid CRP Test