Phadebact®
GC Positive Controls

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Directions for Use

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INTENDED USE
Phadebact® GC Positive Controls are designed to be used for quality control purposes in the identification of *N. gonorrhoeae*. Each vial in this kit contains extract from pure cultures specific for *N. gonorrhoeae* as stated on the label.
Phadebact® GC Positive Controls are designed to be used with Phadebact® Monoclonal GC Test.

REAGENTS
Each Phadebact® GC Positive Controls kit contains two vials of 1.2 mL each of extract from pure cultures of *N. gonorrhoeae*, as stated on each individual vial label.
Antigen levels have been adjusted to give a clear cut-off reaction against homologous reagents. Two droppers are included in the kit.

Precaution
For *in vitro* diagnostic use.
Warning! The control reagents contain sodium azide (NaN_3) 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. The controls have been tested negative for growth of gonococci (*N. gonorrhoeae)*.

Preparation of reagents
Phadebact® GC Positive Controls are supplied ready to use. Simply remove sealing cap from each vial and replace with dropper supplied.

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. Controls must be protected from freezing.

PROCEDURE
Positive antigen controls are designed for use as part of good laboratory quality control procedures for serological testing, and these positive controls should be used accordingly. Using a disposable loop, mix one drop of Positive Control with one drop of its corresponding reagent on the slide.

Materials and equipment required
None, other than materials and equipment, as stated in the Directions for Use for the system being used.

RESULTS
Positive and negative reactions are read as described in Phadebact® Monoclonal GC Test, Directions for Use, or as described for the reagent test system being used.

LIMITATIONS OF THE PROCEDURE
If clearly visibly positive reactions are not observed when these positive controls are reacted with the reagents specific for each, it would indicate that either the control or the active reagent is not functioning properly. Steps should be taken to determine which is defective and replace accordingly.

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.

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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