CLART® SeptiBac

Sepsis Detection

BACTERIA AND FUNGI DETECTED :

Fungal Pathogens

- Candida albicans
- Candida krusei
- Candida glabrata
- Candida spp.
- Universal fungal marker

Gram + Bacteria

- *Streptococcus pyogenes/dysgalactiae*
- *Streptococcus pneumoniae*
- *Streptococcus agalactiae*
- *Streptococcus mitis*
- *Streptococcus sanguinis/parasanguinis*
- *Milleri group Streptococcus (S. anginosus, S. constellatus)*
- *Streptococcus spp.*
- *Staphylococcus epidermidis**
- *Staphylococcus aureus **
- *Staphylococcus hominis**
- *Staphylococcus haemolyticus**
- *Listeria monocytogenes*
- *Enterococcus faecium*
- *Enterococcus faecalis*
- *Clostridium perfringens*

Gram - Bacteria

- *Escherichia coli*
- *Klebsiella (pneumoniae/oxytoca)*
- *Salmonella enterica*
- *Enterobacter (cloacae/aerogenes)*
- *Citrobacter freundii*
- *Serratia (spp./marcescens)*
- *Proteus (vulgaris/mirabilis)*
- *Haemophilus (spp./influenzae)*
- *Acinetobacter baumanii*
- *Bacteroides (spp./fragilis)*
- *Pseudomonas (spp./aeruginosa)*
- *Stenotrophomonas maltophilia*

* Methicillin resistance marker mecA

MAIN ADVANTAGES OF MOLECULAR METHODS IN SEPSIS DIAGNOSTICS :

Molecular methods reduce the limitations and drawbacks of conventional blood cultures:

- **Blood/Sample volume.**
- **Turnaround time to definitive identification.**
- **Higher sensitivity to slow-growing and fastidious organisms.**
- **Co-infections detected.**
- **Methicillin resistance marker included (*mecA* gene).**

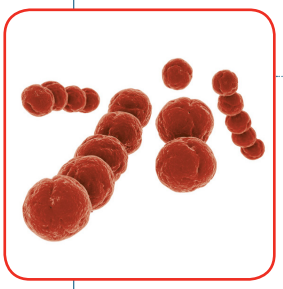
FEATURES :

- The kit is validated for automatic DNA extraction from positive blood cultures.
- High sensitivity and specificity.
- Three quality controls included per sample:
  - **Genomic DNA control:** validates the extraction performance.
  - **Amplification control:** avoids false negative results.
  - **Biotin markers:** check the proper performance of the visualization reagents provided with the kit.
- Targets are detected in triplicate avoiding unspecific bindings.
- Results obtained within a working day (4 hrs).
- Reduces turnaround time, allowing therapy adjustments.
- Compatible with any GENOMICA automation system.

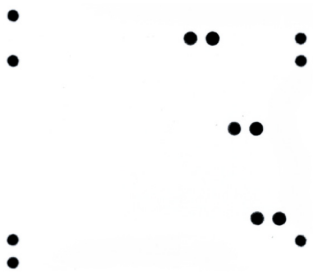
DATA MANAGEMENT :

- Automatic reading and interpretation of results.
- User-friendly report format (html, bmp).
- Samples are analyzed individually and three complementary reports are generated.
- Every report generated can be stored, exported and printed.

REPORTING RESULTS :



- Report and image obtained by CAR® reader.



A2

Result view CLART® SeptiBac	AT code: 50516 Rev. 16sc.3
Sample reference:	3
Array ID:	000000050516 (C1)
Analysis type:	tmb end point detection
Date and time:	Fri Jan 14 15:25:36 2011

Bacteria	Result	Controls
C. albicans	Positive	Passed
C. glabrata	Negative	Passed
C. kruseii	Negative	Passed
C. perfingens	Negative	Passed

ORDERING REFERENCES AND CONTACT DETAILS :

CLART® SeptiBac Amplification

48 tests: CS-0311-48

CLART® SeptiBac Visualization

48 tests: CS-0411-48

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BIBLIOGRAPHY :

1. **"Hemocultivos".** 2nd Ed. (3a). Eds. Cercenado E. and R. Canton. Procedimientos en Microbiología Clínica. Sociedad Española de Microbiología Clínica, SEIMC (2003).

2. **"Diseño y optimización de un sistema de detección molecular por microarrays para la rápida identificación de bacterias gram positivas y hongos en hemocultivos positivos".** Enfermedades Infecciosas y Microbiología Clínica. Vol 29, 33-34 (2011). 15th Congreso de la Sociedad. Española de Microbiología Clínica (SEIMC). Junio 2011.

- CLART® SeptiBact kit accomplish with all the normative described in EU 98/79/EC for IVD.

CE IVD

VERSION 4: **APRIL 2016**