



CLART[®] SEPTIBAC

Detection of Bacteria and Fungi causing Sepsis.

BACTERIA AND FUNGI DETECTED:

Gram + Bacteria

- ⊙ Streptococcus pyogenes/dysgalactiae
- ⊙ Streptococcus pneumoniae
- ⊙ Streptococcus agalactiae/mutans
- ⊙ 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-positive Cocci (CGPs)

* Methicillin resistance marker mecA

Fungal Pathogens

- ⊙ Candida albicans
- ⊙ Candida sp.

Gram - Bacteria

- ⊙ Escherichia coli
- ⊙ Klebsiella pneumoniae
- ⊙ Klebsiella oxytoca
- ⊙ Salmonella enterica
- ⊙ Enterobacter cloacae
- ⊙ Enterobacter aerogenes
- ⊙ Citrobacter sp.
- ⊙ Serratia marcescens/plimutica
- ⊙ Proteus sp.
- ⊙ Haemophilus influenzae/parainfluenzae
- ⊙ Acinetobacter baumannii
- ⊙ Bacteroides spp.
- ⊙ Pseudomonas spp.
- ⊙ Stenotrophomonas maltophilia

MAIN ADVANTAGES OF MOLECULAR METHODS IN SEPSIS DIAGNOSTICS:

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

- ⊙ They do not have variations in sensitivity depending on the sample volume.
- ⊙ They considerably reduce the total time to results.
- ⊙ They allow the detection of slow-growing micro-organisms.

FEATURES:

- ⊙ The kit is validated for automatic DNA extraction from positive blood cultures.
- ⊙ High sensitivity and specificity.
- ⊙ Targets are detected in triplicate.
- ⊙ Results obtained within 5 hours.
- ⊙ Reduces turnaround time, allowing therapy adjustments.
- ⊙ Compatible with any GENOMICA automation system (CAR[®], ACP[®]).
- ⊙ Three quality controls included per sample:
 - **Genomic DNA control:** validates the proper performance of the extraction process and the presence of sample in the test.
 - **Amplification control:** allows detection of inhibition of the PCR reaction.
 - **Biotin markers:** validate the proper performance of the visualization process.



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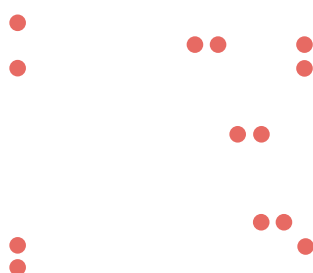
DATA MANAGEMENT:

- ⦿ Automatic reading and interpretation of results (CAR[®], ACP[®]).
- ⦿ User-friendly report format (html, bmp).
- ⦿ Samples are analyzed individually and three complementary reports are generated.
- ⦿ Printable, exportable and storable reports.

REPORTING RESULTS:



- ⦿ Report and image obtained by CAR[®] reader.




Microorganism	Result	Controls
Acinetobacter baumannii	Negative	Passed
Bacteroides sp.	Negative	Passed
Citrobacter sp.	Negative	Passed
Enterobacter aerogenes	Negative	Passed
Enterobacter cloacae	POSITIVE	Passed

ORDERING REFERENCES:

IVD product for the Detection of Bacteria and Fungi causing Sepsis.

CLART[®] SEPTIBAC AMPLIFICATION

- ⦿ 48 tests: CS-0311-48

CLART[®] SEPTIBAC VISUALIZATION

- ⦿ 48 tests: CS-0411-48

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.

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