CLAIMS

1. Disposable cartridge suitable to carry out molecular biology tests starting from biological samples positive for microorganisms, comprising at least one specific reaction mixture for RT-PCR (Real Time Polymerase Chain Reaction) suitable for typing particular microorganisms and/or for providing information on relative resistance to antimicrobial and/or antifungal drugs, wherein said tests are carried out by means of thermal cycles combined with the acquisition of fluorescent signals of specific reagents, wherein said cartridge is made with MEMS (Micro Electro-Mechanical Systems) technology and is selectively suitable at least for:

a) identification of Gram-positive bacteria belonging to the Staphylococcaceae family and/or relative resistance to antibiotics, or

b) identification of Gram-positive bacteria not belonging to the Streptococcaceae family and/or relative resistance to antibiotics, or

c) identification of Gram-negative bacteria, or

d) identification of resistance to antibiotics in Gram-negative bacteria, or

e) identification of yeasts, filamentous and non-filamentous fungi, molds and/or their resistance to antifungals.

2. Cartridge as in claim 1, containing at least one positive control and one negative control to verify the functioning of the cartridge itself and to evaluate the presence of inhibitors in the single biological sample.

3. Cartridge as in claim 1 or 2, containing reaction mixtures for detecting up to 36 different nucleotide sequences.

4. Cartridge as in any claim from 1 to 3, wherein one or more of the reaction mixtures for RT-PCR are lyophilized or subjected to preserving procedures including gelling or drying.

5. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of Gram-positive bacteria belonging to the Staphylococcaceae family and relative resistance to antibiotics comprises the following targets: Staphylococcus spp, Staphylococcus aureus, Staphylococcus epidermidis,

Staphylococcus haemolyticus, Staphylococcus hominis, Staphylococcus lugdunensis, Staphylococcus saprophyticus, Staphylococcus sciuri, Staphylococcus simulans, Staphylococcus xylosus, Mec A, Mec C, SCC mec-orfX, Van A, Van B, Positive control, Negative control.

6. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of Gram-positive bacteria belonging to the Streptococcaceae, Enterococcaceae, Bacillaceae, Listeriaceae family and/or relative resistance to antibiotics comprises the following targets: Bacillus subtilis, Enterococcus spp, Enterococcus faecalis, Enterococcus faecium, Listeria monocytogenes, Streptococcus spp, Streptococcus agalactiae, Streptococcus anginosus, Streptococcus pneumoniae, Streptococcus pyogenes, VanA, VanB, VanC1, VanC 2/3, Positive control, Negative control.

7. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of Gram-negative bacteria comprises the following targets: Acinetobacter baumannii, Enterobacteriaceae, Enterobacter cloacae complex, Escherichia coli, Haemophilus influenzae, Klebsiella aerogenes, Klebsiella oxytoca, Klebsiella pneumoniae, Neisseria meningitidis, Proteus spp, Proteus mirabilis, Pseudomonas aeruginosa, Salmonella typhi, Serratia marcescens, Shigella spp, Stenotrophomonas maltophila, Positive control, Negative control.

8. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of resistance to antibiotics in Gram-negative bacteria comprises the following targets: CTX-M, SHV, TEM, Colistin mcr-1, Colistin mcr-2, Colistin mcr-4, GES, IMP, NDM, OXA-23, CMY-I/MOX, KPC, OXA-48, VIM, CMY-II, PER, FIM, Positive control, Negative control.

9. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of yeasts, filamentous and non-filamentous fungi, molds and/or their resistance to antifungals comprises one or more targets belonging to the following target groups:

a) Aspergillus spp, Aspergillus fumigatus, Aspergillus vescicular, Aspergillus

nidulans, Aspergillus terreus, Aspergillus flavus, Aspergillus niger, Candida spp, Cyp51A (ERG11), Positive control, Negative control;

b) Candida spp, Candida albicans, Candida auris, Candida glabrata, Candida krusei, Candida parapsilosis, Candida tropicalis, Candida lusitaniae, Candida dubliniensis, Candida guilliermondii, Positive control, Negative control;

c) Candida spp, Zygomycetes (Mucorales, Entomophthorales), Fusarium spp, Cryptococcus spp, Pneumocystis, Aspergillus spp, Positive control, Negative control;

d) Candida spp, Blastomyces, Coccidioides, Histoplasma, Paracoccidioides, Talaromyces (Penicillium), Sporothrix, Emmonsia, Positive control, Negative control.

10. Cartridge as in any claim from 1 to 4, wherein the cartridge suitable for the identification of genes that code for resistance to colistin comprises: Mcr-1, Mcr-2, Mcr-3, Mcr-4, Mcr-5, Positive control, Negative control.

11. Panel comprising a plurality of cartridges (10) as in claim 1, comprising at least:

a) a cartridge for the identification of Gram-negatives and/or their resistance to antibiotics,

b) a cartridge for the identification of Gram-positives and/or their resistance to antibiotics,

c) a cartridge for the identification of yeasts, filamentous and non-filamentous fungi, molds and/or their resistance to antifungals.

12. Method to identify at least one microorganism and/or its resistance to antimicrobial or antifungal drugs responsible for a systemic inflammatory state, in particular a generalized infection, said method comprising the following steps:

- preparing a plurality of disposable cartridges (10) as in claim 1, each provided with at least one specific reaction mixture for RT-PCR suitable for typing particular microorganisms and/or providing information on relative resistance to antimicrobial or antifungal drugs, wherein each of the cartridges (10) allows to carry out molecular biology tests starting from biological samples that are positive

for microorganisms;
- supplying a biological sample positive for the presence of microorganisms responsible for generalized infection, the classification of which is preferably known, derived from the microscopic picture,
- selecting at least one specific cartridge (10) from said plurality of cartridges (10) on the basis of the classification deriving from the microscopic picture of the microorganism,
- carrying out at least one molecular biology analysis using RT-PCR with said at least one cartridge (10) selected, wherein the positive biological sample consists of samples deriving from a blood culture positive for the presence of at least one microorganism.

13. Method as in claim 12, wherein if the biological sample is a blood culture positive for the presence of a microorganism, preparing the sample comprises the following steps:
- taking a volume, advantageously between 50 and 500 µl, of the positive blood culture; centrifugation at a speed comprised between 200g and 700g from 20 seconds to 5 minutes, removal of the supernatant, and centrifugation thereof at a speed comprised between 2000g and 7000g from 20 seconds to 5 minutes, elimination of the supernatant and resuspension of the pellet in a volume of ultra-pure water, advantageously between 500 and 1500 µL, free of DNase and RNase, and use of the suspension thus obtained for PCR or RT-PCR.

14. Method as in claim 12, wherein if the biological sample is a blood culture positive for the presence of a microorganism, the preparation of the sample occurs by means of treatment techniques comprising separation systems for obtaining microorganisms or nucleic acids.

15. Method as in claim 12, wherein the biological sample consists of:
- purified DNA/RNA from a biological sample with a presumed positivity for at least one microorganism; or
- single colony of a microorganism, intended as bacterial growth, originating from a biological sample.

16. Method as in claim 15, wherein in the case of a colony of microorganisms it provides the removal of a colony and the dilution thereof in a volume of ultra-pure water free of DNase and RNase.

17. Method as in claim 15, wherein in the case of nucleic acids, the DNA/RNA can derive from extraction from a biological sample with a commercially available kit, or from automated systems dedicated to the type of the starting biological sample.

18. Method as any claim from 12 to 17, wherein the analysis to identify the classification deriving from the microscopic picture of the microorganisms is carried out by means of Gram staining or L-Aminopeptidase.

19. Method as in any claim from 12 to 18, wherein the typing provides information on the family and/or genus and/or species of the microorganisms and/or relative resistance.