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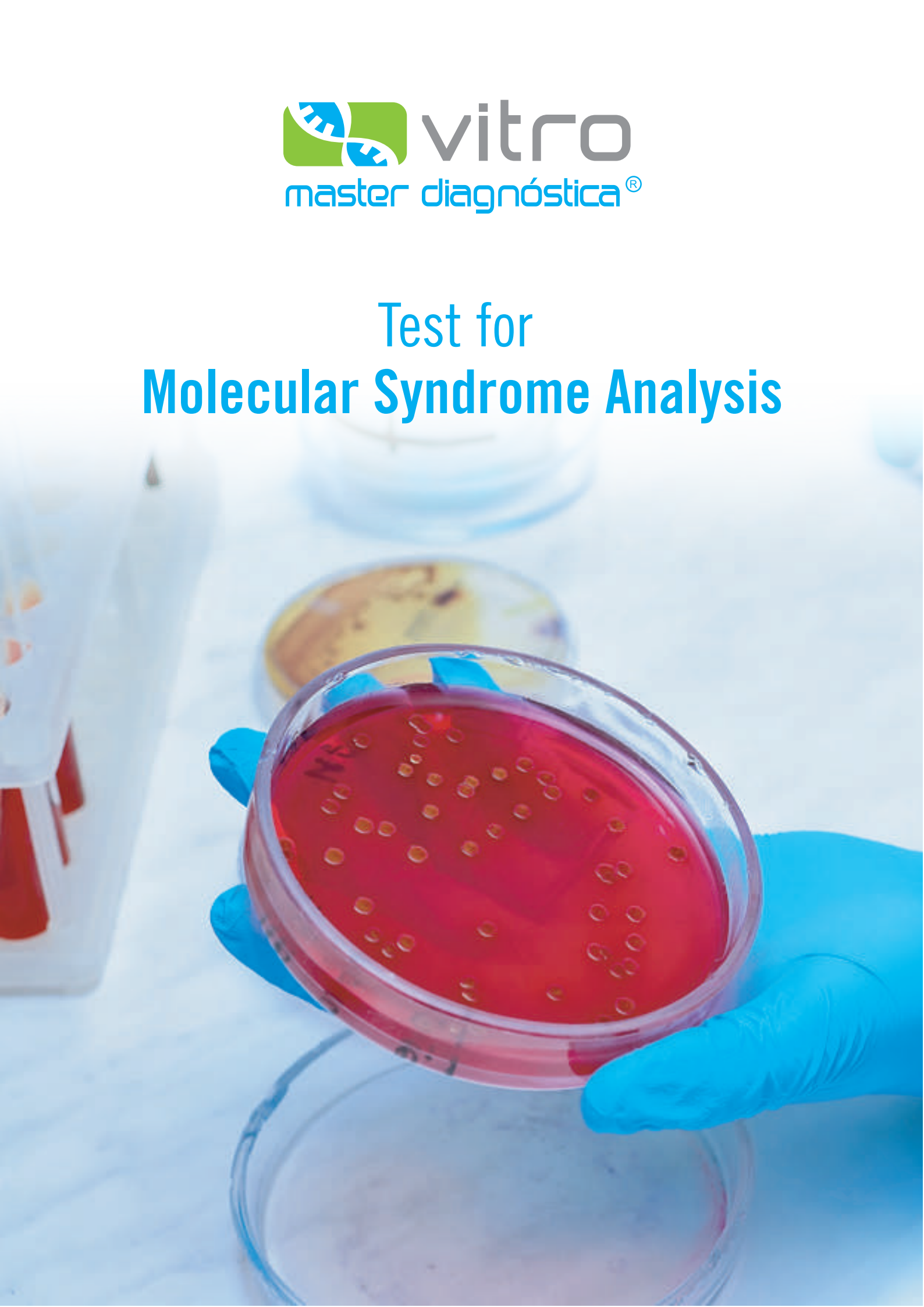
Test for
Molecular Syndrome Analysis



✓ Sepsis and microbial resistances are a huge threat to global public health

- They are the cause of a high rate of morbidity and mortality, around 30-50% [1].
- Adequate treatment is complicated due to the increasing rate of resistance mechanisms [2].
- Incorrect use of antibiotics has contributed to the microbial resistances increase.
- Microbiological identification of the infectious pathogens is crucial for an optimal treatment. The Response towards a treatment is directly related to the time that elapses by before the adequate antimicrobial therapy is administered [3.4].
- The identification through the routine laboratory methods takes a long time [5].

Every 3-4 minutes someone in the world dies due to Sepsis

✓ Fast identification of the microorganism allows for the quick start of specific therapy and reduces the development of resistances

DNA Flow CHIP technology allows the simultaneous identification of bacteria, fungi and resistance mechanisms

- **Hospital stays are reduced with early identification and correct antibiotic treatment.**
- **Hospital costs are reduced.**

- Chalupka AN, Talmor D. The Economics of Sepsis. Critical Care Clinics. 2012
- Hall MJ, Williams SN, DeFrances CJ, Golosinskiy A. Inpatient care for septicemia or sepsis: a challenge for patients and hospitals. NCHS Data Brief. 2011;(62). PMID: 22142805
- Orsini J, Mainardi C, Muzylo E, Karki N, Cohen N, Sakoulas G. Microbiological profile of organisms causing bloodstream Infection in critically Ill patients. J Clin Med Res. 2012; 4(6).
- Kollef MH. Broad-spectrum antimicrobials and the treatment of serious bacterial infections: getting it right up front. Clin Infect Dis. 2008; 47.
- Raman G, Avendano E, Berger S, Menon V. Appropriate initial antibiotic therapy in hospitalized patients with gram-negative infections: systematic review and meta-analysis. BMC Infect Dis. 2015; 15.

- DNA FLOW CHIP KITS -

MULTIPLEX PCR LYOPHILIZED MONOTEST

NO DNA EXTRACTION

MULTI SAMPLE TYPES

FAST RESULTS

EASY WORKFLOW

- SEPSIS FLOW CHIP -

Simultaneous detection of 36 species of bacteria and 20 resistances genes.

GRAM+ BACTERIAS

- Streptococcus spp.
- Streptococcus pneumoniae
- Streptococcus pyogenes
- Streptococcus agalactiae
- Staphylococcus coagulasa negativa
- Staphylococcus aureus
- Listeria monocytogenes
- Enterococcus spp.

GRAM- BACTERIAS

- Acinetobacter baumannii
- Serratia marcescens
- Klebsiella pneumoniae
- Escherichia coli
- Pseudomonas aeruginosa
- Enterobacteria spp.
- Proteus spp./ Morganella morganii

FUNGI

- Candida spp.
- Candida albicans

RESISTENCIA

Meticilin: mecA

Vancomicin: vanA y vanB

Carbapenemasa: KPC, SME, NMC/IMI GES, VIM, GIM, SPM, NDM, SIM, IMP3, 15, 19_like, OXA23_like, OXA24_like, OXA48_like, OXA51_like, OXA58_like

- MDR FLOW CHIP -

Simultaneous detection of 5 species of bacteria and 56 resistance genes.

RESISTANCE GENE	SUBCLASS
mecA	BETA-LACTAM
mecC	BETA- LACTAM
VanA	VANCOMYCIN
VanB	VANCOMYCIN
blaSHV* (detección de mutaciones fenotipo BLEE) (3)	CEPHALOSPORIN
blaCTX*	CEPHALOSPORIN
KPC*	CARBAPENEM
SME*	CARBAPENEM
NMC/IMI*	CARBAPENEM
GES*	CEPHALOSPORIN/CARBAPENEM
VIM*	CARBAPENEM
OXA_23_like*	CARBAPENEM
SPM*	CARBAPENEM
OXA_51_like*	CARBAPENEM
NDM*	CARBAPENEM
OXA_58_like*	CARBAPENEM
OXA_24_like*	CARBAPENEM
GIM*	CARBAPENEM
OXA_48_like*	CARBAPENEM
SIM*	BETA-LACTAM
IMP_3,15,19_like*	CARBAPENEM
cfr	MACROLIDE/LINCOSAMIDE/STREPTOGRAMIN
msrA	MACROLIDE
mef	MACROLIDE
ermA	MACROLIDE
ermB	MACROLIDE
ermC	MACROLIDE
aac(6´)-Ib	AMIKACIN/KANAMYCIN/TOBRAMYCIN
armA	GENTAMICIN

RESISTANCE GENE	SUBCLASS
rmtB*	AMINOGLYCOSIDE
rmtC	AMINOGLYCOSIDE
rmtF*	AMINOGLYCOSIDE
DHA*	CEPHALOSPORIN
CMY*	CEPHALOSPORIN
sul1	SULFONAMIDE
sul2	SULFONAMIDE
sul3	SULFONAMIDE
Punctual mutations in E.Coli´s DNA girase A subunit (4) Punctual mutations in P. aeruginosa´s DNA girase A subunit (3) Punctual mutations in E.Coli´s DNA topoisomerase IV, subunit A (2)	QUINOLONE
qnrA*	QUINOLONE
qnrB*	QUINOLONE
qnrS*	QUINOLONE
oqxA*	PHENICOL/QUINOLONE
oqxB*	PHENICOL/QUINOLONE
mcr1*	COLISTIN
mcr2*	COLISTIN
catB3	CHLORAMPHENICOL

Total: 56 resistance genes.* Generic detection of these markers covering most allelic variants described so far.

BACTERIA	Staphylococcusaureus Escherichia coli Klebisella pneumoniae Pseudomonas aeruginosa Acientobacter baumannii

✓ Clinical evidence demonstrates the benefits of using DNA Flow Chip kits

STUDY 1: Impact of the use of the Sepsis Flow Chip kit in the antimicrobial therapy prescribed by AST in bacteremia caused by Gram-negative bacteria

Merino E et al. Impact of Sepsis Flow Chip, a novelty fast microbiology method, in the treatment of bacteremia caused by Gram-negative bacilli. Rev Esp Quimioter. 2021 Jun;34(3):193-199

Study Population

- 74 patients: 33 men, 41 women
- 65 monomicrobial and 9 polymicrobials infections
- Average Age: 64 yrs STD: 29 yrs
- Previous hospital stayl (3 mths): 24/74ts (32,4%)

Detection of pathogens
95.38% Sensitivity *
100% Specificity

Resistance gene detection
100% ESBL Sensitivity
98.5% Sensitivity CPMs

Percentage of correct treatments applied based on the different tests

	Empirical treatment	Gram Stain	MALDI-TOF	Sepsis Flow Chip kit (SFC)
Clinic 1	62/74 (83,8%)	64/74 (86,5%)	64/74 (82,2%)	73/74 (98,6%)[a]
Clinic 2	66/74 (89,1%)	68/74 (91,9%)	71/74 (95,9%)	73/74 (96,6%)[a]

Index p < 0.05. SFC: Sepsis Flow Chip Kit

Only 1.4% of antimicrobial therapies were inappropriate.
The use of the Sepsis Flow Chip kit not only reduced the combined treatment, but also decreased the prescription of carbapenemes

Conclusión: The study demonstrates the clinical utility of implementing the Sepsis Flow Chip kit in the work routine, which together with the intervention of multidisciplinary groups will allow the information provided by the kit to be optimally managed

STUDY 2: Clinical evaluation of AMR Direct Flow Chip kit in the detection of multi-resistant organisms

1 Torres I et al. Evaluation of the DNA microarray "AMR Direct Flow Chip Kit" for detection of antimicrobial resistance genes from Gram-positive and Gram-negative bacterial isolated colonies. Enferm Infecc Microbiol Clin (Engl Ed.). Aug-Sep 2019;37(7):454-457

2 Rica-Martínez A. Clinical evaluations of a new molecular method for the detection of multidrug-resistant microorganisms. Enferm Infecc Microbiol Clin (Engl Ed.). 2021 Feb 8; S0213-005X(21)00003-3

Preclinical validation [1,2]

- 210 bacterial colonies +
- 104 bacterial colonies -

100% Sensivity
100% Specificity

Clinical validation-number of samples[2]

- 210 swabs: 90 nasals and 120 rectals

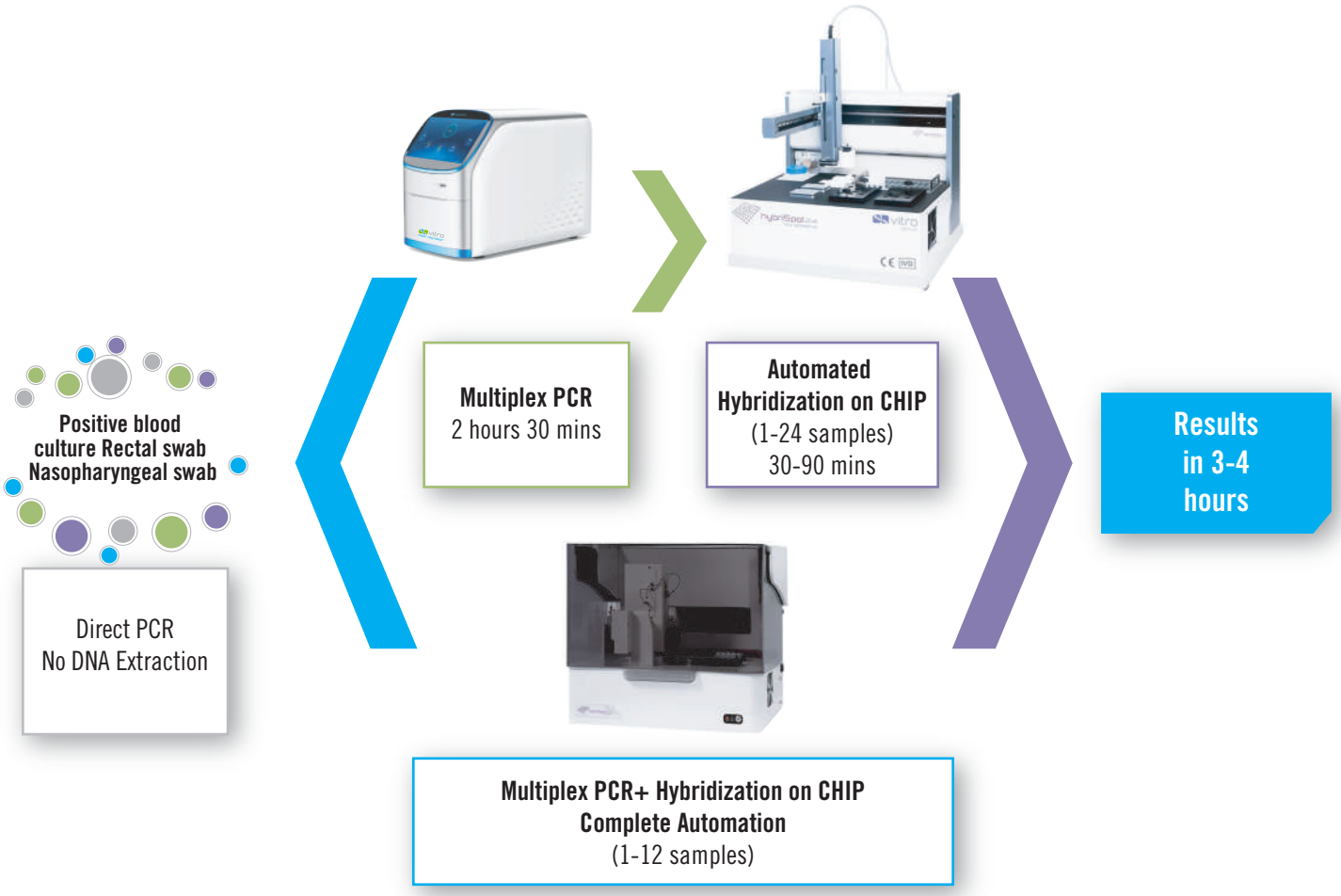
100% Sensitivity in both swabs
100% Rectal swab
and 97% nasal swab
Specificity

mecA, vanA, vanB, blaSHV, blaCTX-M, blaGES, blaSIM, blaSME, blaNMC, blaKPC, blaVIM, blaNDM, blaSPM, blaIMP, blaOXA-23, blaOXA-24, blaOXA-48, blaOXA-51, blaOXA-58

- Confirmation of the genetic pattern of resistance in clinical isolates.
- Usefulness in the screening of patients with multidrug-resistant microorganisms directly from clinical samples.
- Useful tool in resistance surveillance programs.

Conclusion: AMR Direct Flow Chip kit is a fast and accurate tool for detecting the most common genes that confer resistance to lactams, carbapenemes and vancomycin.

✓ Workflow with DNA Flow Kits



REFERENCE	DESCRIPTION	AMOUNT
MAD-003936M-HS	Sepsis Direct Flow CHIP kit	24 Test
MAD-003937M-HS	AMR Direct Flow CHIP kit	24 Test
MAD-003946M-HS	MDR Direct Flow CHIP kit	24 Test

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www.vitro.bio

C/ Luis Fuentes Bejarano 60 Ed.
Nudo Norte (local3) 41020 Sevilla
Teléfono: +34 954 93 32 00
sales@vitro.bio
www.vitro.bio