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INTRODUCTION

Parenteral nutrition mixtures (PNM) are sterile preparations made in an aseptic environment.

Routine sterility testing is used to control the microbiological quality of finished products.

The reference methods proposed by the European Pharmacopoeia are membrane filtration and direct plating which are slow and low sensitivity methods.

BACT/ALERT®VIRTUO® (Biomérieux) is an alternative method that allows indirect detection of bacterial growth with faster results and increased sensitivity

PURPOSE

Validate a rapid microbiological method with BACT/ALERT®VIRTUO® for routine sterility testing

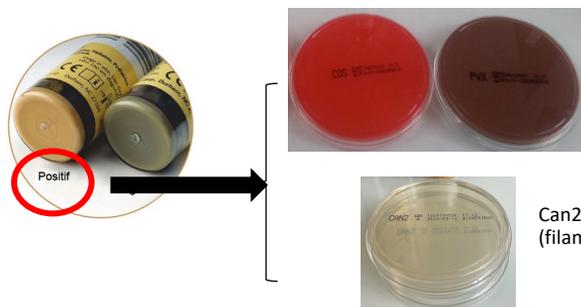
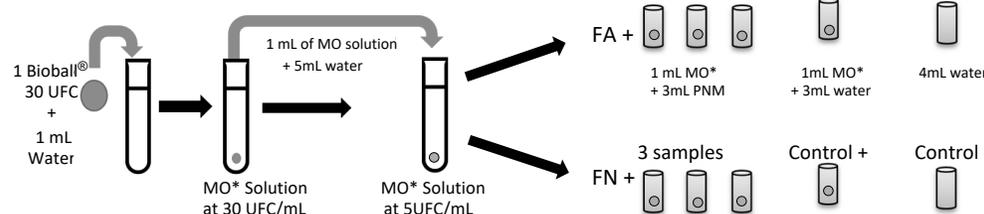
METHOD

- 1 Demonstration of the blood culture bottles abilities (FA+ and FN+) to detect the presence of germs
- 2 Demonstration of absence of inhibiting effect of the preparation

*MO = Microorganism

Bacterial and fungi strains :

- *Staphylococcus aureus*
- *Bacillus subtilis*
- *Pseudomonas aeruginosa*
- *Clostridium sporogenes*
- *Aspergillus brasiliensis*
- *Candida albicans*



Cos agar → 35°C anaerobic conditions 24 to 48 h

PVX agar → 35°C aérobie conditions (CO2) 24 to 48 h

Can2 agar → 35°C aérobie conditions 48h (filamentous fungi and yeasts)

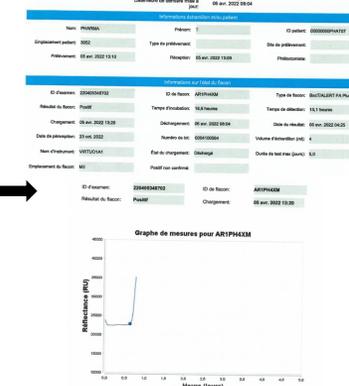


BACT/ALERT®VIRTUO® 5 days at 35°C



Microflex, Bruker®
Bacteria identification by mass spectrometry (MALDI-TOF)

Incubation graph and report



RÉSULTS

- 1 Conformity certificates for FA+ and FN+ blood culture bottles supplied by Biomerieux
- 2 No inhibitory effect of PNM

	Control -	Control +	Samples (FA+ /FN+)					
	Négative	Positive						
			Staphylococcus aureus	Bacillus subtilis	Pseudomonas aeruginosa	Clostridium sporogenes	Aspergillus brasiliensis	Candida albicans
Average time of positivation			17,6 h	11,6 h	15,5 h	-	35,9 h	47,8 h
			18,5 h	24,5 h	70,3 h	22,3 h	-	-

Confirmation of the inoculated germ

- by spectrometry (bacteria)
- on Can2 agar plates (yeast and filamentous fungi)

CONCLUSION

These results allow to validate the method for the control of the microbiological quality of finished products. This alternative method will then be applied on a test production before the beginning of the production and its use in routine.