

CENTRALIZATION OF VITAMIN-LIPID BLEND PRODUCTION: VALIDATION OF THE ALTERNATIVE BACTEC® METHOD FOR STERILITY TESTING

A. Ressel, B. Mathat, E. Olivier, C. Baguet, N. Cormier

Pharmacie, CHU de Nantes site Hôtel-Dieu, 5 Allée de l'Île Gloriette, 44000 Nantes

CONTEXT

Vitamin-Lipid Blend (VLB) are sterile preparations used for nutritional supplementation for premature newborns

The production of VLB syringes, previously carried out within patient care units, has recently been centralized within the Pharmaceutical Technology department. In this context, a microbiological control method using membrane filtration, in accordance with the European Pharmacopoeia (EP) has been validated. This technique requires a prolonged incubation time, which is incompatible with the limited shelf life (7 days) of VLBs, making its practical application difficult

The Bactec® system is an automated blood culture system whose use as a rapid alternative method could help reducing the release time for VLBs

2 standardized formulas

OBJECTIVE

To validate the rapid Bactec® method for daily sterility testing of VLBs

CONCLUSION

Validation of the Bactec® alternative method for sterility testing of VLB syringes

METHOD

MANIPULATIONS

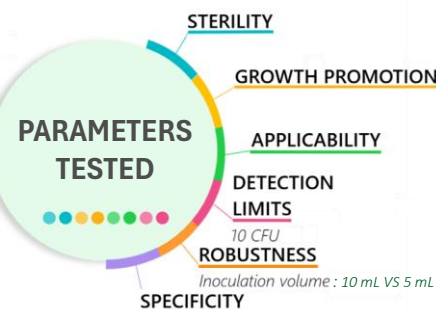
6 microbial strains, defined by the PE, obtained by rehydration of BioBall®

50 and **10** CFU per strain

2 culture media: casein soy broth (CSB) and thioglycolate broth (TB)

3 repetitions, different operators, and different days

 *C. sporogenes* • *P. aeruginosa* • *S. aureus* • *A. brasiliensis* • *B. subtilis* • *C. albicans* 



VLB contamination: reconstitution and insertion of BioBall® into the syringes

Positive (PC) and negative (NC) controls

VLB sampling and inoculation into blood culture bottles

Incubation in the automated system at 35°C, until a positive signal is detected

Advantages of the technique :

- Good sensitivity
- Shorter detection times

→ **Compatible with daily use**

RESULTS

	<i>Staphylococcus aureus</i>					<i>Pseudomonas aeruginosa</i>					<i>Clostridium sporogenes</i>				
	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL
Mean time to positivity (h)	16	16,5	14,5	16	15	17	18	14,5	16	15	16	15,5	15	14,5	14,5
	15,5					16					15				
Identification	<i>Staphylococcus aureus</i>					<i>Pseudomonas aeruginosa</i>					<i>Clostridium sporogenes</i>				

	<i>Bacillus subtilis</i>					<i>Aspergillus brasiliensis</i>					<i>Candida albicans</i>				
	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL	PC 10 CFU	VLB 10 CFU	PC 50 CFU	VLB 50 CFU	VLB 5 mL
Mean time to positivity (h)	12,5	13,5	12	12	12	54,5	66,5	44,5	40	41,5	27	24,5	23	22	21,5
	12,5					49,5					23,5				
Identification	<i>Bacillus subtilis</i>					<i>Aspergillus brasiliensis</i>					<i>Candida albicans</i>				

Mean time to **positivity** for **bacteria** = **15h**

Mean time to **positivity** for **fungi** = **24h - 48h**

No microbial contamination of négatives controls after 5 days

Microorganism **identification**: **consistent**

Equivalent growth between VLB canisters and positive controls, and across **variations in inoculum volume** and **CFU count**

Routine workflow :

