



VALIDATION OF A CUSTOMIZED COMBINED CHEMICAL AND MICROBIOLOGICAL TEST FOR QUALIFICATION OF ASEPTIC PREPARATION PROCESSES

Gils M.<sup>1</sup>, Hanze C.<sup>1</sup>, Gava E.<sup>1</sup>, Roland I.<sup>1,2</sup>

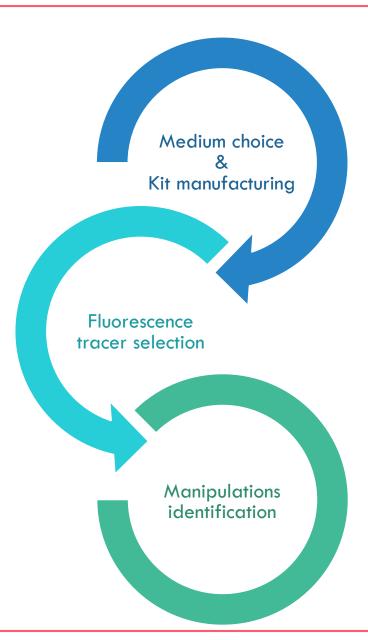
<sup>1</sup> Hospital Pharmacy, University Hospital of
Liege (CHU), Liège, Belgium

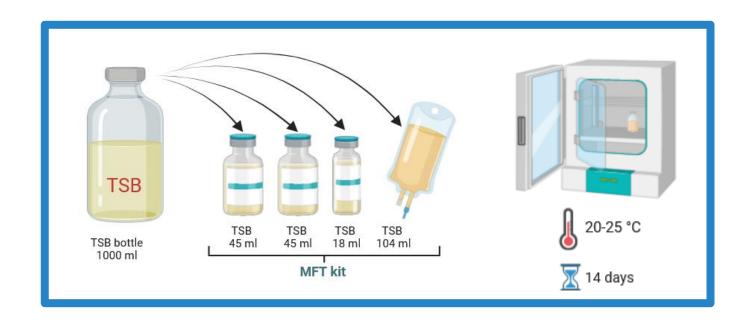
<sup>2</sup> Center for Interdisciplinary Research on
Medicines, University of Liege (ULiege), Liège,
Belgium

⊠ marie.gils@chuliege.be



RESULTS





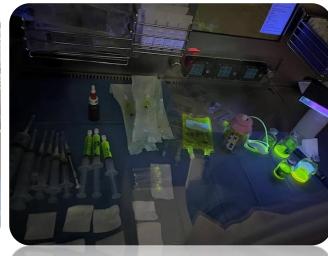
## List of manipulations

- Aseptic transfer of a solution into a 100 ml bag;
- Aseptic transfer of a solution into a 10 ml eye drop vial;
- Aseptic transfer of a solution in syringes with stopper;
- Aseptic transfer of a solution into a 120 ml elastomeric diffuser.

Introduction Results Conclusion

	Fluorescence (λ=366 nm)	Fertility (Ph.Eur. 2.6.1.)
TSB	✓	✓
TSB + acidified quinine 5.0 mg/ml	✓	x
TSB + fluorescein 0,01%	✓	<b>✓</b>



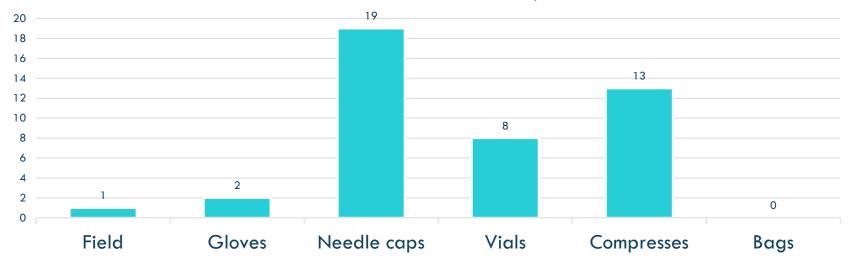


Microorganisme	Milieux	Croissance bactérienne visible à l'œil après inoculation de 13 CFU	Croissance bactérienne visible à l'œil après inoculation de 38 CFU
Staphylococcus aureus	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24H	Positive à 24h
Microorganisme	Milieux	Croissance bactérienne visible à l'œil après inoculation de 10 CFU	
Pseudomonas aeruginosa	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24h	Positive à 24h
Microorganisme	Milieux	Croissance bactérienne visible à l'œil après inoculation de 8 CFU	
Bacillus subtilis	Milieu 1	Négative à 72H	Négative à 72H
	Milieu 2	Positive à 24h	Positive à 24h
Microorganisme	Milieux	Croissance fongique visible à l'œil après inoculation de 24 CFU	• •
Candida albicans	Milieu 1	Positive à 24h	Positive à 24h
	Milieu 2	Positive à 24h	Positive à 24h
Microorganisme	Milieux	Croissance fongique visible à l'œil après inoculation de 12 CFU	
Aspergillus niger	Milieu 1	Positive à 24h	Positive à 24h
	Milieu 2	Positive à 24h	Positive à 24h





## Distribution of areas spotted by the technician during MFT/CCT (n=20 technicians - several areas per technician were sometimes observed)



The development of this combined MFT/CCT protocol is promising

It opens up excellent prospects for the training and (re-)qualification of operators involved in aseptic handling.

The cost of producing in-house "MFT kits" is much lower than the cost of commercial kits, and also makes it possible to involve teams in the implementation of MFT/CCT.

A stability study on the shelf life of the kits will be conducted, with the aim of manufacturing them on a larger scale and making them available at cost price for other hospitals.









## Keywords:

combined MFT/CCT, fluorescent tracers, microbiological contamination, chemical contamination, operators' validation, sterile compounding.









