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INTRODUCTION

In nuclear medicine, patient globular volume is determined through a preparation of autologous red cells radiolabelled with technetium-99m (^{99m}Tc-RC).

Complex, multistep, open
system aseptic process

High-risk level of microbiological
contamination

Objective

To control the sterility of our ^{99m}Tc-RC preparations thanks to a **sterility test (ST)**, with the aim of validating the asepsis of the red cell radiolabelling process

METHODS

Development of an ST
by rapid alternative
method over 7 days

European Pharmacopoeia (2.6.27)
on the microbiological examination
of cell-based preparations

Use of the BACT/ALERT®
system and paediatric
blood culture bottles



ST's
protocol

Inoculation of the blood cultures bottles with 1 mL of ^{99m}Tc-RC → Storage at room temperature in the nuclear medicine department for 48h (radioactivity decrease) → Samples sent to the bacteriology department to be incubated at 35°C in the detection device for 5 days

Validation of the
ST's methodology

Growth promotion test of blood cultures bottles

Method suitability test: search for an inhibitory effect of ^{99m}Tc-RC on microbiological growth

Detection limit: 5 ≠ concentrations of *Staphylococcus epidermidis* x 6 bottles

Robustness : 4 ≠ period of radioactive decay tested

5 microbiological
strains

Validation of the asepsis of the
^{99m}Tc-GR preparation's process

Sterility of 3 ^{99m}Tc-GR preparations tested

RESULTS

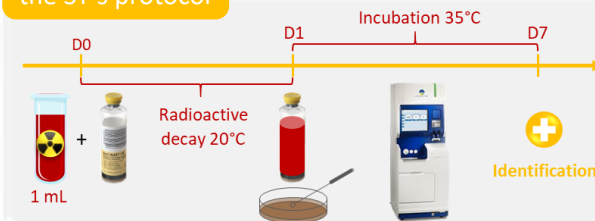
Validation of the
ST's methodology

Growth promotion & suitability tests ✓ Except for *P. aeruginosa*
→ 2 false negatives (FN) → After a dosimetric study, decrease of the radioactive decay period to **24h**

Detection limit: estimated at 1 UFC/mL of preparation

Robustness : 100% of FN for 52h, 33% of FN for 50h and 48h, 0% of FN for 24h → Lack of robustness → **Double check** by inoculating an agar in parallel of each ST

Adaptation of
the ST's protocol



Validation of the asepsis of the
^{99m}Tc-GR preparation's process

3 consecutive ST ✓
(negative blood cultures and agars)

CONCLUSION

The ST's methodology was validated for a radioactive decay period of 24h.

3 STs (+ 3 aseptic simulation tests) ✓

→ Asepsis of the ^{99m}Tc-GR preparation's process validated

Advantages of this ST: results over 7 days maximum, automated method, quick and easy to set up. It is not a release control but in case of positivity, the prescriber can be informed to adjust the patient's care.

In the future → Possible implementation of STs for our operators' qualification and routinely to monitor the sterility of ^{99m}Tc-GR preparations.