BACKGROUND AND IMPORTANCE
Sterility test of Parenteral Nutrition (PN), is described in pharmacopoeias and establishes the minimum number of units that must be tested. 1-3
Normally, no quality control testing is performed for extemporaneously prepared products.2,4 Even though, in our procedure, to evaluate the efficacy of the working method, samples are taken from personalized and stock PN mixtures as part of the process control (figure 1).

AIM AND OBJECTIVES
To evaluate the number of PN samples taken for microbiological control and its compliance with pharmacopoeial specifications.
To test the possibility of reducing on PN samples taken and economic impact associated.

MATERIALS AND METHODS
Retrospective study of the microbiological control of PN bags from October 2018 to September 2019. Data were obtained from pharmacy and microbiology laboratory records. The parameters measured were: PN bags produced, PN samples taken versus recommended by pharmacopoeial specifications.
Risk assessment approach and microbiological results since 2014 have also been performed. Costs were calculated considering the value of the sterility test.

RESULTS
As it can be seen in Table 1, during the studied period, 12466 PN bags were performed from which 1723 were tested. According to pharmacopoeial specifications, for a production less than 100 units, the minimum number of units to be tested should be 10% or 4 units, whichever is the greater (theoretical sample).

Four of the controlled bags had a positive result (0.23%), in red on table 2. In neither cases a clinic compatible with infection was verified or an isolation of the same microorganism in blood culture.
This number of positive results is in line with the history results since 2014 (table 3).

CONCLUSIONS AND RELEVANCE
The procedure in place consists of random sampling of 1 out of every 5 produced PN bags. These results, as well as the history of low and stable positive controls, will allow the increase of the sampling interval to 1/10. The predictable decrease in the number of analysis will imply a cost saving of about €9575/year. This reduction also improves the possibility of making other studies with the microbiology with better material and human resources management.

References and/or acknowledgements:
3. Annex 6 to note for evaluation and recommendation of pharmacopoeial texts for use in the ich regions on sterility test general chapter.
(EMEA/CHMP/ICH/645592/2008)