Hospital Vila Franca de Xira

THE OUTCOME OF MICROBIOLOGICAL MONITORING IN CYTOTOXIC DRUG PREPARATION

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OBJECTIVES

Microbiological contamination risk can be minimized using a vertical laminar flow cabinet (VLFC) placed in a cleanroom. Cytotoxic (CTX) drugs must be prepared according to the work instructions in order to guarantee that all the quality, hygiene and disinfection standards are complied (1, 2).

The primary objective of this study was to assess the impact of microbiological monitoring in established procedures for CTX preparation.

METHODS

The microbiological control is performed by a pharmacist according to hospital procedures:

- settle plates at the direct Working Environment (WE), Sterile Preparation (SP) and Glove Fingers dabs (GF) at the end of each working session;
- Background Environment (BE) and WE Surface (SWE) weekly;
- BE Surface monthly (SBE).

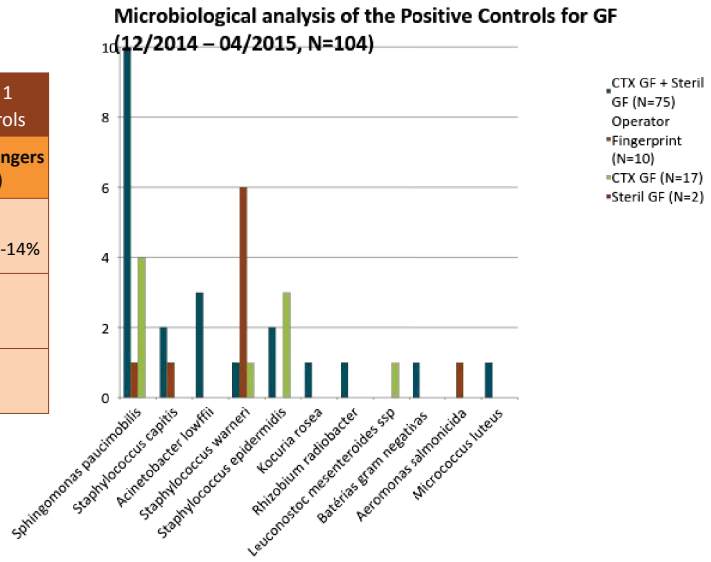
Blood agar plates are used for these controls, with the exception of SP (calcium folinate) that are made in Brain-heart infusion.

A retrospective analysis was performed from April 2014 to August 2015.

RESULTS

Recommended limits for microbial contamination (a) - PIC/S 010-3, annex 1
Results (b) – Number of positive controls/Total number of microbiological controls

Grade	Air sample (cfu/m³)	Settle plates (cfu/4hours)	Surface samples (swab) (cfu/plate)	Glove print, 5 fingers (cfu/glove)
A (VLFC)	a)<1 b)NA	a) <1 b) 3/290 (WE) -1%	a) <1 b) 2/70 (SWE) -3%	a) <1 b) 43/301 (GF) -14%
B (Clean room)	a)10 b)NA	a) 5 b) 13/72 (BE) -18%	a) 5 b) 1/17 (SBE) -6%	a) 5 b) NA
Sterile Preparation	a) NA b) 8/447 (SP) -2%			



DISCUSSION

Positive microbiological controls should trigger corrective/preventive measures (1).

Results obtained for **BE** and **SBE** were within the limits for Zone B (<5CFU), contrary to what was verified for **WE** and **SWE** (>1CFU) where *Staphylococcus* and *Micrococcus*, which are common on human skin, have predominated.

Further the high number of positive controls in **GF**, forced us to additional tests in the CTX and sterile gloves and fingers. *Sphingomonas paucimobilis* and *Staphylococcus epidermidis* were detected at GF matched the bacterias found in the CTX gloves. It was necessary to change CTX gloves since they were not appropriate. *Staphylococcus warneri* was detected in the tests performed on the fingers, which reinforced the importance of good practices on washing hands.

After three consecutive days of **SP** positive results, it was decided that pathology laboratory would use sterile gloves when handling these samples. After six months of SP negative controls, there was one positive so it was decided that a sample of the product must be stored in order to allow a second analysis. After this, all SP positive controls had a negative second analysis.

CONCLUSION

The microbiological control is a good indicator for early detection of problems and definition of corrective actions.

REFERENCES

(1) Cytotoxic Preparation Manual. Portuguese Pharmaceutical Society. 2013
(2) Hospital Pharmacy Manual. INFARMED. 2005

No potential conflict of interest to disclose.