

MICROBIOLOGICAL CONTROL IN A STEM CELL BANK: A STANDARDISATION

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INTRODUCTION

The transplant of cells of human origin is a sector of medicine which shows a high increase and which entails great opportunities for the treatment of certain diseases as Parkinson and Alzheimer diseases, Myocardial infarctation... Stem cell banks should assure the quality, the traceability and the safety of cultures in order to avoid the transmission of diseases.

MICROBIOLOGICAL CONTROL IN DONORS

The presence of risk infectious microorganisms like HIV, HBV, HCV, CMV, EBV, and *Treponema pallidum* should be evaluated in addition to other new infectious agents (prions, coronavirus, HTLV, herpesvirus, polyomaviruses...). The introduction of the amplification techniques of the nucleic acids (NAT) can avoid the window period of these viral infections.

This list might be expanded even further in the light of developing knowledge and technology.

Before using human cell products they should remain under "quarantine".

MICROBIOLOGICAL CONTROL OF STEM CELL LINES

The routine screening of bacteria, fungi, yeast, mycoplasma, fastidious microorganisms and both exogenous and endogenous virus helps in the early detection of contamination. Bacterial contamination is usually evident by increase in turbidity and colour change of the culture medium. The effects of mycoplasma infection are more insidious. Some cell cultures may contain endogenous or exogenous virus or may be contaminated with prions from animal products or from feeder cells used for stem cell line culture.

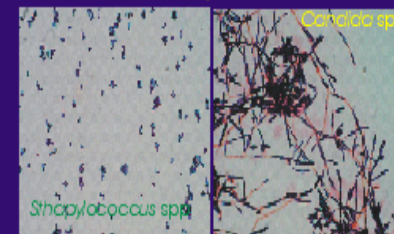


CONTROL OF BIOTECHNOLOGY PRODUCTS

The products of animal origin (bovine serum, mouse feeders, trypsin, ...) used in the development of embryonic stem cell lines, should be tested for prions and virus of animal origin that assure an acceptable quality.

Table. Examples of serious diseases that may be transmitted in transplanted tissues and currently available screening tests (U.S. Food and Drug Administration, 1999)

Infections	Diagnostic Tests
HIV type 1	Anti-HIV-1; NAT
HIV type 2	Anti-HIV-2; NAT
HBV	HB _s Ag; anti-core HB _s ; NAT
HCV	Anti-HCV; NAT
<i>Treponema pallidum</i>	TPHA
HTLV-I y II	Anti-HTLV-I y II
CMV	Ig G anti CMV
Epstein-Barr virus	NAT
Transmissible spongiform encephalopathies	Western-blot; NAT
<i>Neisseria gonorrhoeae</i> *	Bacterial culture
<i>Chlamydia trachomatis</i> *	Ig G anti-Chlamydia



ENVIRONMENTAL CONTROL

It is good practice and necessary to carry out routine environmental microbiological monitoring both passive monitoring (settle plates, count-Tact plates) and active monitoring with an air sampler of the cleanrooms where the cell cultures and their products are prepared.

CONCLUSIONS

- 1- Stem cell banks should guarantee an appropriate source of cell line in a standardised way for the development of therapies.
- 2- The advantages of a system of accredited cell banks includes the assurance of safe starting materials that have also been checked for authenticity, stability and performance.