



CELL AND TISSUE CULTURE

Inspector Instructions:

	<ul style="list-style-type: none"> • Sampling of cell and tissue culture policies and procedures • Sampling of records of microbial contamination and other cell line testing
	<ul style="list-style-type: none"> • How does the biorepository ensure that the quality of cell lines is maintained? • How do you define and monitor maximum cell line passage?

BAP.05312 Culturing Environment

Phase II



Culturing is performed under aseptic conditions in a biological safety cabinet.

BAP.05315 Cell Line Loss

Phase I



There is a system in place to prevent loss of the cell line in case of culture failure, contamination or other problems.

NOTE: Potential systems include duplicate or independently established cultures, harvesting in duplicate or at different times, or other control processes.

BAP.05318 Monitoring of Passage Numbers

Phase I



The biorepository defines the maximum number of passages for each cell line by either reference or laboratory method.

NOTE: When passages have reached the maximum passage number, the cell line should be re-established using working stock with a lower passage number.

Evidence of Compliance:

- ✓ Records of tracking of cell line passages **OR**
- ✓ Records of growth curves

BAP.05321 Testing for Microbial Contamination

Phase I



The biorepository tests cell lines for microbial contamination at intervals defined by the biorepository director.

Evidence of Compliance:

- ✓ Records detailing the type(s) of tests and test outcomes

****REVISED** 12/26/2024**

BAP.05324 Testing for Functionality and/or Unique Characteristics

Phase I